WRITTEN TESTIMONY
FOR DR. CHARLES L. MILLER, DIRECTOR
OFFICE OF FEDERAL AND STATE MATERIALS AND ENVIRONMENTAL MANAGEMENT PROGRAMS
UNITED STATES NUCLEAR REGULATORY COMMISSION
TO THE
SUBCOMMITTEE ON TECHNOLGY AND INNOVATION
COMMITTEE ON SCIENCE AND TECHNOLOGY
UNITED STATES HOUSE OF REPRESENTATIVES
REGARDING THE LOW-LEVEL PLUTONIUM SPILL AT THE NATIONAL INSTITUTE OF STANDARDS AND TECHNOLOGY IN BOULDER, COLORADO

July 15, 2008

INTRODUCTION

Mr. Chairman and Members of the Committee, I am honored to appear before you today to discuss the U.S. Nuclear Regulatory Commission's (NRC's) role in regulating and inspecting radioactive materials facilities. I hope that my testimony will be helpful to you in understanding the regulatory framework and oversight of facilities such as the National Institute of Standards and Technology (NIST), and how the NRC responds to events at these facilities. The NRC's work in response to the June 9, 2008 event at NIST's Boulder facility is ongoing. Mr. Elmo Collins, Regional Administrator for the NRC's Region IV office, and the home base for the agency's special inspection team for this event, is here with me today to answer any questions about our inspection activities up to this point.

SUMMARY OF EVENT AND NRC ACTIONS

On June 10, 2008, the NRC received a report of a contamination event at the NIST facility in Boulder, Colorado. The previous day, a junior researcher had broken a glass vial containing one fourth of a gram of plutonium powder. The junior researcher and other individuals, working both inside and outside the specific laboratory suite were contaminated. The researcher apparently washed his hands to remove the plutonium contamination thus introducing a small amount of plutonium into the sewer system. More importantly, analysis confirmed that the junior researcher as well as others ingested or inhaled some of the plutonium.

The NRC dispatched a health physics inspector to the site on June 12, who verified that the lab was acceptably isolated for the short term. A second health physics inspector was dispatched by NRC on June 19. NRC's initial assessment of the event and NIST's follow-up actions indicated that there was no immediate threat to additional workers or to public health and safety. However on the basis of the inspectors' observations on site, NRC management determined that an enhanced agency response was needed to ensure that the licensee conducted licensed activities safely in the short term and that further inspection follow-up was needed to more fully understand the circumstances, causes, and licensee actions. Additionally, on June 27, the licensee reported that the junior researcher received a potentially significant radiation dose. On June 30, a five

member Special Inspection Team (SIT), dispatched from NRC's Region IV Office in Arlington, Texas, began conducting a more detailed review of the event. I will further explain the SIT later in this testimony. The team's inspection is in progress. As I will discuss further elsewhere in this testimony, NIST – in consultation with NRC – has also agreed to suspend all use of plutonium sources pending NRC approval of the resumption of such activities.

NRC REGULATORY FRAMEWORK TO ENSURE SAFE USE OF RADIOACTIVE MATERIAL

Before I address the specifics related to the NIST license and the event, I would like to briefly describe NRC's structure and regulatory approach to licensing, inspection, and enforcement. Through the Agreement States Program, the NRC shares its regulatory authority to license and oversee the use of certain types of radioactive material. Although Colorado is one of the 35 Agreement States, NRC retains regulatory jurisdiction for NIST-Boulder because it is a federal facility. Therefore, this testimony will focus on NRC's program and not on the role of Agreement States.

OVERALL FRAMEWORK AND MISSION

The mission of the NRC is to license and regulate the Nation's civilian use of byproduct, source, and special nuclear material to ensure adequate protection of public health and safety, promote the common defense and security, and protect the environment. The Atomic Energy Act of 1954, as amended, grants NRC the authorities and responsibilities needed to accomplish this mission. NRC has issued regulations that are designed to protect the public and occupational workers from radiation hazards. NRC issues licenses for use of radioactive material to qualified applicants who meet regulatory requirements. The responsibility for safety and security of the radioactive material lies with the licensees who possess and use the material. NRC inspects the users of radioactive material to ensure compliance with both NRC safety regulations and any additional conditions imposed during the licensing. Enforcement against licensees as well as individuals can be pursued by NRC for noncompliance with these regulations and conditions.

