Nuclear Regulatory Commission

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NRC RESPONDS TO REQUESTS FOR ENFORCEMENT ACTION AGAINST NIH FOR CONTAMINATION EVENT

The Nuclear Regulatory Commission staff has denied a petition from Dr. Maryann Wenli Ma and her husband, Dr. Bill Wenling Zheng, to revoke or suspend the nuclear materials license of the National Institutes of Health following a 1995 contamination event there involving radioactive phosphorous-32 (P-32), but granted the petitioner's request for other actions.

During the incident, Dr. Ma, then a pregnant NIH researcher, was exposed to radiation in excess of NRC occupational limits. Dr. Zheng, who also worked at that time at NIH, and 25 others, were exposed to radiation from a contaminated water cooler. One of the 25 individuals, classified as a non-radiation worker, received an exposure in excess of NRC limits for members of the public.

The P-32 contamination was the subject of an NRC augmented inspection team (AIT) inspection and two special NRC team inspections, as well as investigations performed by the NRC Office of Investigations (OI), in cooperation with the Federal Bureau of Investigation, the Health and Human Services Office of the Inspector General and the NIH Police Department. A redacted report and its associated exhibits from the NRC's AIT was issued

on January 29, 1996, and a full report on January 13 of this year. The report from the NRC's OI investigation, "National Institutes of Health: Wrongful Administration of P-32, Case No. 1-96-033," was released on September 17, 1997.

NRC investigators concluded that the contamination was deliberate but could not definitively identify who caused the contamination with P-32. Also, the NRC did not definitively identify the means of administering the phosphorous-32 to Dr. Ma.

Normally, radiation overexposures of this sort would be subject to significant enforcement action by NRC. However, in this case, the Commission decided to exercise enforcement discretion because there is no evidence that NIH contributed directly or indirectly to the deliberate misuse of licensed material; because NIH could not reasonably have foreseen that an employee would maliciously misuse licensed material as appears to have been done in this case; and because NIH cooperated fully in the investigation.

Although the NRC denied the petition to suspend or revoke NIH's license, it has granted the petitioners' request that NRC take other appropriate actions. NRC granted the petitioners' request 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. In addition, the NRC's Region I office in King of Prussia, Pennsylvania, issued a notice of violation (without a civil penalty) to NIH on September 17, for failure to submit a written report to NRC within 30 days after learning that Dr. Ma received an occupational radiation dose in excess of NRC limits.

Other NRC actions included a series of Confirmatory Action Letters between July 1995 and June 1996. They confirmed that NIH had agreed to take various corrective measures, 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, and (5) modifications to the surveillance plan for NIH laboratories. The NRC has determined that NIH has made significant efforts to improve its control of radioactive material. This has included NIH staff meetings, training and audits. NIH also completed a comprehensive physical inventory of radioactive materials that now serves as the baseline for on-line, real-time tracking of all radioactive materials. NRC concluded that additional enforcement action for security and control violations was not warranted.

Copies of the OI report and exhibits, the letter to NIH, and the director's decision will be available for public inspection and copying at the NRC Public Document Room, 2120 L Street, NW, Washington, DC 20555; telephone: 202/634-3273. All but the OI report and exhibits have been placed on the NRC Internet homepage at www.nrc.gov.

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