Arizona Public Service Company, et al., Docket No. STN 50-529, Palo Verde Nuclear Generating Station, Unit No. 2, Maricopa County, Arizona

Date of application for amendment: August 28, 1997, as supplemented by letter dated September 3, 1997.

Brief description of amendment: The amendment revises Technical Specification Table 4.3-2 to allow for a one-time, five-day extension of the required surveillance interval for the main steam isolation system portion of the engineered safety feature actuation system logic.

Date of issuance: September 4, 1997

Effective date: September 4, 1997

Amendment No.: 105

Facility Operating License No. NPF-51: The amendment revised the Technical Specifications. Press release issued requesting comments as to proposed no significant hazards consideration: Yes. September 1, 1997. Arizona Republic Newspaper (Arizona). Comments received: No. The Commission's related evaluation of the amendment, finding of exigent circumstances, consultation with the State of Arizona and final determination of no significant hazards consideration are contained in a Safety Evaluation dated September 4, 1997.

Local Public Document Room location: Phoenix Public Library, 1221 N. Central Avenue, Phoenix, Arizona 85004

Attorney for licensee: Nancy C. Loftin, Esq., Corporate Secretary and Counsel, Arizona Public Service Company, P.O. Box 53999, Mail Station 9068, Phoenix, Arizona 85072-3999

NRC Project Director: William H. Bateman

Public Service Electric & Gas Company, Docket No. 50-311, Salem Nuclear Generating Station, Unit No. 2, Salem County, New Jersey Date of application for amendment: August 19, 1997, as supplemented August 20, 1997.

Brief description of amendment: This amendment to the Technical Specifications increases the allowable band for control and shutdown rod demanded position versus indication position from plus or minus 12 steps to plus or minus 18 steps when the power level is not greater than 85% rated thermal power.

Date of issuance: September 10, 1997

Effective date: As of date of issuance, to be implemented within 7 days.

Amendment No. 183

Facility Operating License No. DPR-75: This amendment revised the Technical Specifications. Public comments requested as to proposed no significant hazards consideration: Yes. The NRC published a public notice of the proposed amendment, issued a proposed finding of no significant hazards consideration, and requested that any comments on the proposed no significant hazards consideration be provided to the staff by the close of business on September 3, 1997, and stated that, should circumstances change during the notice period, such that a failure to act in a timely way would result, for example, in derating or shutdown of the facility, the Commission may issue the license amendment before the expiration of the notice period, provided that its final determination is that the amendment involves no significant hazards consideration. The notice was published in the Wilmington News Journal on August 22, 1997, and in Today's Sunbeam on August 24, 1997. No public comments were received. The Commission's related evaluation of the amendment, finding of exigent circumstances, consultation with the State of New Jersey and final no significant hazards consideration determination are contained in a Safety Evaluation dated September 10, 1997.

Local Public Document Room location: Salem Free Public Library, 112 West Broadway, Salem, NJ 08079

Attorney for licensee: Jeffrie J. Keenan, Esquire, Nuclear Business Unit - N21, P.O. Box 236, Hancocks Bridge, NJ 08038

NRC Project Director: John F. Stolz

Dated at Rockville, Maryland, this 17th day of September 1997.

For the Nuclear Regulatory Commission

Elinor G. Adensam,

Acting Director, Division of Reactor Projects—III/IV, Office of Nuclear Reactor Regulation

[Doc. 97-25210 Filed 9–23–97; 8:45 am]

BILLING CODE 7590–01–F

NUCLEAR REGULATORY COMMISSION

[Docket No. 030–01786]

National Institutes of Health Issuance of Director's Decision Under 10 CFR § 2.206

Notice is hereby given that the Director, Office of Nuclear Material Safety and Safeguards, U. S. Nuclear Regulatory Commission (NRC), has acted on a Petition for action dated October 10, 1995, submitted by Maryann Wenli Ma, M.D., Ph.D., and Bill Wenling Zheng, M.D., Ph.D. (Dr. Ma and Dr. Zheng or Petitioners), as supplemented by letters dated March 25, 1996, and July 10, 1997, with regard to NRC Licensee, the National Institutes of Health (NIH or the Licensee).

Petitioners requested, pursuant to 10 C.F.R. 2.206, that NRC suspend or revoke the materials license of NIH, NRC License No. 19–00296–10, pending resolution of the issues raised by the Petition, and that NRC take other appropriate enforcement action, including the imposition of civil penalties against NIH for willful and reckless violations of 10 CFR part 20. Broadly stated, the Petitioners assert that, as the direct and proximate result of NIH's: (1) Deliberate failure to control and secure radioactive materials in violation of 10 CFR 20.1801 and 20.1802; (2) failure to maintain an effective bioassay program; and (3) failure to otherwise adhere to the requirements of 10 CFR part 20, Dr. Ma was contaminated with phosphorus-32 (P–32), resulting in both her and her unborn fetus receiving intakes of radioactive material significantly in excess of regulatory limits, additional NIH employees were also internally contaminated with P–32, and NIH failed to take proper actions to assess accurately the level of Dr. Ma's internal contamination or provide appropriate medical care and follow-up treatment.

In their March 25, 1996, supplemental Petition, Petitioners state that NIH's repeated denials that it has any problem with its security over radioactive materials suggests that the NIH radioactive materials license should be suspended or revoked, because the Licensee poses a threat to public health and safety, the Licensee has not responded adequately to other enforcement actions, and is unwilling or unable to comply with NRC requirements. On July 10, 1997, Petitioners submitted another supplement to their Petition, requesting immediate revocation or suspension of the NIH license on the grounds that NIH continues in its failure to implement and maintain a program to oversee licensed radioactive materials sufficiently secure to prevent another contamination incident of the type Dr. Ma experienced in 1995.

For the reasons stated in the ''Director's Decision Under 10 CFR 2.206,'' (DD–97–22) the Director of the Office of Nuclear Material Safety and Safeguards has granted the following requests of Petitioners in part: for enforcement action against NIH for violations of NRC security and control requirements and for violation of NRC requirements related to radiation safety training, ordering radioactive materials, inventory control of radioactive materials, monitoring, and the issuance, use, and collection of dosimetry.

Petitioners' request for NRC action to ensure adequate procedures and instructions to exposed persons for sample collection was granted as described in DD–97–22. The following requests of Petitioners for enforcement action against NIH were denied: for the exposure of Dr. Ma beyond regulatory limits, for the exposure of Dr. Ma's fetus, and for the contamination of the water cooler; regarding notification to Dr. Ma of her level of contamination; regarding Dr. Ma's declaration of pregnancy; regarding the conduct of surveys after Dr. Ma's contamination; and for the failure to accurately calculate Dr. Ma's occupational radiation dose. Finally, Petitioners' request to suspend or revoke the NIH license was denied.

The complete text of DD–97–22 follows this notice and is available for public inspection at the Commission's Public Document Room, the Gelman Building, 2120 L Street, N.W., Washington, D.C., 20003–1527 and at NRC's Region I Office located at 475 Allendale Road, King of Prussia, PA, 19406–1415.

A copy of this Decision will be filed with the Secretary of the Commission for Commission review in accordance with 10 CFR 2.206(c) of the Commission's regulations. As provided by this regulation, the Decision will constitute the final action of the Commission 25 days after issuance, unless the Commission, on its own motion, institutes a review of the Decision within that time.

Dated at Rockville, Maryland, this 17th day of September, 1997.

For the Nuclear Regulatory Commission.

Carl J. Paperiello,

Director, Office of Nuclear Material Safety and Safeguards.

Director's Decision Under 10 CFR 2.206

I. Introduction

By a Petition addressed to the Director, Office of Nuclear Material Safety and Safeguards (NMSS), dated October 10, 1995, Maryann Wenli Ma, M.D., Ph.D., and Bill Wenling Zheng, M.D., Ph.D. (Dr. Ma and Dr. Zheng or Petitioners) requested that the Nuclear Regulatory Commission (NRC) take action with respect to the National Institutes of Health (NIH or the Licensee).

Petitioners request that NRC suspend or revoke the materials license of NIH, NRC License No. 19–00296–10, pending resolution of the issues raised by the Petition, and that NRC take other appropriate enforcement action, including the imposition of civil penalties against NIH for willful and reckless violations of 10 CFR part 20.

As a basis for their requests, the Petitioners assert that NIH has willfully and recklessly committed numerous violations of 10 CFR part 20. Broadly stated, the Petitioners assert that, as the direct and proximate result of NIH's: (1) Deliberate failure to control and secure radioactive materials in violation of 10 CFR § 20.1801 and 20.1802; (2) failure to maintain an effective bioassay program; and (3) failure to otherwise adhere to the requirements of 10 CFR part 20; Dr. Ma was contaminated with phosphorus-32 (P–32), resulting in both her and her unborn fetus receiving intakes of radioactive material significantly in excess of regulatory limits, additional NIH employees were also internally contaminated with P–32, and failure of NIH to take proper actions to assess accurately the level of Dr. Ma's internal contamination or provide appropriate medical care and follow-up treatment. A more detailed description of the concerns raised by Petitioners appears in Section III., below.

By letter dated October 30, 1995, Carl J. Paperiello, Director, NMSS, acknowledged receipt of the Petition and denied Petitioners' request for immediate suspension or revocation of the NIH license because, although certain weaknesses had been identified in the 1995 inspections of NIH, these weaknesses were not sufficiently widespread or egregious as to warrant suspension or revocation of the license.

On November 2, 1995, NRC issued a Demand for Information (EA 95–240) to NIH, requesting that NIH respond to the concerns raised in the Petition. On December 11, 1995, NIH submitted its ''Response to Demand for Information (EA–95–240).'' John N. Weinstein, M.D., Ph.D. (Dr. Weinstein), submitted a response to the Petition dated December 15, 1995.

On March 25, 1996, Petitioners supplemented their Petition in a written reply to the Licensee's December 11, 1995, ''Response to Demand for Information (EA–95–240).'' In their supplemental Petition, Petitioners contend that NIH's repeated denials that it has any problem with its security over radioactive materials suggest that the NIH radioactive materials license should be suspended or revoked, because the Licensee poses a threat to public health and safety, the Licensee has not responded adequately to other enforcement actions, and is unwilling or unable to comply with NRC requirements. On July 10, 1997, Petitioners submitted another supplement to their Petition, requesting immediate revocation or suspension of the NIH license on the grounds that NIH continues in its failure to implement and maintain a program to oversee licensed radioactive materials sufficiently securely to prevent another contamination incident of the type Dr. Ma experienced in 1995. By letter dated August 5, 1997, the supplemental Petition was acknowledged and the request for immediate action was denied because NIH has made continuing progress in improving the security and control of licensed radioactive material since the 1995 contamination event. By letter dated September 10, 1997, NIH responded to the July 10, 1997, supplement to the Petition.

II. Background

NRC license No. 19–00296–10 is a broad-scope license that authorizes possession and use of radioactive material for medical diagnosis, therapy, and research in humans, as well as non-human research and development, at facilities in Bethesda, Rockville, Baltimore, and Poolesville, Maryland. The NIH main campus in Bethesda has 21 buildings housing nearly 3000 biomedical research laboratories. There are more than 800 Authorized Users and more than 5000 supervised users of radioactive material under NIH's licensed program. NIH's Materials License No. 19–00296–10, originally issued on December 7, 1956, was renewed on June 16, 1997, and will expire on June 30, 2002.

The internal contamination of Dr. Ma was discovered by Dr. Zheng (Dr. Ma's husband) during a survey of the NIH laboratory in which they both worked, on the evening of June 29, 1995. At 5:58 p.m., Dr. Zheng reported the internal contamination of his wife to the NIH emergency number, and then to their immediate supervisor, Dr. Weinstein, who was on the premises at the time. Dr. Weinstein notified the NIH Radiation Safety Branch of Dr. Ma's contamination.

Shortly after 6:00 p.m., an NIH ambulance with two emergency medical technicians responded to the scene, and at approximately 6:40 p.m., two personnel from the NIH Radiation Safety Branch (RSB) responded to the scene. Petitioners told RSB personnel that they believed Dr. Ma had been internally contaminated as a result of eating leftovers she had stored in a conference room refrigerator. The RSB performed surveys with portable radiation detection instruments to determine whether radioactive contamination was present in the laboratory, the adjacent hallways and corridors, and in the conference room. The RSB took smears of Dr. Ma's hands,

neck and face to determine if any of the contamination was removable and then had Dr. Ma change out of her clothes into clean scrubs to see if her clothing was radioactive. None of the smears, clothing, or surveys of Dr. Ma showed external contamination. The RSB asked Dr. Ma to submit a urine sample. The sample was surveyed by the RSB and found to contain radioactivity (later determined to be P–32), indicating that Dr. Ma's contamination was internal. Shortly after 8:00 p.m., the NIH ambulance departed with Dr. Ma en route to Holy Cross Hospital (Holy Cross).