Within NRC, the Office of Federal and State Materials and Environmental Management Programs, of which I am the Director, is responsible for the development, implementation, and oversight of the regulatory framework for industrial, commercial and medical uses of radioactive material, uranium recovery activities, and the decommissioning of previously operating nuclear facilities and power plants. NRC also has Regional Offices which conduct inspection, enforcement, investigation, licensing, and emergency response programs for radioactive material licensees. NRC currently has approximately 3700 licensees for radioactive material, and conducts approximately 1200 inspections annually.

LICENSING AND REGULATIONS

Prospective licensees wishing to possess and use radioactive material such as those possessed and used by NIST must submit a license application to the NRC showing

how their planned facilities, personnel, program controls, and equipment meet NRC regulations and protect the workers, public, and environment, and provide adequate security of the radioactive material. Each application is reviewed by NRC staff according to established procedures and criteria, and if the regulatory requirements are met, NRC issues a license outlining the conditions under which the company or individual can possess the radioactive material. In addition, licensees must request and obtain a license amendment to alter a license or its conditions.

As mentioned above, the responsibility for safety and security of the radioactive material lies with the licensee. Assignment of this responsibility varies from licensee to licensee and facility to facility, but is delineated in the license application and license conditions. In general, each licensee's environmental health and safety (EH&S) officials and management have the responsibility for establishing the policies and procedures to ensure safe handling of radioactive material and compliance with regulatory requirements; for ensuring that those individuals using radioactive material have adequate training; and for oversight of the program and users to ensure adherence to established policies and procedures. Individuals using radioactive material have the responsibility to adhere to established policies and procedures, including reporting any deviations or issues to Radiation Safety Officer (RSO) and/or management.

NRC expects licensees to conduct their programs with meticulous attention to detail and a high standard of compliance and holds them accountable for doing so through inspections and enforcement. Because of the potentially serious consequences that can result from failure to comply with NRC regulations, every licensee must conduct its radiation safety program according to the conditions of its NRC license, representations made in its license application, NRC regulations, and NRC Orders. Specifically, licensees are subject to NRC regulations in 10 CFR Part 19, "Notices, Instructions and Reports to Workers: Inspection and Investigations," 10 CFR Part 20, "Standards for Protection Against Radiation," and other applicable regulations. The regulations also specify reporting requirements to inform the NRC of significant events, including loss of material, release of material to the environment, radiation exposures to workers or the public that exceed limits specified in the regulations, damaged sources or devices, equipment that fails to function as designed, and leaking sources.

The following items are the key requirements in NRC regulations that must be addressed by applicants before NRC issues a license authorizing possession and use of radioactive material:

- Applicants must be qualified by reason of training and experience to use special nuclear material of the types and quantities requested;
- Applicants must have the facilities and equipment to protect health and safety and minimize danger to life or property;
- Applicants must have the procedures to protect health and to minimize danger to life or property.

NRC INSPECTION AND ENFORCEMENT PROGRAM

NRC conducts periodic inspections of licensees to ensure compliance with regulatory requirements and license conditions. To enable NRC to apply its resources most effectively to the highest risk activities, an inspection priority code from 1 to 5 is assigned to each type of use authorized by a license. The priority code equals the normal inspection interval in years, with code 1 being the greatest potential risk to the health and safety of workers, members of the public, and the environment. In the licensing process, an inspection frequency of once every five years was assigned to the NIST Boulder facility because its activities are relatively low risk given the small amount of radioactive material that the lab is authorized to possess and the approved uses of this source within the lab.