NIH RSB staff contacted the on-call physician from the Radiation Emergency Assistance Center/Training Site (REAC/TS) [1] in Oak Ridge, Tennessee, and had the REAC/TS physician speak directly with the emergency room (ER) physician at Holy Cross. The REAC/TS physician stated that he discussed with the Holy Cross ER physician the possibility of administering a phosphate solution for dilution and displacement of the P–32, but that the ER physician choose not to follow this suggestion. The REAC/TS physician also advised the ER physician of the need to collect 24-hour urine samples for determination of Dr. Ma's occupational radiation dose. After consultation with REAC/TS and the NIH Radiation Safety Officer (RSO), the Holy Cross ER physician ordered intravenous infusions of fluids (hydration) in order to dilute Dr. Ma's internal contamination.

The Petitioners did not return to work in the NIH Laboratory of Molecular Pharmacology after the discovery of Dr. Ma's contamination, but eventually returned to work at other laboratories at NIH.

On June 30, 1995, NIH informed an NRC inspector on site at the time that Dr. Ma had been internally contaminated with P–32. On June 30, 1995, NRC initiated an Augmented Inspection Team (AIT) evaluation of the event and presented its preliminary findings to NIH on August 8, 1995. During October 23–24, 1995, and November 6–10, 1995, the NRC staff conducted two special team inspections of NIH. On December 21, 1995, NRC Inspection Report No. 030–01786/95–203 was issued describing the results of those inspections. The AIT issued a redacted version of its report on January 29, 1996, and, upon completion of NRC's investigation, issued the full, unredacted report on January 13, 1997. NRC's Office of Investigations (OI) began an investigation on June 30, 1995. Additionally, the Federal Bureau of Investigation began an investigation, as did the Department of Health and Human Services Office of the Inspector General, and the NIH Police Department. These investigative groups worked in cooperation with each other and shared their findings on an ongoing basis. On January 24, 1997, NRC's OI issued its report, ''National Institutes of Health: Wrongful Administration of P–32, Case No. 1–95–033.'' That report and its associated exhibits are being publicly released concurrent with issuance of this Director's Decision.

NIH performed an assessment of Dr. Ma's intake of P–32, the resultant radiation exposure received by Dr. Ma, and the radiation exposure received by her fetus. In its initial notification to NRC on July 3, 1995, NIH indicated that its estimated ingestion for Dr. Ma was approximately 300 microcuries (μCi) or 11.1 megabequerel (MBq) of P–32.[2] On August 29, 1995, NIH reassessed Dr. Ma's dose and calculated her effective dose equivalent to be 4.17 rem [41.7 millisievert (mSv)], based upon an intake of 500 μCi (18.5 MBq), and the dose to her fetus to be 3.2 rem (32 mSv). Most recently, on July 30, 1996, NIH revised its committed effective dose equivalent (CEDE) estimates for Dr. Ma to between 4.7 and 7.0 rem (47 and 70 mSv), corresponding to an intake range of between 570 and 840 μCi (21.1 and 31.1 MBq). The revised dose to the fetus was between 3.7 and 5.4 rem (37 and 54 mSv). Additional discussion of NIH's dose estimates appears in Section III.K., below.

NRC's estimates indicate that Dr. Ma ingested between 30.3 and 48.1 MBq (820 and 1300 μCi) of P–32. Based on these values, Dr. Ma's estimated internal CEDE was between 80 and 127 mSv (8.0 and 12.7 rem). The annual occupational exposure limit applicable to Dr. Ma was, however, 5 mSv (5 rem) total effective dose equivalent per 10 CFR § 20.1201(a)(1)(i). The estimated dose received by Dr. Ma's fetus was between 51 and 81 mSv (5.1 and 8.1 rem).

NRC estimated that of the 26 other NIH employees who received P–32 contamination from a water cooler situated in a hallway near the Petitioner's laboratory, including Dr. Zheng, one individual who was not an occupational radiation worker received a dose of between 1.5 and 2.5 mSv (150 and 250 millirem), in excess of the applicable dose limit of 1.0 mSv (100 millirem) for members of the public specified by 10 CFR § 20.1301.

NRC issued a series of Confirmatory Action Letters (CALs) to NIH between July 21, 1995, and June 7, 1996, addressing various measures to be taken by NIH, such as: (1) Reduction of the possibility of further ingestion of radioactive material by NIH employees; (2) determination of the full scope of the personnel contaminations at NIH; (3) further enhancement and training of NIH staff regarding security of radioactive material; (4) documentation of corrective actions with respect to enforcement of a new NIH security policy; (5) modifications to the surveillance plan for NIH laboratories; and (6) other specific actions for inspections for NRC compliance.[3]

NRC continued its onsite inspection through July 28, 1995. The AIT conducted a technical debrief with NIH RSB management and staff on August 3, 1995, and with NIH senior management on August 8, 1995. Further NRC inspection activities, including assessment of radiation dose to the exposed individuals, and evaluation of a third-party independent dose assessment, continued through November 15, 1995.

On August 23, 1996, NRC issued a Notice of Violation (NOV) and Proposed Imposition of Civil Penalty of $2500 (EA 96–027) to NIH for failure to physically secure licensed material or maintain surveillance over it to prevent unauthorized removal. Other violations of NRC requirements were also cited, involving: (1) Workers not wearing extremity dosimetry, or returning dosimetry promptly each month, as required; (2) users obtaining radioactive materials without providing required information regarding the identity of the intended user(s) or the signature of the authorized investigator; (3) researchers performing licensed activities without first receiving the required training; and (4) failure to perform thyroid bioassay measurements of researchers who handled gigabequerel [millicurie (mCi)] quantities of volatile iodine-125. On May 20, 1997, NRC issued an Order Imposing Civil Monetary Penalty in the

[1] REAC/TS is a Department of Energy response asset that maintains a radiological emergency response team consisting of physicians, nurses, health physicists and other support personnel. It is on 24-hour call to provide first-line responders with consultative or direct medical and radiological assistance at the REAC/TS facility, accident site, or attending hospital.

[2] Because the system of units employed by NIH and the Petitioner's Consultant were non-metric, the English unit is listed first, followed by its metric equivalent in brackets. However, for those instances where NRC has issued a report, metric units are listed first as primary units, followed by the English units in brackets, which is the usual NRC style.

[3] CAL 1–95–011 (July 21, 1995); CAL 1–95–011, Rev. 1 (July 21, 1995); CAL 1–95–018 (October 27, 1995); CAL 1–95–018, Supplement 1 (November 8, 1995); CAL 1–95–018, Supplement 2 (December 1, 1995); and CAL 1–95–018, Supplement 3 (June 7, 1996).

amount of $2500 (EA 96–027), which NIH paid on June 6, 1997.

III. Discussion

A. Violations of NRC Requirements for Security and Control of Licensed Material

Petitioners assert that, as the direct and proximate result of NIH's deliberate failure to control and secure radioactive materials in violation of 10 CFR §§ 20.1801 and 20.1802, and to otherwise adhere to the requirements of 10 CFR part 20, Dr. Ma was contaminated with P–32, resulting in both her and her unborn fetus receiving an intake of radioactive material in excess of regulatory limits. In addition, Petitioners state that 26 other NIH employees, including Dr. Zheng, were also internally contaminated with P–32.

Petitioners state that NIH has been unwilling to comply with NRC safety requirements in accordance with 10 CFR part 20. Specifically, Petitioners state that during the summer of 1994, NIH officials deliberately failed to lock up radioactive material as part of an experiment with a liberalized policy concerning security and use of radioactive materials, which effectively excused laboratories from locking up radioactive materials, in violation of 10 CFR § 20.1801. NIH requested a license amendment on October 31, 1994, to establish and permanently implement a previously submitted ''Interim Security Policy,'' and an exemption from the requirements to secure (under lock and key), or maintain constant surveillance of, licensed radioactive materials not in excess of 10 times the activity listed in Appendix C to 10 CFR part 20, on a per-container basis. Petitioners state that the resultant breakdown in security led to the issuance of CAL 1–95–018, on October 27, 1995, which required NIH to take immediate steps to secure radioactive materials. Petitioners state that NIH objected to complying with security regulations, and did not withdraw its application for an exemption from the security requirements until after the contamination of Petitioners.

Petitioners state that NRC's repeated discovery of unsecured radioactive materials and of absence of security controls in several NIH laboratories indicates a systemic failure of security rather than an isolated problem, and that NIH's lax control and security of radioactive materials created an environment where acts such as the deliberate contamination of Dr. Ma were bound to occur, given that the means to commit such an offense were readily available. Petitioners state that security over radioactive materials used in the Petitioners' laboratory was nonexistent. Specifically, the refrigerator and freezer used to store radioactive reagents were not locked, the lab was frequently left unattended during non-working hours, and there were no procedures to document individuals' access to the refrigerator or freezer, or to check to see if records were kept regarding the documented use of radioactive materials in that laboratory.

Petitioners state that despite NIH's reckless disregard of NRC requirements, since 1986 NRC has taken no enforcement action against NIH or the National Cancer Institute (NCI)[4] for repeated violations of 10 CFR. Part 20 regulations related to security and control of radioactive material, occupational exposure, notification of exposure, incineration, surveys, monitoring, and dosimetry.

Contrary to the assertions in the Petition, since 1986, and before the June 1995 contamination incident, NRC had taken enforcement action against NIH for violations of NRC requirements concerning security and control of radioactive materials, occupational overexposures, surveys, monitoring and dosimetry.[5] Although many of these enforcement actions involved Notices of Violation for SL IV violations and no civil penalty, they still constitute enforcement action taken by NRC.[6]

The requirements of 10 CFR 20.1801 and 20.1802 to secure and control licensed material are absolute in that the rules specify no radioactivity thresholds. NIH established a threshold amount for the security of radioactive materials located in laboratories based on 10 CFR part 20, Appendix C, quantities and NUREG/CR–6204, ''Questions and Answers Based on Revised 10 CFR part 20'' (January 1994). The answer to Question 129 indicates, in part, that the security requirements described in 10 CFR 20.1801 and 20.1802 will not be enforced for quantities of radioactive material described in 10 CFR part 20, Appendix C, which are exempt from labeling by 10 CFR 20.1905(a). By an amendment request dated October 31, 1994, NIH asked for permission to store up to ten times Appendix C quantities of radioactive material per container in posted radioactive material use areas without the requirement for direct oversight or lock and key. In March 1995, NIH requested an exemption from the requirements of 10 CFR 20.1801 and 20.1802 to store less than Appendix C quantities in unlocked (and unattended) refrigerators or freezers in corridors. NRC approved the NIH request in June 1995 because these quantities did not require labeling.[7] In response to the event of June 1995, NIH revised its security policy for

[4] NIH and NCI are two different licensees. Science Applications International Corp. holds NRC broadscope license for activities at the NCI-Frederick Cancer Research and Development Center facility located at Fort Dietrick in Frederick, MD (NRC License No. 19–21091–0). Prior to March 1995, the license was held by Program Resources Incorporated (PRI). Since 1985, NRC has issued to PRI six NOVs associated with either cited severity level (SL) IV violations or a monetary civil penalty: (1) During a February 1995 inspection, three SL IV violations were cited for inadequate surveys for P–32 personnel contamination, failure to perform thyroid bioassays, and failure to perform proper package surveys; (2) during a January 1993 inspection, two SL IV violations were cited for failure to wipe test packages and perform thyroid bioassays; (3) during a February 1991 inspection, one SL IV violation was cited for failure to perform package surveys; (4) during a January 1989 inspection, one SL IV was cited for failure to perform survey instrument calibration; (5) a $2500 Civil Penalty was issued on February 27, 1987, for an SL III violation from an inspection performed earlier that month; and (6) a December 1986 inspection resulted in five violations being cited for extremity overexposure, inadequate training, improper transfer and disposal of radioactive material, and exceedance of the license possession limits.

[5] (1) The June 11–13, 1990, inspection resulted in an NOV categorized at an SL IV, for failure to obtain specific user estimates of solid radwaste generation, as well as other non-cited violations for loss of radioactive material that was licensee-identified (Report No. 90–001). (2) The July 8–12, 1991, inspection resulted in an NOV categorized at an SL IV for failure to secure radioactive material (Report No. 91–001). (3) The July 20–24, 1992, inspection identified as inadequate dose assessment for a lutetium-177 contamination incident, and resulted in an NOV characterized as an SL IV (Report No. 92–001). (4) The January 13, 1993, inspection resulted in an escalated enforcement action (EA 93–009) categorized at two SL IVS and one SL III for failure to survey after use of radioactive material, a failure to supply dosimetry for a P–32 worker, and a P–32 contamination extremity overexposure, respectively (Report No. 93–001). (5) The April and May 1994 inspection, resulted in enforcement action (EA 94–123) categorized as two SL IVS for failure to secure, as well as a failure to survey, after using radioactive material (Report No. 94–001). The security violations from the April-May 1994 inspection also resulted in the issuance of a CAL on May 5, 1994. On July 12, 1994, an additional security violation resulted in the loss of a package containing 2.6 MBq (70 μCi) of iodine-125. The 1994 security violations were discussed at an enforcement conference held with the Licensee on July 27, 1994, and subsequently were cited as an SL IV in an NOV issued to NIH on August 16, 1994. (6) During the April and May 1994 inspections, an apparent violation was identified for incinerator operations (Report No. 94–001). On August 10, 1994, however, NIH informed NRC that it had permanently discontinued incineration operations at NIH in May 1994. Consequently, no enforcement action regarding incineration was taken.

[6] *See* ''General Statement of Policy and Procedures for NRC Enforcement Actions,'' 10 C.F.R. Part 2, Appendix C (1986–1995) and NUREG–1600, ''General Statement of Policy and Procedures for NRC Enforcement Actions'' (July 1995), Section VI.

[7] See NMSS Technical Assistance Request dated June 19, 1995, from L. Camper, NRC Headquarters to R. Bellamy, NRC Region I.

radioactive materials to require that all licensed material must be in locked storage, or in a locked room, if otherwise unattended, effective October 26, 1995. On January 19, 1996, NIH submitted a license amendment to, among other things, permit licensed material that is exempt from the labeling requirements of 10 CFR 20.1905(a) to be exempted from the revised October 26, 1995, NIH security policy. NRC renewed the NIH license on June 13, 1997, but did not authorize any exemptions to the security and control requirements of 10 CFR 20.1801 and 20.1802.

Petitioners are correct in stating that there have been security and control problems at NIH that required amelioration. In particular, the failure to secure refrigerators and freezers used to store radioactive reagents, and the failure to secure or maintain surveillance over laboratories, formed the basis for a series of NRC enforcement actions. Several CALs were issued to address security and control of radioactive material after the June 1995 contamination of Dr. Ma.[8] On August 23, 1996, NRC issued a NOV and Proposed Imposition of Civil Penalty of $2500 (EA 96–027) to NIH for failure to physically secure licensed material or maintain surveillance over it to prevent unauthorized removal. On May 20, 1997, NRC issued an Order Imposing Civil Monetary Penalty in the amount of $2500 (EA 96–027), which NIH paid on June 6, 1997. Based on the inspections and the investigation, the NRC staff does not conclude that these violations were willful, contrary to the assertions of Petitioners. Moreover, although the AIT Report stated that the Licensee's violations of NRC security and control requirements could have been a contributing factor, after review of the various inspection and investigative results, the NRC staff concludes that the violations of NRC security and control requirements did not contribute to the internal contamination of Dr. Ma, her fetus, or the other 26 NIH employees, including Dr. Zheng.

Since the 1995 contamination event at NIH, NRC performed several inspections of NIH. Additionally, over this period, NIH performed 90,857 laboratory audits. The most recent NRC inspection report in July 1997 found that NIH has made continuing and significant progress in improving the security and control of licensed radioactive material since the 1995 contamination event. For example, the average rate of noncompliance with NRC security and control requirements has declined to 0.25 percent of laboratories surveyed, from an average rate of 0.57 percent since the last NRC inspection of September 1996. *See* NRC Inspection Report No. 030-01786/97–001 (July 29, 1997). Additional enforcement action for security and control violations is not warranted.

In view of the above, Petitioners presented valid concerns regarding security and control of licensed material at NIH, and their request for enforcement action with respect to violations of NRC security and control requirements was granted in part as described above.

B. Dosimetry, Radiation Safety Training, and Ordering Radioactive Materials

Petitioners state that Dr. Weinstein, the Senior Investigator in the Laboratory of Molecular Pharmacology and the former supervisor of Petitioners, insisted that the Petitioners begin working with radioactive materials before they were given radiation safety training and, on two occasions, directed the Petitioners to use Dr. Weinstein's and another Authorized User's identification number to order radioactive material before Petitioners were assigned their own identification numbers. Petitioners state that the AIT found that during the first 3 months of their research, the Petitioners were given radioactive materials that had been ordered by a researcher who had since left NIH, which was not reported by the Authorized User, Dr. Weinstein, as required on NIH Form 88–1; and that in November 1994, Petitioners were using phosphorus-33 (P–33), a low-energy beta-emitting isotope requiring whole body dosimetry (or whole body badges) during its use, but that Petitioners had not been trained to use radioactive material. In addition, Petitioners state that an NRC interview of a former researcher revealed that she had ordered radioactive materials for herself and shared them with other researchers, although these users were not listed on NIH's Form 88–1.[9]

NIH worker training, use of identification numbers for procurement of licensed materials with NIH Form 88–1, and dosimetry issuance and collection, were reviewed during the October 23–24 and November 6–10, 1995, NRC inspections. As a result of those inspections, NRC cited NIH for several violations. Specifically, the Licensee was cited for allowing users to order radioactive materials electronically between October 3 and November 20, 1995, without the signature of the authorized investigator. This violation was cited as a SL IV (EA 96–027). Additionally, NIH was cited for permitting the use of sulfur-35, P–32, and P–33 by two researchers in October 1994, before providing the researchers with the training course entitled, ''Radiation Safety in the Laboratory,'' on November 29, 1994. This violation was also cited as an SL IV (EA–96–027). NIH was not cited for Petitioners' use of P–33 without the use of whole body dosimetry because neither the NIH License nor NRC regulations require such dosimetry for low-dose material. *See* Section III.C. and n. 12, below. NIH was cited, however, for violations of license requirements to use extremity dosimetry when using more than 185 MBq (0.5 mCi) of P–32 (EA 96–027).

Accordingly, Petitioners' request for enforcement action against NIH for violations of dosimetry, training, and ordering radioactive materials requirements was granted in part as described above.

C. NIH Routine Monitoring of, and Dosimetry for, Petitioners

Petitioners state that Dr. Ma was internally contaminated, in part as a result of NIH's failure to document Dr. Ma's exposure history at NIH, and failed to properly assess Dr. Ma's internal radiation doses, in violation of 10 CFR §§ 20.1202, 20.1204, 20.1501, and 20.1502. Petitioners state that NIH did not routinely monitor Petitioners' exposure to radiation and radioactive material through use of an appropriate dosimetry program. Specifically, the dosimetry given to Petitioners when they first arrived at NIH was never collected or analyzed, no dosimetry was assigned to them at the time of Dr. Ma's contamination, and as a result

[8] On July 21, 1995, CAL 1–95–011 was issued, which described the actions that NIH would take to reduce the possibility of further ingestion of radioactive material and to determine that the full scope of the personnel contaminations was known. On July 21, 1995, CAL 1–95–011, Revision 1, was issued to clarify certain points in the first CAL. On October 27, 1995, NRC issued CAL 1–95–018, which described the actions that NIH would take following an NRC special inspection on October 23 and 24, 1995, to further enhance and train NIH staff regarding security of radioactive material. On November 8, 1995, NRC issued CAL 1–95–018, Supplement 1, to further document the corrective actions that NIH took with respect to enforcement of the new NIH security policy, modifications to the surveillance plan for NIH laboratories, and other specific actions for inspections for NRC compliance. On December 1, 1995, NRC issued CAL 1–95–018, Supplement 2, to adjust each deadline within CAL 1–95–018 and its supplement. This supplement described the ongoing upgrades, to the radioactive material security program, that required that any posted room or area which contained radioactive materials in use, radioactive waste, or radioactive materials in unsecured storage, would be required to be locked when unoccupied. On June 7, 1996, NRC issued CAL 1–95–018, Supplement 3, to further clarify issues with regard to security and control of licensed radioactive material in building corridors and laboratory freezers at NIH.

[9] These facts do not constitute a violation of NRC regulations or the NIH license.

Petitioners were not wearing dosimetry at the time of Dr. Ma's contamination. Petitioners state that in November 1994, Petitioners were using P–33, a beta-emitting isotope requiring whole body dosimetry during its use, but Petitioners were not wearing required dosimetry, and Petitioners had never been issued dosimetry by Dr. Weinstein although they used P–32 in December 1994, and until March 1995.

NIH was not required to routinely monitor Petitioners' occupational exposure to radiation, or to document their occupational exposure history. 10 CFR § 20.2106(a), ''Records of Individual Monitoring Results,'' provides, in part, that ''Each licensee shall maintain records of doses received by all individuals for whom monitoring was required pursuant to § 20.1502 * * *.'' (Emphasis added) 10 CFR § 20.1502(a) provides that ''Each licensee shall monitor occupational exposure to radiation and shall supply and require the use of individual monitoring devices by—(1) Adults likely to receive, in 1 year from sources external to the body, a dose in excess of 10 percent of the limits in § 20.1201(a).'' (Emphasis added) Based on NRC's review of information maintained by NIH for the past 10 years regarding occupational exposures at NIH, it is evident that it is not likely that any NIH user of NRC-licensed radioactive materials would exceed 10 percent of the applicable occupational standard in 10 CFR § 20.1201.[10]

Accordingly, issuance of personnel dosimetry monitoring, although done by NIH as a prudent measure in operating its Radiation Safety Program, was not required by 10 CFR § 20.1502. Since monitoring of Petitioners was not required, the recording requirements of 10 CFR § 20.2106 were not applicable to Petitioners.[11]

Condition 29 of the NIH License required the use of extremity (wrist or finger) monitors by occupational workers using P–32 in quantities greater than 0.5 mCi (185 MBq), but did not require the use of whole-body dosimetry by persons using P–32 or P–33.[12] Based on a review of the Petitioner's laboratory notebooks, it appears that Dr. Ma did not use P–32. Additionally, Dr. Ma states that she advised her obstetrician that she had previously been working with low dosage material (P–33) and, upon learning of her pregnancy, stopped handling radioactive isotopes altogether. Nonetheless, NIH internal documents demonstrate that NIH provided whole body dosimetry to Petitioners on October 28, 1994.[13] Although Petitioners' laboratory notebooks indicate that Dr. Zheng used P–32 on October 17, 1994, 11 days before receipt of a whole body dosimeter, this was not a violation of NIH License Condition 29. Moreover, because Petitioners never worked with more than 185 MBq (0.5 mCi) of P–32, they were not required to wear extremity dosimetry. Additionally, since the monitoring required by License Condition 29 is not required pursuant to 10 CFR § 10.1502, the results of that monitoring would not be subject to NRC dose recording requirements, contrary to the Petitioners' assertion. See n. 11, *supra.*

NRC conducted two special team inspections on October 23–24, 1995, and November 6–10, 1995, in which NIH personnel dosimetry issuance and collection were evaluated. Although review of exposure records during this inspection indicated that occupational doses to individuals from exposure to licensed materials were well below NRC limits, NIH was cited for one SL IV violation involving the failure to issue, wear, and return, individual monitoring devices (EA 96–027).

Accordingly, Petitioners' request for enforcement action against NIH for violations of monitoring and dosimetry requirements was granted, in part, as described above.

D. Inventory Control of Radioactive Materials

Petitioners assert that NIH exercised poor inventory control of radioactive materials. Specifically, if NIH had accurately monitored the use and disposal of radioactive materials, particularly P–32, it might be possible to ascertain who had ordered, but not used, the requisite amounts of P–32 within the timeframe of Petitioners' contamination, and possibly assist law enforcement officials to ascertain who contaminated Petitioners. Petitioners relied on the findings of the AIT that: (1) The accuracy of inventory records is questionable because researchers only estimate the amount of material removed from each vial, radioactive decay is rarely accounted for, and if the vial is not emptied (because the expiration date has passed), the users do not check the balance before disposal; and (2) the computerized inventory system NIH used to replace Form 88–1 does not comply with the NIH license because the electronic document does not include the signature of the Authorized User, and has no mechanism to reasonably verify that an Authorized User had placed an order for radioactive materials and had received those materials.

NIH places ultimate responsibility for the proper use of radioactive material on the Authorized User who orders the material. Authorized Users are permitted by NIH policy to order and share radioactive material with other users, and a Supervised User may work under more than one Authorized User. If an Authorized User wishes to transfer responsibility for material ordered under her/his authorization, an NIH 88–1 form must be completed transferring responsibility to another Authorized User. The RSO stated that routine laboratory audits include checks to see who is using radioactive material and that unauthorized use is dealt with severely.

NIH License Condition 29 makes Authorized Users responsible for maintaining a record of the receipt, use, and disposal of radioactive materials under their authorization by use of Form NIH–88–16, ''Isotope Receipt, Utilization, and Disposal Record'' or equivalent. In addition, the RSO, in a memorandum dated October 3, 1995, reminded Authorized Users that transfers among other Authorized Users must be documented by completion of the same form and submittal of the form to the RSB before the transfer. During NRC inspections conducted October 23–24 and November 6–10, 1995, the inspectors were informed, during discussions with Authorized Users and RSB staff, that each shipment of radioactive material delivered has normally been accompanied by Form NIH 88–1. Authorized Users stated that they knew that they were required to

[10] In addition, during 1995, 6374 individuals at NIH were issued monitoring devices. Only one individual (other than Dr. Ma) using NRC licensed materials exceeded 10 percent of the applicable occupational external dose standard [the total deep dose equivalent to this individual was reported as 550 millirem (5.5 mSv)].

[11] In addition, Regulatory Guide 8.34, ''Monitoring Criteria and Methods to Calculate Occupational Radiation Doses'' addresses the applicability of the dose recording requirements when monitoring is not required. Regulatory Guide 8.34, paragraph 1.4 states that ''While the results of required monitoring are subject to the dose recording requirements of § 20.2106, the results of monitoring provided when not required by § 20.1502 are not subject to the dose recording requirements.''