If there are licensee performance issues, or events, NRC may supplement the periodic inspections with "reactive" inspections. A reactive inspection is a special inspection in response to an incident, allegation, or information obtained by NRC (e.g., report of a medical event or other Federal agency interest). The scope of the reactive inspections is normally to focus on the sequence of events leading up to the incident, the contributing and root causes of the event, corrective actions taken or proposed by the licensee, and a discussion of the regulations applying to the incident and if and where they were not met. Reactive inspections can focus in on one or several issues, using more specialized technical or management expertise than a normal inspection, and thus do not necessarily examine the totality of a licensee's program.

All NRC inspections are documented and the results are provided to the licensee; with the exception of some security inspections, these documents are publicly available. If deficiencies are identified, the inspector brings them to the attention of licensee management at the exit meeting and also in the cover letter transmitting the inspection report or Notice of Violation (NOV). An NOV is a formal notification to the licensee that an apparent noncompliance with regulations or conditions has been identified. The NOV requires a written response including a description of the proposed corrective actions. It is the first step in the NRC's enforcement process.

Failure to conduct operations according to regulations and license conditions may result in enforcement action against the licensee as well as individuals. This could include more frequent inspections; issuance of a notice of violation; imposition of a civil penalty; and/or an order suspending, modifying, or revoking the license. NRC's enforcement program is built around potential or actual safety significance, and considers performance factors such as repeat violations, willfulness, or disregard for requirements.

Because of its relevance to today's hearing subject, I would like to mention that one of several tools that NRC uses with its licensees is a confirmatory action letter (CAL). A CAL documents agreed upon actions that the licensee will take to address concerns with their activities. These actions can either be permanent or can be on a temporary basis to address concerns until a final assessment can be made regarding the need for permanent changes. A CAL can also ensure a clear understanding of and commitment to necessary actions to control and assess an unexpected event. In cases where a CAL

is neither appropriate nor sufficient to ensure safety, the NRC may issue an Order requiring mandatory licensee action.

NIST LICENSE

Let me now turn to the specifics of the NIST facility in Boulder with respect to its license conditions and requirements, as well as the event that occurred on June 9, 2008.

NRC initially issued a Byproduct Material License (No. 05-03166-05) for the Boulder facility to the Department of Commerce, National Bureau of Standards on December 19, 1968. The license has been amended a total of 29 times since it was issued. Amendment No. 28 added the special nuclear material (e.g., plutonium) to the existing research and development license and Amendment No. 25 authorized research and development activities on the license using sealed sources. The most recent amendment, Amendment No. 29, was issued to NIST on June 22, 2007 to increase the amount of Iron-55 and limit the amount of Nickel-63.

NIST is licensed to use solid, encapsulated plutonium in quantities less than critical mass. Use of the material must be in accordance with procedures. In the case of the NIST plutonium calibration source involved in the June 9 event, the material was contained in a glass vial. In addition, the glass vial was heat sealed in a plastic bag, and the resultant package was heat sealed in a second plastic bag. This package, composed of the sealed glass vial and the two heat-sealed plastic bags, was in turn placed in a third plastic bag by the NIST Radiation Safety Officer.

The NIST license includes a commitment that all individuals working with licensed sources or those who frequent areas where licensed sources are present shall receive radiation safety training at a level appropriate for their assigned duties. It is the responsibility of the licensee's management and RSO to ensure individuals who access those sources or facilities receive the appropriate training.

NIST's license requires an RSO whose role is to ensure license conditions are met and radiation safety practices are followed. Radiation Worker Training is required for any individual where there is a reasonable potential for an individual to receive doses greater than 100 millirem in a year. This training must be performed by the RSO or an appropriately trained designee. The RSO must assure documentation of Radiation Worker Training and maintain a list of trained and authorized radiation workers. Individuals using special nuclear material must also be trained pursuant to the conditions specified in NIST's letter dated February 15, 2007. NIST license conditions state that refresher training must be provided annually.

Radiation Worker Training covers fundamental practices and concepts in radiation protection, including: (1) basic regulatory requirements in 10 CFR Part 20 such as dose limits, posting and labeling, survey and monitoring, radioactive material control and security, and incident or emergency response; (2) radiation risks and protection strategies such as time, distance, and shielding from the source, and contamination

control; and (3) general and job duty-specific training on the internal policies and practices for implementing the radiation safety program.