[12] License Condition 29 requires conduct of the NIH program in accordance with the NIH license application dated July 28, 1986. Attachment 10–D of the July 28, 1986, application states that persons using or in close proximity to persons using gamma emitters, P–32, or radiation-producing machines ''* * * should wear body film badges.'' This is a recommendation, not a requirement, regarding whole-body dosimetry for only P–32. P–33 usage does not require any dosimetry. In addition, Attachment 10–D states that the ''* * * license requires extremity monitors for P–32>0.5 mCi.'' *See* p. 35.

[13] NIH ''Response to Apparent Violations in Inspection Report Nos. 030–01786/95–002 (Redacted) and 030–01786/95–203'' (May 23, 1996), Exhibit AIT–AV2–1.

keep records of the material currently on hand after loss by decay or disposal of material, and all those interviewed used the Form NIH 88–1. The inspectors did not identify any instances in which the inventory was not being kept current.

Regarding the Petitioner's concern about the accuracy of inventory records, NIH has recognized a need to review its radioactive material accountability portion of the Radiation Safety Program. Accordingly, the NIH RSO directed a complete and thorough physical inventory for radioactive materials during the latter half of 1996.[14] As of June 23, 1997, this inventory was completed, and now serves as the baseline for an on-line, real-time tracking of all radioactive materials within the RSB's centralized database system. Each Authorized User receives a complete inventory of his/her materials from the centralized database each month and is requested by the RSB to adjust records consistent with his/her use and disposal of radioactive materials.

For the NIH Authorized User to track the use of individual items of NRC-licensed materials, a new computer-generated inventory and disposal form was developed and is currently in use at NIH. This system permits Authorized Users to make changes in users, if required, and to report disposal and other inventory changes to RSB for update in the centralized database. This system, not present before 1996, substantially enhances NIH's accountability for radioactive material. Increased accountability has received NIH senior management attention and is considered by NRC staff to be a potential deterrent to the use of licensed radioactive materials for unauthorized purposes.

Initial use of the computerized inventory system, however, involved violation of NRC requirements. NIH License Condition 29 requires that the radiation safety identification number and name of all persons who will use the radioactive material, the name and signature of the Authorized User, be entered on form NIH 88–1.[15] Between October 3 and November 20, 1995, however, the licensee allowed users to order radioactive materials electronically, without the signature of the Authorized User. In addition, an NIH 88–1, submitted for order and use of radioactive materials received on September 9, 1994, did not include the radiation safety identification number and name of all persons who would use the radioactive material. NIH was cited for these irregularities as an SL IV violation (EA 96–027).

Accordingly, Petitioners' request for enforcement action against NIH for poor inventory control of radioactive materials was granted in part as described above.

E. Timeliness of NIH Emergency Personnel Response to Contamination Incident

Petitioners contend that NIH personnel responding to the scene of the incident failed to respond in a timely manner to the contamination event, resulting in Dr. Ma's transport to Holy Cross Hospital more than 3 hours after discovery of her contamination. Petitioners state that after Radiation Safety Branch (RSB) officials confirmed Dr. Ma's contamination, they took 1 hour searching for a shower to decontaminate her, that RSB officials surveyed the conference room and refrigerator, and that RSB officials directed Dr. Ma to provide a urine sample, which confirmed that her contamination was internal.

Dr. Zheng reported the internal contamination of Dr. Ma to the NIH emergency number at approximately 5:58 p.m., shortly after discovery of her contamination. The first NIH personnel (two emergency medical technicians) responded immediately and arrived on the scene with an ambulance at approximately 6:00 p.m. Dr. Zheng also notified Petitioners' immediate supervisor, Dr. Weinstein, who was on the premises at the time. Dr. Weinstein, the Authorized User, contacted the RSB at 6:00 p.m. and notified the Chief of the Radiation Safety Operations Section about the contamination incident. In addition, the NIH Fire Department independently notified the Deputy RSO, at approximately the same time, of a possible radioactive material contamination event involving an ''injection of radioactive material.'' (The Deputy RSO is at the top of the emergency call list for response to incidents involving radioactive materials). The Deputy RSO advised the RSO of the report at approximately 6:00 p.m. and contacted the NIH Occupational Medical Service (OMS) for information on the incident.

At approximately 6:15 p.m., the first of two responding RSB health physicists was notified by the RSB receptionist that a second health physicist was on the phone with the RSB Section Chief talking about a possible contamination event in Building 37. The two responding RSB health physicists picked up spill and skin decontamination kits (which is a routine and necessary event response function) and responded to Building 37. Both health physicists met the Deputy RSO in the RSB parking lot at Building 21, and were informed that Dr. Ma was being transported to OMS at Building 10. The health physicists responded directly to OMS and were advised by the physician on duty that Dr. Ma was still in Building 37. The health physicists then responded to the fifth floor of Building 37, arriving at approximately 6:40 p.m.

To determine if Dr. Ma's contamination was external or internal and to identify the source of the contamination, the RSB took several measures. The emergency medical technicians and the RSB both evaluated Dr. Ma's condition and questioned Petitioners about the source of her contamination. The RSB took smears of Dr. Ma's hands, neck, and face to determine if any of the contamination was removable and then had Dr. Ma change out of her clothes into clean scrubs to see if her clothing was radioactive. None of the smears, surveys, or clothes of Dr. Ma showed external contamination.[16] The RSB asked Dr. Ma to submit a urine sample at approximately 7:00 p.m. The sample was surveyed by the RSB and found to contain radioactivity, indicating that the contamination was internal. The RSB health physicists performed surveys with portable radiation instruments to determine whether radioactive contamination was present in the laboratory, adjacent hallways and corridors, and in the conference room. Shortly after 8:00 p.m., NIH transported Dr. Ma to Holy Cross Hospital, where Dr. Ma arrived at approximately 8:20 p.m. Holy Cross was selected over Suburban Hospital, which was much

[14] See letter from M. Gottesman, NIH, to R. Blough, NRC Region I, dated June 23, 1997.

[15] License Condition 29 requires conduct of the NIH program in accordance with the NIH license application dated July 28, 1986. Item 10.6 of the July 28, 1986, application required, in part, that the Authorized User provide to the Radiation Safety organization a completed Form NIH 88–1, ''Request for Purchase and Use of Radioactive Materials,'' for each incoming shipment before the materials are released to the investigator. Form NIH 88–1, was provided as attachment 10–F to the July 28, 1986, application. Form NIH 88–1 requires, in part, that the radiation safety identification number and names of all persons who will use the radioactive material, the name of the authorized investigator, and the signature of the authorized investigator, be entered on the form.

[16] Because Dr. Ma's clothing was not contaminated, there was no need for her to shower in order to remove external contamination. Petitioner's assertion that RSB took 1 hour searching for a shower to decontaminate Dr. Ma was not substantiated by the inspections or the investigation.

closer, because Suburban Hospital did not have an obstetrics department.

Based on the inspections and the investigation, NRC staff concludes that NIH personnel responded properly and in a timely fashion to the incident. The actions taken by NIH to determine whether Dr. Ma was externally or internally contaminated and to identify the source of her contamination are time-consuming steps that must be taken during event response to ensure that the spread of radioactive contamination is prevented, especially when the event involves the transfer of personnel off the licensee's site and into a hospital setting. Moreover, because there were no signs of a life-threatening condition or immediate danger to Dr. Ma, which would have made immediate transport necessary, the Licensee's attention to these measures was eminently reasonable before transport of Dr. Ma to the hospital.

F. Defects in NIH Emergency Response to Dr. Ma's Contamination

Petitioners state that NIH's emergency response to Dr. Ma's contamination was defective in that NIH gave inappropriate and inadequate information and advice to Dr. Ma regarding her level of contamination, and failed to advise Dr. Ma concerning precautions to prevent spreading that contamination. Specifically, Petitioners state that one of the two RSB health physicists who responded to the event erroneously told Petitioners, before Dr. Ma's transport to Holy Cross Hospital and before any analysis concerning the extent of Dr. Ma's contamination, that the exposure Dr. Ma received was well within the allowable limits, that there was no risk to her, and, although it was not certain, that there appeared to be no problem posed to Dr. Ma's fetus. Additionally, Petitioners state that no one warned Dr. Ma about the possibility of vomiting as a consequence of her contamination, or instructed Dr. Ma as to appropriate steps to prevent contamination of her home as a result of vomiting. As a result, Dr. Ma contaminated her car and apartment.

The Petitioners are correct in stating that at the time that the two RSB staff responded to the event, there was no way (within the first few minutes) to determine if the radiation exposure that Dr. Ma received was within NRC regulatory limits, or if the dose received was harmful. Indeed, the only thing that could be determined at that time was whether or not the radioactive contamination was internal or external, which the RSB staff did effectively.

There are no NRC requirements concerning advice by licensees to their employees during emergencies concerning the possibility of further contamination of the employee's home and belongings. As occupational radiation safety workers at NIH, the Petitioners were required to, and did, complete formal radiation safety training on November 29, 1994. As part of that training, personnel protective procedures were described to limit the exposures from both external and internal sources of radiation. In addition, as part of their required daily radiation surveys, the Petitioners were aware of the potential hazards associated with contamination and radioactive material in their control and the need to isolate and remove any detected contamination.

On the evening that Dr. Ma became internally contaminated with P–32, the RSB staff at NIH and the hospital staff at Holy Cross informed Dr. Zheng that Dr. Ma's blood and urine were contaminated. The next day, the RSB staff surveyed the Petitioners' automobile because Dr. Ma had indicated that she had vomited in it earlier that morning. RSB staff found contamination inside the passenger's side of the car and decontaminated the affected area immediately. RSB staff also surveyed the Petitioners' apartment where contaminated areas were cleaned up or physically removed material for radioactive decay. Effective communications during emergencies are difficult, at best, and might have been improved by reminding Dr. Ma of the potential for not only her excreta being contaminated, but also any other bodily fluids released as well. However, the failure to fully advise Dr. Ma of the potential spread of contamination via body fluids was not a violation of any NRC requirement.

Petitioners also state that the NIH response to Dr. Ma's contamination was defective because RSB officials failed to secure the area, thus providing an opportunity for NIH personnel to tamper with or contaminate evidence.[17] In fact, before departing the scene of the event on June 29, 1995, NIH RSB personnel locked the conference room and marked it with security tape. The NIH RSB also asked Dr. Weinstein to secure the laboratory, which he did by locking it. On June 30, 1995, the NIH RSB changed the locks to the conference room, and again locked the laboratory and then secured it with police tape. Based on a review of the evidence, NRC concludes that NIH took all reasonable measures to secure the scene after responding to the event.

G. NIH Conduct of Surveys After Contamination Incident

Petitioners state that in violation of 10 CFR § 20.201(b) and an October 14, 1992, commitment by NIH to emphasize to all users the importance of notifying Radiation Safety promptly of spills of radioactive materials when there is personnel contamination, NIH failed to conduct surveys reasonably necessary under the circumstances surrounding discovery of Dr. Ma's contamination on June 29, 1995, and thus failed to detect P–32 contamination of a water cooler until July 14, 1995, which caused an additional 26 people, including Dr. Zheng, to become internally contaminated.

NRC stated in its AIT report of January 13, 1997, that because NIH did not survey the water cooler in the corridor near Petitioners' laboratory until July 14, 1997, 26 other individuals (besides Dr. Ma) were internally contaminated with P–32 by drinking water from the cooler. After review of all the evidence, however, the staff concludes that, although it would have led to a more desirable outcome to have identified the contaminated water cooler earlier, under the circumstances, NIH conducted all reasonably necessary surveys. When NIH safety response personnel were called to the scene, Dr. Ma and Dr. Zheng insisted that Dr. Ma had been contaminated by food that she had stored in the conference room refrigerator. Dr. Ma and Dr. Zheng also told RSB personnel that they brought all their own food and beverages to work with them. Immediately after the event, Dr. Ma and Dr. Zheng denied that they drank any liquid from Building 37, and stated that they brought all liquids from home. In the days after the incident, Dr. Zheng denied drinking water from the water cooler. Nonetheless, NIH sought to determine if other individuals also had been internally contaminated. After specimens provided by other NIH employees on July 13, 1995, demonstrated their internal contamination with P–32, and in an attempt to identify a common source of contamination, NIH surveyed the water coolers and coffee stations on the fifth floor of Building 37 on July 14, 1995, and identified contamination in a water cooler located in the hallway. Only later

[17] Petitioners assert that this provided Dr. Weinstein with an opportunity to ''find'' a coffee cup with a centrifuge tube, both contaminated, that RSB officials attest were not present when they surveyed the same area earlier, and that, on his own initiative, Dr. Weinstein put the items in a plastic bag and moved the items into his lab and locked the door. In fact, two NIH employees had seen the coffee cup and centrifuge tube in the hallway near Petitioners' lab over a period of 1 to 7 days before the event. Additionally, the NIH RSB directed Dr. Weinstein to put these items aside for the NIH RSB's later examination and to secure the laboratory.

did Drs. Ma and Zheng tell the NIH RSB that they had drunk from the contaminated water cooler. Finally, although NRC's AIT inspection arrived at NIH on June 30, 1995, one day after the discovery of Dr. Ma's contamination, NRC staff did not consider the possibility that Dr. Ma might have been contaminated by using a water cooler or suggest surveying water coolers.

Accordingly, the NRC staff concludes that under the circumstances, NIH did not fail to conduct reasonably necessary surveys after discovery of Dr. Ma's contamination in violation of 10 CFR § 20.1501(b).[18]

H. Procedures for Collection of Samples in Contamination Events

Petitioners state that before Dr. Ma's internal contamination, NIH failed to have a procedure in place to provide clear instructions to Dr. Ma about sample collection. Petitioners note that John Glenn, Ph.D. (Dr. Glenn), Chief, Radiation Protection and Health Effects Branch, Office of Nuclear Regulatory Research, NRC, stated at the December 19, 1995, Commissioner briefing that NIH ''* * * lost information about early excretion of P–32 because clear instructions were not provided to the exposed individual about sample instruction [collection of samples].'' [19]

The events and transcript from the December 19, 1995, Commissioner briefing on The Generic Implications of Recent Events Involving Ingestion of Radioactive Material at Research Facilities reveal a similarity between the NIH AIT and the Massachusetts Institute of Technology (MIT) Incident Investigation Team (IIT) events in that both licensees lost information about early excretion of P–32 because clear instructions had not been provided to the exposed individual about how to collect samples. Although there is a considerable amount of guidance in the scientific literature available on the management of contaminated persons, NRC staff determined that it would be beneficial to provide guidance to licensees on the levels of intake that should be considered for medical evaluation, the available methods to reduce the committed dose resulting from an intake, as well as guidance for the collection of samples for analysis. Consequently, NRC staff has completed its evaluation of current regulatory guidance on the collection of samples for analysis, as well as the analysis of intakes, and will revise the existing regulatory guidance to licensees.

Accordingly, the Petitioners' request for NRC action to ensure adequate procedures and instructions to exposed persons for sample collection is granted as described above.

I. Dr. Weinstein's Interactions With NIH Radiation Safety Response Personnel

Petitioners state that Dr. Weinstein interfered with the NIH radiation safety response to Dr. Ma's contamination, and delayed transport of Dr. Ma to the hospital for emergency treatment. Specifically, Petitioners state that Dr. Weinstein performed smear tests; directed Dr. Ma to drink a lot of water; argued with NIH RSB officials about how to save urine samples in order to get a correct determination of the amount of radiation Dr. Ma had ingested; attempted to interfere with RSB personnel efforts to question and counsel Dr. Ma about the biological effects of radioactive materials and her contamination; tried to answer questions asked of Dr. Ma by RSB personnel; and attempted to usurp RSB functions by conducting a survey of the NIH conference room where Dr. Ma had stored her food.

Based on the inspections and the investigation, NRC concludes that Dr. Weinstein did not interfere with the reasonable and necessary NIH radiation safety personnel measures in response to the contamination event, delay Dr. Ma's transport to the hospital, or usurp or attempt to usurp RSB functions. Both Dr. Weinstein and Dr. Zheng provided assistance to NIH RSB personnel in counting smears taken from Dr. Ma by RSB personnel. Dr. Weinstein reasonably asked Dr. Ma to drink liquids. (Dr. Weinstein recalled that the NIH RSB recommended over the phone that Dr. Ma drink liquids to stay hydrated.) The Holy Cross Hospital ER physician and the NIH RSO agreed that intravenous hydration of Dr. Ma was advisable. Petitioners state that Holy Cross Hospital issued instructions to Dr. Ma on her discharge to maintain good hydration. Additionally, the RSB directed Dr. Ma to provide a urine sample for immediate survey, a measure necessary for the NIH RSB to determine with certainty whether Dr. Ma was internally contaminated and thus whether to transport Dr. Ma to the hospital. The evidence does not corroborate the Petitioners' assertion that Dr. Weinstein argued with RSB personnel about the proper procedure for saving specimens from Dr. Ma. NIH RSB personnel at the scene described Dr. Weinstein as urging Dr. Ma's immediate transport to the hospital, along with Dr. Zheng, and as being impatient. Dr. Weinstein was not the only non-RSB person to survey the conference room. Dr. Zheng told an NIH colleague that he had found radioactive contamination in the conference room by surveying it. That colleague and a second colleague then surveyed the conference room for contamination shortly before arrival of the RSB. Dr. Weinstein went to survey the conference room after a third and a fourth colleague had already begun surveying the room.

J. Medical Care of Dr. Ma and Treatment To Reduce Her Contamination

Petitioners state that NIH personnel gave conflicting and harmful directions to Holy Cross ER personnel which delayed Dr. Ma's treatment, that NIH provided inadequate medical treatment of Dr. Ma, which was completely ineffective to reduce her contamination, and that the only effort NIH made to hasten the removal of the ingested radioactivity was to give Dr. Ma intravenous infusions of fluid at Holy Cross Hospital. Petitioners state that the Holy Cross ER Physician's attempt to consult with REAC/TS in Oak Ridge, Tennessee, was frustrated because the Holy Cross Hospital telefax machine was unable to receive information from REAC/TS. Petitioners believe that Dr. Ma should have been given phosphate orally as the buffered sodium salt, calcium intravenously, and parathyroid intramuscularly, but was only given intravenous infusions of fluid (hydration therapy), based on directions by NIH personnel, which resulted in no discernible enhancement of P–32 elimination.

Petitioners state that Dr. Weinstein's presence in Dr. Ma's treatment points up fundamental flaws in NIH medical intervention and investigative security protocols, and the fact that Dr. Ma was directed by the Holy Cross ER physician to follow-up with Mr. Zoon, Dr. Weinstein, and Dr. Ma's personal obstetrician-gynecologist (OB–GYN) ''demonstrate[s] that the ER physician looked to NIH officials, including Dr. Weinstein, to direct treatment of Dr. Ma for internal contamination.''

Petitioners state that NIH provided inadequate medical care to and follow-up on Dr. Ma. Specifically, NIH had no plan in place to ensure that one single person was in charge of directing and coordinating a contaminated employee's medical care and follow-up. No one from NIH met with Dr. Ma to discuss

[18] At the time of the incident, 10 CFR § 20.1501(a) required licensees to perform surveys that are reasonable under the circumstances. On January 1, 1993, 10 CFR § 20.201, with a similar requirement, became extant.

[19] Dr. Glenn's comment was made before full information was available regarding sample collection after the NIH event. With the benefit of all the evidence, it is now apparent that clear instructions were provided to Dr. Ma and that no information was lost. See Section III.K.(2).

her contamination levels, and what, if any, medical treatment might decrease her contamination levels, except for a copy of the early NIH contractor, Oak Ridge Institute for Science and Education (ORISE) intake calculation of 9.8 MBq (265 μCi), given to Dr. Ma in July 1995 by the NIH RSO. The NIH OMS failed to provide any medical care or follow-up treatment to remove the ingested radioactivity. Petitioners state that Dr. Stansbury of OMS examined Dr. Ma on June 30, 1995, and that no services were provided by OMS after that date, except to request blood work results. Petitioners state that although Dr. Ma told Dr. Stansbury of her severe lower thoracic pain, Dr. Stansbury attributed the pain to Dr. Ma's pregnancy and recommended no follow-up other than for Dr. Ma to see her OB–GYN.

Petitioners state that on August 4, 1995, they visited OMS and reported that Dr. Ma was experiencing vomiting and severe pain in her lower right side, but that Dr. Ma was again referred to her OB–GYN. Petitioners state that on August 8, 1995, Dr. Ma again reported to OMS that she continued to experience frequent vomiting and nausea, and again no treatment or intervention was suggested. After the end of July 1995, no one from NIH requested additional urine samples from Dr. Ma, only blood samples. Dr. Ma states that subsequent tests revealed that the cause of Dr. Ma's lower thoracic pain was a significant liver function abnormality resulting from her contamination.[20]

NIH took reasonable and appropriate measures to determine whether Dr. Ma's contamination presented a life-threatening condition or immediate danger to Dr. Ma and her fetus, and whether her contamination was external or internal, before transporting Dr. Ma to a hospital for treatment. See Section III.E., *supra.* NIH also contacted the on-call physician from REAC/TS and put the REAC/TS physician in direct contact with the ER physician at Holy Cross Hospital, thus making expert advice available to Holy Cross Hospital and expediting Dr. Ma's treatment by Holy Cross Hospital. The ER physician decided not to follow the recommendation of the REAC/TS physician to administer a phosphate solution for dilution and displacement of the P–32 because of Dr. Ma's pregnancy. After consultation with both the REAC/TS physician and the NIH RSO, the ER physician ordered intravenous infusions of fluids (hydration) in order to dilute Dr. Ma's internal contamination, as was his prerogative. Additionally, based on the inspections and the investigation, NRC cannot conclude that Dr. Weinstein influenced or interfered with the Holy Cross ER physician's treatment decision regarding Dr. Ma's contamination. Before he arrived at Holy Cross at approximately 11:15 pm, Dr. Weinstein was aware that the NIH RSB recommended that Dr. Ma ''push'' fluids in order to maintain hydration. See Section III.I., *supra.* The IV hydration ordered for Dr. Ma was started around 9:00 p.m., long before Dr. Weinstein arrived at Holy Cross or spoke to the ER physician.

Moreover, based on the medical information made available by Petitioners to NRC's Medical Consultant, the NRC concludes that the symptoms reported by Dr. Ma were not related to her ingestion of P–32. The professional literature reveals three cases in which persons were inadvertently administered high levels of P–32.[21] The intakes in these cases were approximately 15 to 30 times greater than Dr. Ma's intake of 820 to 1300 mCi of P–32. 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. Blood count depressions, with no symptoms, were observed in the other two cases. NRC's Medical Consultant concluded that Dr. Ma's white blood cell count, white blood cell differential count, and her platelet count were all within normal limits, and that minor abnormalities in Dr. Ma's hematological profile, which did not include blood count depression, were consistent with typical plasma volume expansion during pregnancy. Additionally, radiation intakes sufficiently large to cause nausea and vomiting are accompanied by a depression or ablation of the bone marrow, which was not indicated by Dr. Ma's laboratory data. Finally, experience with intakes of P–32 much larger than Dr. Ma's intake, both accidental and as part of medical treatment, in which P–32 is frequently injected intravenously in doses 7 to 15 times great than Dr. Ma's intake, has not been observed to produce clinical symptoms. Accordingly, the NRC concludes that any symptoms Dr. Ma may have experienced, such as nausea and vomiting,[22] resulted from causes other than her ingestion of P–32.

NRC licensees are clearly required to determine the nature and extent of radiological overexposures to occupational workers and members of the public, to maintain records of such exposures, and to provide notifications to exposed individuals and reports to NRC. See, for example, 10 CFR §§ 19.13, 20.1204, 20.1501, 20.1502, 20.2106, 20.2107, 20.2202, 20.2203, 20.2205, and 20.2206. NRC requirements, however, impose no additional obligations upon licensees to provide medical care and follow-up to individuals exposed to radioactive materials for the purpose of removing radioactive contamination or ameliorating the medical effects of contamination.

In view of the above, to the extent that Petitioners are dissatisfied with the medical treatment provided to Dr. Ma by Holy Cross Hospital, or with any medical care provided by NIH to Dr. Ma apart from dose assessment, dose recordkeeping, or notification and reporting of Dr. Ma's dose, Petitioners' remedies, if any, do not lie with NRC.

K. Estimates of Internal Contamination of Dr. Ma and Her Fetus

Petitioners state that NIH failed to take proper actions to accurately assess, and as a result, greatly underestimated Dr. Ma's internal contamination, that NIH failed to consider all the relevant data in assessing Dr. Ma's internal contamination, demonstrating that NIH is not able or willing to impartially evaluate its worker's radiation exposure levels when exposures are in excess of Federal limits, and that NIH lied to Dr. Ma, to Federal regulators and to the public, about the magnitude of the exposure and the likely harm to Dr. Ma and her fetus. Specifically, the Petitioners state the following:

- NIH failed to take suitable and timely measurements from Dr. Ma to accurately calculate her occupational dose, in violation of 10 C.F.R. § 20.1204(a). NIH should have taken a full 24-hour urine sample following detection of Dr. Ma's contamination. Over the first two days urine was collected as spot samples at each void, rather than collecting the entire urinary excretion over a 24-hour period as recommended by NUREG/CR–4884, ''Interpretation of Bioassay Measurements,'' (1987). Additionally,

[20] Medical data provided by Petitioners did not substantiate this assertion.

[21] Blood, Vol. 61, No. 4 (1983), pp. 746–750; Schweizerische Medizinische Wochenschrift (Journal Suisse de medecine) Vol. 124, No. 42, pp 1848–51 (October 22, 1994); and American Journal of Medical Sciences, Vol. 254, No. 4, pp. 451–63 (October 1967). See also ''Ingestion of P–32 at Massachusetts Institute of Technology, Cambridge, Massachusetts, Identified on August 19, 1995,'' NUREG–1535 (December 1995).

[22] Dr. Ma's reported nausea and vomiting started long before her ingestion of P–32. An NIH technician observed Dr. Ma ''always'' vomiting at NIH for approximately two months prior to the contamination event.

NIH should have continued 24-hour urine collections and analysis until the activity level of the samples no longer yielded useful results. Instead, the NIH dose evaluation was based solely on samples collected during the first month following the intake.