THE JUNE 9, 2008 NIST EVENT AND RESPONSE

On June 9, 2008, the NIST RSO was notified that a vial containing standard reference material was discovered broken in one of the research laboratory suites. The reference material contained plutonium. NIST's health physics personnel responded to the area and determined that low levels of contamination were spread outside of the laboratory suite into the adjoining hallway. The hallway was decontaminated and the lab was isolated. Environmental sampling and bioassays and urinalyses of individuals affected were initiated.

On June 10, 2008, NIST's Boulder, Colorado, facility reported the plutonium contamination event to NRC. This event resulted in contamination of certain areas within the facility and radioactive contamination of at least two employees.

Once the initial significance of the event was understood by the RSO, NIST's initial efforts were to protect workers and the public. NIST restricted access to the lab suite, and began to evaluate the extent of contamination to the lab and the potential for exposure to workers and members of the public. NIST informed NRC of the event and has cooperated with our agency staff and the other regulatory authorities in support of inquiries and inspections.

Upon the initial inspectors' observations and consideration of risk significance, complexity, and generic safety implications, NRC determined, in accordance with our internal procedures, that a Special Inspection Team (SIT) was warranted. The SIT process allows NRC to assess an event and its causes and to quickly elevate the NRC response if the findings reveal more significant concerns (e.g., an apparent release of plutonium that results in an exposure to a member of the public or a worker in excess of the allowable limit). As mentioned earlier in this testimony, on June 29, a five-member SIT was dispatched from NRC's Regional Office in Arlington, Texas, to conduct a more detailed review of the event at the Boulder facility. The team consists of the Region IV Division Director for Nuclear Materials Safety, a Branch Chief, for Nuclear Materials Safety, and three health physicists. On July 2, NRC staff executive management met with the SIT and determined that additional escalation was not warranted at that point in time. The team's inspection is continuing. A report documenting the results of the special inspection team's work will be issued within 45 days of the team completing their inspection effort.

On July 2, 2008, NRC issued a CAL to NIST confirming the agreed upon actions that NIST took and planned to take as a result of the June 9 event in order to ensure safety and to adequately evaluate the event in a timely manner. Pursuant to the CAL, NIST has agreed to take several actions, including: (1) suspending use of the plutonium sources pending NRC approval and determination of procedural adequacy for safety and procedural compliance; (2) thoroughly determining the radiation doses to all individuals

potentially exposed by August; (3) reviewing and assessing training and procedural adequacy prior to using any licensed material; (4) providing NRC, for review and approval, a written plan for stabilizing the contamination within the laboratory; and (5) obtaining authorized services for the decontamination of the facility and NRC approval of the licensee's decontamination plan.

Although our inspection team has not completed its work and we have not finalized our inspection conclusions, the NRC staff is concerned about a number of issues. These include: the amount of radiation dose received by individuals as a consequence of the event; the amount of radioactive materials released into the sewer; the use of procedures at NIST's Boulder facility – particularly those related to the handling and storage of radioactive material; and the training of the individuals performing NRC-licensed activities.

SUMMARY

In conclusion, Mr. Chairman and Members of the Committee, it is the policy of the U.S. Nuclear Regulatory Commission to ensure that significant operational events involving reactor and materials facilities licensed by the NRC are investigated in a timely, objective, systematic, and technically sound manner; that the factual information pertaining to each event is documented; and that the cause or causes of each event are ascertained; and that corrective actions are implemented to preclude recurrence.

I hope my testimony provides you with an understanding of NRC's regulatory role with regard to facilities such as NIST, how the NRC responds to events at these facilities, and the seriousness with which we take our duty to protect public health and safety and the environment.

Our assessment to this point has not identified any aspects of the June 9, 2008, event which would result in significant impacts to public and health safety, and we are continuing our investigation into the circumstances of the event itself, including whether NIST's programs, procedures, and policies may have contributed in some way to the event. NRC's efforts will ensure that, if and where violations occurred, NIST will be required to develop and implement effective and lasting corrective actions.

Mr. Collins and I would be pleased to respond to your questions.