• NIH incorrectly suggests that Dr. Ma is responsible for NIH's inadequate urine analysis because she returned a weekend's collection of urine in one carboy (a container), rather than three, and failed to follow through with continuing urine collection despite urging by NIH personnel. Dr. Ma did everything requested of her by NIH until it became evident that NIH had little interest in her health or in providing her medical care. NIH OMS and RSB officials asked Dr. Ma to collect all of her urine over the weekend following her contamination. Dr. Ma returned a weekends' urine collection in one carboy rather than three because two of the three wide-mouthed containers provided by RSB officials were defective and leaked. Dr. Ma was asked to bring in urine samples for the couple of weeks following her contamination. Dr. Ma collected her urine voluntarily until the end of July 1995, and submitted urine samples through July 27, 1995. Dr. Ma stopped providing samples because she did not receive any assistance or information from NIH. NRC estimated a significantly greater dose than did NIH, using the same information available to NIH.

• Between June 29, 1995, and July 27, 1995, Holy Cross provided NIH with twenty-five urine samples collected by Dr. Ma.

• Based on a whole body scan performed by NIH on June 30, 1995, Dr. Jorge Carrasquillo, Acting Chief, Nuclear Medicine Department, NIH, estimated that Dr. Ma had still retained a total of 862 μCi (31.9 MBq) of P–32 on that date.

• NIH's preliminary estimate of Dr. Ma's ingestion of P–32 on July 3, 1995, was approximately 300 μCi (11.1 MBq), which was not based on a 24-hour sampling of standard systemic excreta data as recommended by NUREG/CR–4884 and the National Council on Radiation Protection and Measurements (NCRP) Report No. 87, ''Use of Bioassay Procedures for Assessment of Internal Radionuclide Deposition'' (1987). Additionally, the initial dose estimate relied entirely on analysis of urine samples and was not confirmed through analysis of fecal samples, which led to significant understatement of Dr. Ma's internal contamination.

• The July 5, 1995, NIH estimate of Dr. Ma's intake was 265 μCi (9.8 MBq) of P–32 and was not based on the total volume Dr. Ma excreted, but was based on a sample. When the NIH RSO provided Dr. Ma with a copy of the ORISE estimate, he told Dr. Ma that the NIH estimate was ''more or less the same.''

• By letter dated July 28, 1995, Mr. Zoon advised NRC's Region I Office that evaluation of the total intake of Dr. Ma was continuing and could result in an estimated intake potentially exceeding the 10 CFR part 20, Appendix B, Annual Limit on Intake (ALI) for P–32 of 600 μCi (22.2 MBq).

• At NRC's request, NIH asked its first consultant, ORISE, to confirm isotopic analyses performed by the NIH RSB with four of the first 15 urine specimens taken on June 29 and 30, 1995, and with three urine samples and one blood sample. None of the samples was taken from a full 24-hour period and NIH failed to take any fecal samples. The August 15, 1995, revised estimate of Dr. Ma's intake performed by ORISE for NIH was between 740 and 820 μCi (27.4 and 30.3 MBq), resulting in an effective dose. equivalent to Dr. Ma of between 5.8 and 6.4 rem (58 and 64 mSv), and to her fetus a dose of between 4.6 and 5.1 rem (46 and 51 mSv).

• On August 29, 1995, NIH transmitted to NRC the ''final'' NIH assessment of Dr. Ma's effective dose equivalent as 4.17 rem (41.7 mSv), based upon an estimated intake of 500 μCi (18.5 MBq), and of the dose to her fetus as 3.2 rem (32 mSv). This analysis was not conducted in accordance with draft ANSI N13.30, ''Performance Criteria for Bioassay'' (1989). NIH also failed to continue the collection and analysis of excreta to ensure that Dr. Ma's excretion of P–32 followed the mathematical model NIH had used to predict her initial dose, and NIH failed to account for the effect of hydration therapy when initially evaluating the urine data. NIH's use of the ''weighted least squares fit'' method to assign its final dose is unacceptable because actual excretion does not follow the anticipated model.

• NRC's estimate of Dr. Ma's intake was between 30.3 and 48.1 MBq (820 and 1300 μCi) and of her internal committed effective dose equivalent (CEDE) was between 80 and 127 mSv (8.0 and 12.7 rem). Although both NRC and Petitioners' consultant excluded data from the first 2 days of urine collection as unreliable, NIH relied on that data primarily.

• The Petitioners' consultant estimated that Dr. Ma ingested 1000 μCi (37 MBq) of P–32 corresponding to a CEDE of 9.2 rem (92 mSv), and that her fetus received a dose of between 3 and 6.4 rem (30 and 64 mSv), based on an analysis of eleven urine specimens collected from Dr. Ma between June 29 and August 23, 1995.

Despite the inherent limitations in analysis based on excreta data and some differences in the assumptions used to evaluate the ingested activity and radiation dosimetry, the final estimates obtained by NIH, the Petitioners', and NRC are reasonably close. See Table, *infra*. Accordingly, the Petitioners concerns that NIH did not accurately assess Dr. Ma's dose and the dose to her fetus are unsubstantiated.

FINAL ESTIMATES OF RADIATION DOSE TO DR. MA AND HER FETUS

Organization	Date	Dr. Ma's dose estimate		Dr. Ma's Fetal dose estimate	
		(rem)	(mSv)	(rem)	(mSv)
NIH	7/96	4.7–7.0	47–70	3.7–5.4	37–54
NRC	12/95	8.0–12.7	80–127	5.1–8.1	51–81
Petitioners' Consultant	10/95	9.2	92	3.0–6.4	30–64

(1) *Petitioners' Estimates:* Petitioners retained the services of David A. Dooley, Ph.D., a Certified Health Physicist with expertise in internal dose assessment, to perform an assessment of the radiation dose and its effects upon Dr. Ma and her fetus. Based upon radioanalysis conducted by TMA/Norcal Laboratory, of 11 urine specimens collected by Dr. Ma between June 29 and August 23, 1995, Dr. Dooley estimated that Dr. Ma received an exposure of 9.2 rem (92 mSv) and that her fetus received an exposure of 3.0 and 6.4 rem (30 and 64 mSv). Although Dr. Ma continued to submit urine samples to Dr. Dooley until October 4, 1995, analysis of those samples did not

result in revision of Dr. Dooley's estimates.[23] Dr. Dooley estimated that, because of the P–32 intake, Dr. Ma would suffer an increased lifetime excess cancer risk of approximately 30 percent to 83 percent, and her fetus would experience a risk of childhood cancer ''. . . 30 to 150 times that of an unexposed child.''[24]

(2) *NIH Estimates:* NIH performed an assessment of Dr. Ma's intake of P–32, the resultant radiation exposure received by Dr. Ma, and the radiation exposure received by her fetus based on urine specimens collected by Dr. Ma.

On June 29, 1995, the NIH RSB gave instructions to collect all of Dr. Ma's urine to Dr. Ma, to the paramedics who transferred her to the hospital, and to the Holy Cross ER physician. The Licensee also contacted radiation emergency medical professionals via telephone at REAC/TS and arranged for the REAC/TS physician to speak directly with the Holy Cross Hospital ER physician, to assist with the evaluation of Dr. Ma's P–32 intake and the radiation dose to Dr. Ma and to her fetus. Given the apparent level of P–32 internal contamination, Dr. Ma's pregnancy, and the ER physician's lack of experience in dealing with radioactive material internal contamination events, this was an eminently reasonable measure. The REAC/TS physician, who also happened to be an OB/GYN, believed that medical intervention at the hospital would not have been very effective in inhibiting phosphorus absorption from the gastro-intestinal tract because, by the time Dr. Ma had arrived at Holy Cross, and based on discussion with the RSB, the REAC/TS physician understood that over 9 hours had elapsed since the suspected ingestion and the P–32 would have essentially been totally absorbed over this time period. The REAC/TS physician also asked the ER physician to instruct Dr. Ma to collect 24-hour urine samples for evaluation of P–32 kinetics.'' [25] The Holy Cross ER physician recalled that the NIH RSO requested that all of Dr. Ma's urine was to be measured, the volume for each void recorded, and then all of the urine to be placed in one container every 24-hours. In addition, Dr. Weinstein suggested to the ER physician that each urine void, at least during hospitalization, be saved separately, so that more time points would be available for modeling in determining the radiation exposure. He also suggested that the same could be accomplished by saving a small sample from each void (and recording the volume collected), separate from the continuing 24-hour collection. Dr. Weinstein believed that either procedure, if followed, would result in the availability of more information and no loss of urine.

The Holy Cross ER physician decided to develop his own method for collection of urine, and instructed his nurses that each time Dr. Ma voided, the amount would be measured, a small sample of each void would be maintained separately, and the rest would be put into one large container. The instructions given by the Holy Cross ER physician to Dr. Ma for collection of urine did not differ significantly from the recommendation of the REAC/TS physician, or of Dr. Weinstein, and were appropriate for proper assessment of Dr. Ma's intake and exposure, as well as that of her fetus. Holy Cross Hospital instructed Dr. Ma to collect urine on a 24-hour basis. When Dr. Ma reported to RSB on June 30, 1995, she brought the urine collected since departing Holy Cross, and was instructed to continue collecting urine on a 24-hour basis.

NIH states that when Drs. Ma and Zheng reported to the RSB for follow-up at 11:00 a.m. on June 30, 1995, they brought with them Dr. Ma's urine, in tubes and a container, and stated to RSB staff that was all the urine collected at the hospital and since discharge. Later that day, when Dr. Ma complained of back pain, she was escorted, at RSB's recommendation, to the NIH OMS where she was examined by a physician, and additional urine and blood samples were taken for radioanalysis. The results of the blood samples were within the expected range for a woman in her 17th week of pregnancy. Dr. Ma returned for a gamma camera scan at 5:00 p.m. at the NIH Clinical Center, and at that time was provided three carboys by RSB for the upcoming weekend and was advised to collect all her urine over the weekend using one carboy for each day. NIH states that on Monday, July 3, 1995, Dr. Ma returned only one carboy full of urine, stating to RSB staff that it was the urine from the evening of June 30 to July 1, 1995.

Based on NIH's preliminary notification, NRC issued PNO-I–95–025, ''Internal Contamination of Researcher,'' on July 3, 1995, which stated that NIH had indicated that a 32-year old female, who was in her fourth month of pregnancy, had received an estimated ingestion of approximately 11.1 MBq (300 μCi) of P–32.[26]

Subsequent urine samples, when received from Dr. Ma, were analyzed promptly. NRC's AIT determined that the licensee analyzed all samples accurately, as confirmed by the analyses performed for NRC by ORISE, and by NRC's Region I Laboratory. The periodic reanalysis of samples by the Licensee to ensure that the samples contained no additional radioactive contaminates was appropriate.

On August 29, 1995, based upon additional urine analysis, NIH performed another assessment of Dr. Ma's exposure. NIH calculated Dr. Ma's effective dose equivalent to be 4.17 rem (41.7 mSv), based upon an estimated intake of 500 μCi (18.5 MBq), and the dose to Dr. Ma's fetus to be 3.2 rem (32 mSv). This reassessment was based on a total of 26 urine samples obtained from Holy Cross Hospital and Dr. Ma.

In 1996, NIH contracted with Skrable Enterprises, Inc., to perform a reassessment of all available urine data, as well as an evaluation of creatinine levels in the urine samples in order to confirm sample validity. This consultant suggested modification of the standard model parameters for the short-term retention compartments and use of creatinine normalized data to improve the fit of the estimate to the sample data. These suggestions accounted for the varying time periods of sample collection. Based upon this reassessment, NIH revised its estimate of Dr. Ma's CEDE to between 4.7 and 7.0 rem (47 and 70 mSv), corresponding to an intake range of between 570 and 840 μCi (21.1 and 31.1 MBq). The revised dose to the fetus was calculated to be between 3.7 and 5.4 rem (37 and 54 mSv). Also on July 30, 1996, NIH RSB staff delivered its revised estimates entitled, ''Report of 1995 Radiation Dose, NRC License 19–00296–10, '' to Dr. Ma at NIH, which summarized the doses described above and stated that the ''levels (received by Dr. Ma) are considered to be safe and are not expected to result in a health impact.'' [27]

Regarding the concerns of the Petitioners' that NIH failed to account for the effect of hydration therapy, NIH's report of its last estimate of Dr. Ma's

[23] See Letter dated April 16, 1996, from Judith A. Wolfer, Esq., to Cynthia Jones, NRC.

[24] See Letter from Dr. David Dooley, dated April 15, 1996, to Debra C. Katz, Esq.

[25] Letter from Ronald E. Goans, Ph.D., M.D., REACT/TS, dated November 8, 1995, to Shawn W. Goggins, NIH, and memorandum from Ronald E. Goans, Ph.D., M.D., dated July 17, 1995, to Dr. Robert Ricks, REAC/TS.

[26] PNs constitute early notice of events of possible safety or public interest significance. Information contained in PNs is received without any verification or evaluation, and is basically all that is known by the licensee and NRC staff as of the date of issuance to the public. They are also known as preliminary notifications of occurence (PNOs)

[27] See NIH memorandum from the NIH RSO, dated July 30, 1996, to Dr. Ma.

1995 occupational radiation dose states that NIH's Consultant was not only aware of the large variation exhibited by the bioassay data as a result of hydration therapy, but accounted for these differences by using a modified biokinetic model and creatinine-normalized urine data to account for the large variances in the bioassay data. Moreover, the last NIH estimates are reasonably close to those of NRC and the Petitioners. Accordingly, the effects of hydration therapy upon the NIH dose estimates appear to raise no cause for concern.

As to the Petitioners' concerns that NIH's use of the weighted least squares fit method was unacceptable because actual excretion does not follow the anticipated models, NRC's second consultant, Lawrence Livermore National Laboratory (LLNL), performed an independent assessment of the NIH data to determine if differences in the dose estimates may have been due to the use of the different internal dose assessment codes. When the first two data values were removed from the NIH data set, the unweighted least squares intake assessment using the CINDY code was 30 MBq (810 μCi). Intake assessments from CINDY using the LLNL treated data set ranged from 20.7 to 40.7 MBq (560 to 1100 μCi). This range of results is also consistent with the ORISE intake estimates of between 22.9 and 30.3 MBq (620 and 820 μCi). These results indicate that differences in correcting for 24-hour excretion also do not significantly influence the intake estimates. Therefore, the differences in the dose assessments between NIH's August 29, 1995, estimate and NRC's estimate were mainly due to differences in data handling. The major difference in these two dose estimates was the treatment of the sample data from the first few days post intake. However, since the last NIH estimates now yield relatively close results with those of the Petitioners and NRC, NIH's use of the least squares method in its earlier estimate is not cause for concern.

After the surveys and bioassays of persons who had access to the contaminated conference room, NIH determined that 26 individuals, including Dr. Zheng and in addition to Dr. Ma, were positive for P–32 contamination. All of the 21 individuals who were occupational workers as defined by 10 CFR § 20.1003 received radiation exposures of less than 10 percent of NRC's annual occupational exposure limit of 50 mSv (5 rem) specified by 10 CFR § 20.1201(a)(1)(i). Of the five individuals who were members of the public, as defined by 10 CFR § 20.1003, one individual received a dose in excess of NRC's annual limit of 1 mSv (0.1 rem) for members of the public specified by 10 CFR § 20.1301(a)(1). This individual's dose was estimated to be between 1.5 and 2.5 mSv (150 and 250 millirem].

Petitioners are correct in stating that the July 3, 1995, preliminary NIH estimates for Dr. Ma and her fetus' intake were not based upon full and complete data. NRC requires licensees to notify NRC within 24 hours of any event which may have caused, or threatens to cause, an individual to receive a dose exceeding 50 mSv (5 rem). 10 CFR § 20.2202(b)(1)(i). Once information is reported to NRC, NRC issues a preliminary notification in accordance with NRC Inspection Manual Chapter 1120, Sections 1120–07 and 1120–08. These notifications promptly provide information to the Commissioners, as well as other NRC and Agreement State management on matters that are of significant safety concern or have, or potentially could have, high public interest. These notifications, however, are not assumed to constitute final estimates.

As far as the Petitioners' concern that the NIH bioassay program was faulty in not collecting and analyzing fecal samples, NRC-approved models and methods provides guidance for the use of either urine or fecal samples. *See* ''Interpretation of Bioassay Measurements, '' NUREG/CR–4884, (1987). Based on descriptions in the International Commission on Radiological Protection Publication 30, the biokinetic model for phosphorus predicts that about 80 percent of the ingested phosphorus is absorbed from the gastrointestinal tract and enters the blood stream. 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, 40 percent is incorporated into soft tissue and 30 percent is incorporated into the skeleton. The 15 percent that goes to early excretion is considered to enter directly into the kidney/bladder compartment, from which it is eliminated within a 4-hour retention time. Because the route of Dr. Ma's intake was via ingestion, and because there is little excretion of P–32 from the systemic compartment into the feces, NIH's use of urinary excretion data and decision not to use fecal excretion data was entirely appropriate.

Although NIH did not follow ANSI N13.30, they were not required to do so. Not only was this guidance issued as a draft for public comment at the time of the event, but NRC had not endorsed its use in any NRC Regulatory Guide.[28] Moreover, ANSI N13.30 is industry-issued guidance only, and does not constitute a regulatory requirement.

Petitioners are correct in stating that early reports from NIH of July and August 1995 were not based upon full and complete data. In hindsight, the August 29, 1995, report of NIH should not have been referenced as ''final'' assessments of dose. As NRC's LLNL evaluation points out, documented intakes of P–32 demonstrate an increase in urinary output of radiation over the first few days after intake. Since the concentration of phosphorus in the systemic compartments of the body is reflected in the urine, it is reasonable to conclude that urine activity may establish an equilibrium within a few days after the intake. Therefore, the early NIH dose assessments during the first month after the incident tended to underestimate the dose because of the nature of phosphorus biokinetics and the limited usefulness of internationally-accepted models derived primarily for standard-setting. It is understandable, however, that an internal dosimetrist may have a strong desire to maintain and use the first few days of bioassay samples. Continued use of these early excretion values also provides more consistency with early dose estimates, since these early values have more statistical weight. However, at long times after an intake (i.e., 20 to 30 days for P–32), an evaluation of the entire set of data must be performed relative to the projected values. It is during this time that a reevaluation should be made regarding the validity, usability, and statistical weight of the early times after intake. NIH's last set of consultants, as well as the NRC's and Petitioners' consultants, had the advantage of retrospective insight into the data, and based on that insight, did not use the urinary excretion data from the first few days after intake.

(3) *NRC Estimates:* ORISE, serving as a scientific consultant to NRC, and using bioassay data provided by NIH, performed an assessment for NRC of the intake by, and resultant P–32 radiation Dr. Ma was exposed to, and of the radiation exposure received by her fetus. One of the major differences between the early estimates of the Licensee and NRC was NIH's use of the annual limit on intake (ALI) that was based on Reference Man [70 kilograms (kg)], versus NRC's use of an ALI based on Reference Woman (57 kg). NRC

[28] ANS N13.30, ''Performance Criteria for Radiobioassay,'' was issued as a draft standard for comment in September 1989, and was finalized in May 1996. NRC has not yet endorsed it for licensee use in any NRC Regulatory Guides.

requires licensees to calculate doses to individuals in accordance with ALIs that are based on Reference Man. See 10 CFR part 20, Appendix B, notes to Table 1, ''Occupational.'' Because NRC's understanding was that Dr. Ma weighed approximately 53 kg, the model to calculate the ALI that more appropriately represented the circumstances of Dr. Ma's contamination was Reference Woman, and consequently all NRC dose estimates were based upon that model.

Because of the differences in the results of the assessments performed by the Licensee (dated August 26, 1995) and by NRC's scientific consultant to the AIT, ORISE (dated August 9, 1995), NRC contracted with a third party, LLNL, to independently review the assessments performed by the Licensee, and by ORISE, for NRC.

Based on the work of its consultants, NRC estimates that Dr. Ma ingested between 30.3 and 48.1 MBq (820 and 1300 μCi) of P–32, an amount of P–32 in excess of the 22.2 MBq (600 μCi) annual limit specified by 10 CFR part 20, Appendix B, Table 1, Column 1. Based on these values, NRC estimates that Dr. Ma's internal CEDE was between 80 and 127 mSv (8.0 and 12.7 rem). The estimated radiation exposure received by Dr. Ma's fetus was between 51 and 81 mSv (5.1 and 8.1 rem). A more detailed discussion of NRC's dose assessment can be found in the AIT final report of January 13, 1997.

NRC also contracted with one of its medical consultants to review and characterize the safety significance of the exposures to Dr. Ma and her fetus, summarized in his final report dated September 4, 1996. Based on NRC's estimated exposures to Dr. Ma and her fetus, NRC's medical consultant concluded that no deterministic or stochastic effects to Dr. Ma, and no deterministic effects to her fetus are expected. In regard to potential stochastic consequences to the fetus, although there is moderate uncertainty in the data used for cancer risk estimation as a result of *in utero* radiation exposure, in this case, an excess risk of 0.33% is estimated (for comparative purposes, the natural risk of childhood cancers is about 0.1%). Thus the probability that the exposed fetus will **NOT** develop a radiation-induced childhood cancer is 99.67% (range 99.60 to 99.74%). It is unknown whether this risk estimate should be reduced because of the low dose and low dose-rate associated with this internal exposure from P–32.

NRC performed a review of both the NIH AIT and the MIT IIT contamination events in order to determine if NRC guidance to licensees regarding instructions for collection of excreta and analysis of fetal dose based upon maternal uptake is adequate. As a result of this review, the staff issued additional guidance to licenses on analysis of fetal doses, NUREG/CR–5631, Rev. 2, ''Contribution of Maternal Burdens to Prenatal Radiation Doses,'' (May 30, 1996).

One of NRC's scientific consultants reviewed and confirmed the NIH estimates of dose received by the 26 individuals who drank from the contaminated water cooler. NRC concluded that no deterministic or stochastic consequences are expected for any of the 26 individuals, including Dr. Zheng, who were internally contaminated with P–32.

L. Directions to Hospital Emergency Room Personnel Concerning Assessment of Dr. Ma's Level of Contamination

Petitioners state that NIH personnel gave conflicting and harmful directions to Holy Cross ER personnel, which interfered with efforts to properly assess Dr. Ma's contamination. Specifically, the NIH RSO directed the ER physician at Holy Cross to collect the total volume of urine for a 24-hour period, whereas Dr. Weinstein instructed the ER physician to aliquot a small part of the samples already taken and to discontinue efforts to collect urine over a 24-hour period, in conflict with NUREG/CR–4884, ''Interpretation of the Bioassay Measurements'' (1987). Petitioners also state that the Holy Cross ER physician did not know whose instructions to follow and so developed a compromise plan, and when Dr. Ma was released from Holy Cross, no instructions were given to her to collect her urine at any interval.

NRC concludes that the NIH RSB gave appropriate instructions, in view of the limited NRC guidance available to licensees at the time of this event regarding urine collection, *see* Section III.H., *supra*, to Dr. Ma, to the paramedics who transferred her to the hospital on June 29, 1995, and to the Holy Cross ER physician for urine collection. Additionally, the three methods for collection of Dr. Ma's urine recommended to the ER physician by the REAC/TS physician, the NIH RSO, and Dr. Weinstein were not significantly different from each other or conflicting, and the instructions given by the Holy Cross ER physician to Dr. Ma for collection of urine were appropriate for proper assessment of Dr. Ma's intake and exposure, as well as that of her fetus. *See* Section III.K.(2), *supra.* Accordingly, NRC staff cannot conclude that Dr. Ma was given inadequate or conflicting instructions.

M. NIH Notification to Dr. Ma of Her Radiation Exposure Level

Petitioners state that in violation of 10 CFR § 19.13(d), NIH deliberately failed to notify Dr. Ma of her estimated radiation exposure level at the same time such notification was provided to NRC. Specifically, the only NIH notification provided to Dr. Ma was a copy of the August 1995 ORISE report estimating her contamination at 265 μCi (9.8 MBq), despite NRC direction to NIH to make notifications required by 10 CFR § 19.13(d). As a result, before NRC's actions to estimate her intake, Dr. Ma had to learn of her exposure levels from indirect sources and consulted with an independent health physicist at great personal cost.

NRC notified NIH by letter dated December 1, 1995, from Thomas T. Martin, Regional Director for Region I, and by letter dated January 29, 1996, from Charles W. Hehl, Director, NRC Region I, Division of Nuclear Material Safety, that NIH was required to make notifications pursuant to 10 CFR § 19.13(d) regarding the estimated radiation exposure of Dr. Ma and her fetus. The December 1, 1995, letter notified NIH that Dr. Ma received a dose in excess of the applicable occupational regulatory limits, 10 CFR § 20.1201(a)(1)(i), specifically that NRC estimates her internal CEDE was between 80 and 127 mSv (8.0 and 12.7 rem) and that NRC estimates the radiation exposure received by Dr. Ma's fetus was between 51 and 81 mSv (5.1 and 8.1 rem).

By letter and facsimile dated May 15, 1997, counsel for Petitioners notified NRC that NIH had revised its dose estimates for Dr. Ma and her fetus, and Petitioners' counsel provided a copy to NRC of an NIH memorandum dated July 30, 1996, containing the revised estimates. Although this document is addressed to Dr. Ma, Petitioners' counsel state that Dr. Ma never received this memorandum and that NIH never notified her directly of her radiation dose after the accident.

NIH revised its original dose estimates after engaging an independent expert on internal dose assessment and bioassay interpretation to perform an analysis of the dose to Dr. Ma and her fetus. NIH's independent consultant completed its analysis and prepared a report to NIH dated March 4, 1996. NIH provided its memorandum dated July 30, 1996, summarizing Dr. Ma's 1995 revised radiation dose estimates for her and her fetus, to NRC at its request, on April 4, 1997, by facsimile. Based on the NIH

consultant's report, NIH revised its dose estimates to a CEDE of between 4.7 and 7.0 rem (47 and 70 mSv) to Dr. Ma, corresponding to an intake range of between 570 and 840 μCi (21.1 and 31.1 MBq), and a dose of between 3.7 and 5.4 rem (37 and 54 mSv) to Dr. Ma's fetus.

NRC regulations at 10 CFR § 19.13(d) require that NIH provide Dr. Ma with a report of her exposure data at a time not later than NIH's transmittal to NRC of NIH's report on Dr. Ma's exposure. NIH denies that it never provided Dr. Ma with the revised dose estimates. NIH states that its Area Health Physicist hand-delivered the July 30, 1996, memorandum to Dr. Ma on July 30, 1996. The Area Health Physicist states that at that time, she explained the contents of the memorandum to both Dr. Ma and Dr. Zheng, asked if they had any questions, and identified NIH personnel to contact if Petitioners had any questions. The Area Health Physicist states that Petitioners opened the envelope and read the memorandum in her presence.[29]

Accordingly, NIH did violate 10 CFR § 20.2203(a)(2)(i), because NIH did not submit a written report to NRC within 30 days after learning of the occupational dose to Dr. Ma in excess of the limits for adults in 10 CFR § 20.1201. A Notice of Violation is being issued concurrently with the issuance of this Director's Decision. However, NIH did inform Dr. Ma of its revised dose estimates on July 30, 1996, in accordance with 10 CFR § 19.13(d). Accordingly, Petitioners' request for enforcement action for violation of 10 CFR § 19.13(d) is denied.[30]

N. Declaration of Pregnancy and Minimization of Radiation Exposure to Dr. Ma

Petitioners state that, in violation of 10 CFR § 20.1208, their supervisor, Dr. Weinstein, coerced Dr. Ma to not submit a written declaration of pregnancy to the NIH RSB, even though it was her clear desire to receive maximum protection for her fetus from exposure to radiation and radioactive materials, and thus Dr. Weinstein constructively denied Dr. Ma her right to receive protection for her fetus from ionizing radiation in excess of 0.5 rem (5 mSv). Petitioners state that between June 19 and June 23, 1995, Dr. Weinstein withheld the NIH form used to file a declaration of pregnancy, and insisted that if Dr. Ma filled out the declaration form, it would ''cause trouble for the lab.'' Petitioners also state that Dr. Weinstein disagreed with the steps proposed by Petitioners to minimize radiation exposure of Dr. Ma during her pregnancy.

As a related matter, Petitioners also state that because Dr. Weinstein was in a hurry to patent the results of their research (a novel method to display more efficiently the existence of expressed genes), which would have had significant scientific and commercial value, Dr. Weinstein urged Petitioners to work tirelessly, and over a period of several weeks before the contamination incident, repeatedly requested Petitioners to terminate Dr. Ma's pregnancy. Based on the several inspections and the investigation, NRC concludes that the evidence does not substantiate Petitioners' assertions that Dr. Weinstein urged Petitioners to work tirelessly, requested Petitioners to terminate Dr. Ma's pregnancy,[31] and was in a hurry to patent the results of Petitioners' research,[32] or that the research would have had significant scientific and commercial value.[33]

Based on the inspections and investigation, NRC concludes that the evidence does not substantiate Petitioners' assertions that Dr. Weinstein, with coercion or otherwise, prevented or tried to prevent Dr. Ma from declaring, or interfered with Dr. Ma's declaration of, her pregnancy in writing,[34] or that Dr. Weinstein objected to or interfered with any measures proposed or taken by Petitioners to minimize exposure of Dr. Ma's fetus to radiation. Additionally, Petitioners both took the ''NIH Radiation Safety in the Laboratory'' training course on November 29, 1994. That training covered NIH procedures on written declarations of pregnancy for occupational workers and instructions for pregnant employees as to how to obtain the NIH form used to submit a written declaration of pregnancy. Although not required to do so, Dr. Weinstein obtained the NIH form for Petitioners and provided it to Petitioners on June 23, 1995. Dr. Ma, however, did not request the form, nor did she submit the formal declaration of her pregnancy to the NIH RSB, as provided in the materials covered in her training. In view of the above, Dr. Ma's failure to submit a written declaration of pregnancy was voluntary. Accordingly, the 5-mSv (0.5-rem) occupational exposure limit specified by 10 CFR § 20.1208(a) for the fetus of a declared pregnant worker was not applicable to Dr. Ma.

Based on the above, Petitioners' request for enforcement action against NIH for violation of 10 CFR § 20.1208 is denied.

O. Responsibility for Contamination of Dr. Ma and 26 NIH Employees

Based on the inspections and the investigation, NRC concludes that Dr. Ma and 26 NIH employees were deliberately contaminated with P–32. Dr. Ma's exposure and the exposure of one of the 26 employees contaminated by the water cooler were beyond regulatory limits, in violation of 10 CFR §§ 20.1201 and 20.1301, respectively. Neither the means of administering P–32 to Dr. Ma,[35] nor the person(s)

[29] See letter dated August 15, 1997, from Robert A. Zoon, Radiation Safety Officer, NIH, to Carl J. Paperiello, NRC, and attached ''Memorandum'' dated August 14, 1997, from Beth Reed, NIH Area Health Physicist, to Robert A. Zoon.

[30] Although there is a dispute as to whether in fact NIH notified Dr. Ma of its revised dose estimates, Dr. Ma was in fact provided with the revised NIH dose estimates from another source.

[31] In addition to the lack of evidence corroborating this assertion, there are significant inconsistencies in Dr. Ma's account of how she learned of the alleged request. In the Petition, Dr. Ma stated that in the evening, after returning from a meeting with Dr. Weinstein at NIH, Dr. Zheng informed Dr. Ma that Dr. Weinstein had made the alleged request earlier that day. Dr. Ma, however, told investigators that she learned of the alleged request during a meeting at NIH with Dr. Zheng and Dr. Weinstein, a week after Dr. Weisnstein made the alleged request to Dr. Zheng, and that Dr. Zheng had not told Dr. Ma of the request.

[32] In addition to the lack of evidence to corroborate this assertion, Petitioners made contradicatory statements regarding Dr. Weinstein's plans for publication of the results of Petitioners' research. Several days after discovery of Dr. Ma's contamination, Dr. Ma told a colleague that the Petitioners wanted to publish their research paper before obtaining a patent application (contrary to usual procedures), but that Dr. Weinstein was trying to delay publication of the reserach paper. Dr. Ma told investigators shortly afterwards that Dr. Weinstein believed that her pregnancy would prevent her from handling radioactive materials, when Dr. Weinstein had applied for a patent and was trying to get the Petitioners' research paper published. A few days later, Dr. Zheng submitted a statement to investigators asserting that over the past 3 or 4 months Dr. Weinstein had been trying to delay publication of the research paper.

[33] The Investigation indicates that the Petitioners' research, which was conducted to investigate a proposal of Dr. Weinstein, did not constitute a major scientific discovery and had little commercial value.

[34] Moreover, the investigation produced evidence that Dr. Ma was not eager to declare her pregnancy. Dr. Ma told an NIH colleague approximately 2 months before the contamination incident that she was reluctant to inform Dr. Weinstein of her pregnancy, because then she might have to stop conducting experiments involving radiation.

[35] Petitioners assert that Dr. Ma was contaminated at NIH on the evening of June 28, when she ate food that she had stored in an NIH conference room refrigerator the previous evening. Dr. Ma's contamination was discovered at approximately 6:00 p.m. on June 29. The evidence indicates that Dr. Ma was not contaminated by food she had stored in the NIH conference room refrigerator. In the evening of June 29, the NIH RSB found no radioactive contamination of the conference room refrigerator, the contents of the refrigerator, Dr. Ma's desk, the table at which Dr. Ma ate, the trash cans or containers or tables in the halls near Petitioners' lab, the lab, or Dr. Weinstein's office. On June 30, the microwave used by Dr. Ma to heat her food at NIH, and the plastic containers and the utensils

responsible for the contamination of Dr. Ma[36] and of the water cooler, which was the source of contamination to the 26 NIH employees, however, was definitively identified. In the absence of any evidence to the contrary, NRC presumes that the violations were caused by an employee(s) of NIH and that the material belonged to NIH. As explained above, NRC also concludes that the contamination of Dr. Ma and of the water cooler was not a result of the Licensee's violations of NRC requirements for security and control of radioactive material. *See* Section III. A, ''Violations of NRC requirements for security and control of licensed material'', *supra.* Normally, the exposures beyond regulatory limits in this case would be subject to significant enforcement action. However, under the circumstances of this case, the Commission has decided to exercise its enforcement discretion and not initiate formal enforcement action against NIH for these violations. Discretion is being exercised because NIH fully cooperated with the investigation, there is no evidence that NIH contributed directly or indirectly to the deliberate misuse of licensed material involved, and NIH could not reasonably foresee that an employee or employees would maliciously misuse radioactive material as was done in this case.

Accordingly, enforcement action against NIH, in addition to that already taken in the NOV and Proposed Imposition of Civil Penalty $2500 (EA 96–027) and the Order Imposing Civil Penalty $2500 (EA 96–027), is not warranted in this case for the occupational exposure of Dr. Ma beyond regulatory limits, the exposure of the member of the public beyond regulatory limits, or the contamination of the water cooler.[37]

used by Dr. Ma to eat the food she brought to NIH, were surveyed, and no contamination was found. Additionally, the evidence indicates that the P–32 contamination of the carpet in front of the conference room refrigerator occurred sometime after 5:00 p.m. on June 29. The AIT report states in the chronology that the NIH RSB initial estimated time of ingestion was noon on June 29, 1995. However, after review of the physical evidence and radiation surveys, NIH used 11:00 am, June 28, 1995, as the most probable initial ingestion time. NIH also used this initial ingestion time for the other 26 contaminated NIH individuals involved. NRC also used this initial time of ingestion in its dose estimates.

[36] The investigation produced no evidence to corroborate Petitioners' assertions that Dr. Weinstein had suggested to several people either that Petitioners already had a child in China, or that Petitioners deliberately contaminated themselves in order to terminate Dr. Ma's pregnancy.

[37] See letter from Ashok C. Thadani, Acting Deputy Executive Director for Regulatory Effectiveness, to Michael M. Gottesman, M.D., Deputy Director for Intramural Research, NIH, dated September 17, 1997.

IV. Conclusions

The following requests of Petitioners are granted in part as described above: for enforcement action against NIH for violations of NRC security and control requirements and for violation of NRC requirements related to radiation safety training, ordering radioactive materials, inventory control of radioactive materials, monitoring, and the issuance, use, and collection of dosimetry. Petitioners' request for NRC action to ensure adequate procedures and instructions to exposed persons for sample collection is granted as described above. The following requests of Petitioners for enforcement action against NIH are denied: for the exposure of Dr. Ma beyond regulatory limits, for the exposure of Dr. Ma's fetus, and for the contamination of the water cooler; regarding notification to Dr. Ma of her level of contamination; regarding Dr. Ma's declaration of pregnancy; regarding the conduct of surveys after Dr. Ma's contamination; and for the failure to accurately calculate Dr. Ma's occupational radiation dose. Finally, Petitioners' request to suspend or revoke the NIH license is denied.

A copy of this Decision will be filed with the Secretary of the Commission for Commission review in accordance with 10 CFR § 2.206(c) of the Commission's regulations. As provided by this regulation, the Decision will constitute the final action of the Commission 25 days after issuance, unless the Commission, on its own motion, institutes a review of the Decision within that time.

This 17th day of September 1997, Rockville, Maryland.

Carl J. Paperiello,

Director, Office of Nuclear Material Safety and Safeguards.

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SECURITIES AND EXCHANGE COMMISSION

Request for Public Comment

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of Filings and Information Services, Washington, DC 20549.

Extension: Rule 13e–1, SEC File No. 270–255, OMB Control No. 3235–0305. Rule 12g3–2, SEC File No. 270–104, OMB Control No. 3235–0119, Trust Indenture Act Rules, SEC File No. 270–115, OMB Control No. 3235–0132.

Notice is hereby given that pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.), the Securities and Exchange Commission (''Commission'') is soliciting comments on the collections of information summarized below. The Commission plans to submit these existing collections of information to the Office of Management and Budget for extension and approval:

''Purchase of Securities by issuer thereof under the Securities Exchange Act of 1934''. Rule 13e–1 under the Exchange Act is designed to provide shareholders and the marketplace with relevant information concerning issuer repurchases during a tender offer for its securities by a third party. Public companies are the respondents. An estimated 20 respondents wiil file submissions annually at and estimated 13 hours per response for a total annual burden of 260 hours.

''Securities Exchange Act of 1934—Rule 12g3–2.'' Rule 12g3–2 provides an exemption for certain foreign securities. It affects approximately 1800 foreign issuer respondents at an estimated one burden hour per response for a total annual burden of 1800 hours.

''Requirements as to Form and Content of Applications, Statements and Reports under the Trust Indenture Act of 1939.'' Rules 7a–15 through 7a–37 under the Trust Indenture Act of 1939 (''TIA'') provides guidance for complying with requirements under the TIA. Persons and entities subject to TIA requirements are the respondents. No information collection burdens are imposed directly by these rules so they are assigned only one burden hour for administrative convenience.

Written comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted in writing on or before November 24, 1997.

Please direct your written comments to Michael E. Bartell, Associate Executive Director, Office of Information Technology, Securities and Exchange Commission, 450 5th Street, N.W., Washington, DC 20549.