

NRC COMPLETES THE STATE OF NEW JERSEY AGREEMENT



The New Jersey Agreement signing at NRC Headquarters

(from left to right: NRC Chairman Gregory Jaczko; Joan Olmstead, OGC; Dennis Sollenberger, FSME; Torre Taylor, FSME; and Terrence Reis, Deputy Director, National Materials Program Directorate, FSME)



On September 2, 2009, the NRC approved an Agreement with the State of New Jersey under Section 274b of the Atomic Energy Act of 1954, as amended. Under the Agreement, the NRC transferred regulatory responsibility to New Jersey for licensing, rulemaking, inspection, and enforcement activities for the following:

- radioactive materials produced as a result of processes related to the production or utilization of special nuclear material
- naturally occurring or accelerator-produced radioactive material
- source material (uranium and thorium)

- special nuclear materials in quantities not sufficient to form a critical mass
- the regulation of the land disposal of source, byproduct material, and special nuclear material received from other persons

On September 30, 2009, New Jersey became the 37th State to sign such an Agreement with the NRC. With the licenses transferred from the NRC and the licenses previously under New Jersey's regulatory authority, NJ has jurisdiction over approximately 700 licenses.

By law, the NRC retained jurisdiction over commercial nuclear power plants and Federal agencies using certain nuclear

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material in New Jersey. In addition, the NRC retained authority for the review, evaluation, and approval of sealed radioactive materials and devices containing certain nuclear materials manufactured in New Jersey and distributed throughout the country.

Before approving the Agreement, the NRC reviewed New Jersey's radiation control program to ensure that it provided adequate protection to public health and safety. The NRC also compared New Jersey's existing radiation control program to the one outlined in the Agreement. On May 27, 2009, the NRC published the proposed Agreement for 4 consecutive weeks in the *Federal Register* to invite comments from the public. The NRC received six comment letters on the proposed Agreement—two supported; two opposed; one supported the rationale of States assuming regulatory



The State of New Jersey Staff

(Top left: Paul Baldauf, Dennis Zannoni, Ed Truskowski, Bill Cszasz, James McCullough and Cathy Biel Center; Jenny Goodman, Nancy Stanley and Janice Baumann. Bottom left: Jack Tway, Rich Peros, Pat Gardner, Jodie Murl, Karen Flanigan and Adria Wentzel. Missing from the picture Emelia Taubel.)

authority, but opposed the fee-associated action; and one did not express support or opposition.

The Governor’s request for the Agreement with the NRC and supporting documents, as well as the NRC staff’s assessment, are available through the NRC’s Agencywide Documents Access and Management System (ADAMS). Help in using ADAMS is available by contacting the NRC Public Document Room staff at 301-415-4737 or 1-800-397-4209 or by sending an e-mail to PDR.Resource@nrc.gov. These documents are also available for public inspection at the NRC Public Document Room at 11555 Rockville Pike, Rockville, MD 20852-2738.

Thirty-six States have previously signed such Agreements with the NRC, including Alabama, Arizona, Arkansas, California, Colorado, Florida, Georgia, Illinois, Iowa, Kansas, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Minnesota, Mississippi, Nebraska, Nevada, New Hampshire,

New Mexico, New York, North Carolina, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Carolina, Tennessee, Texas, Utah, Virginia, Washington, and Wisconsin.

(Contact: Torre Taylor, FSME, 301-415-7900 or e-mail: Torre.Taylor@nrc.gov)

WELCOME



Cynthia A. Carpenter

The FSME staff is excited to welcome Ms. Cynthia A. Carpenter as our new Deputy Office Director.

Before joining FSME, Ms. Carpenter was the Director, Office of Enforcement, since 2006. After graduating from the NRC Senior Executive Service, Ms. Carpenter held a number of senior management positions. Ms. Carpenter earned a bachelor’s degree in civil engineering from the University of Pittsburgh.

The FSME staff is looking forward to working with Ms. Carpenter.

FAREWELL



George Pangburn

The FSME staff bids a fond farewell to our Deputy Office Director, George Pangburn. Mr. Pangburn retired in October 2009 with over 29 years of Federal service.

Mr. Pangburn began his career with the NRC in 1980 and held positions of increasing responsibility. In October 2006, he assumed the responsibilities as Deputy Director of FSME.

Mr. Pangburn earned a bachelor’s degree in geography from the University of Pittsburgh, a master’s degree in geography from the University of Kansas, and a master’s degree in energy resources from

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FROM THE DESK OF THE FSME DIRECTOR

On September 30, 2009, the Federal fiscal year (FY) ended. This is a good time to share the results of our FSME self-assessment and solicit feedback from you, our licensees, on how you believe we are doing as a regulator. We believe that we are doing fairly well, but we also recognize that improvements can be made.

One of our primary mission objectives is to ensure public health and safety while protecting the environment. With that in

mind, we developed strategic- and performance-level operating plan metrics that evaluate our performance. I am pleased to report that we met each of those metrics for FY 2009. Certainly, you deserve much of the credit for this accomplishment. We appreciate your continued focus on maintaining safe operations and protecting the environment from radiological releases. We also met our goals of operating in an open and transparent manner, while maintaining the security of information and nuclear materials. However, the communication with licensees and security of radioactive materials issues will continue to challenge us as we move into FY 2010.

We would like to share some of our 2009 achievements with you:

- We worked with our international partners to ensure that the U.S. perspective was represented in discussions on a number of radioactive materials and waste issues. I led the U.S. delegation at the Steering Committee for Nuclear Energy and compiled comments made by the U.S. agencies. I also met with France's Nuclear Safety Authority representative to discuss how we can address the medical isotope shortage. Other FSME managers participated on waste and radiation safety committees to offer input on international policy and regulatory standards.
- FSME and NRC Region I worked closely with Virginia and New Jersey to transfer over 800 byproduct materials licenses from Federal to State oversight. We hope that the licensees experienced a relatively seamless transition.
- The National Source Tracking System (NSTS), a major security initiative, became operational, providing a highly secure and accessible system to track high-risk nuclear materials.
- Several rulemakings were initiated, published for comments, or completed. These included the NSTS expansion, General License Restrictions, changes to 10 CFR Part 37, "Physical Protection of Byproduct Material," 10 CFR Part 72, "Licensing Requirements for the Independent Storage of Spent Nuclear Fuel and High-Level Radioactive Waste, and Reactor-Related Greater Than Class C Waste," and spent fuel cask certifications.
- Working with the States, we reprioritized our working groups, streamlined their efforts, and focused our resources on the most pressing regulatory issues.
- We briefed the Commission on our uranium recovery program.
- We conducted workshops and meetings across the country to discuss a variety of policy issues and potential rule changes that could impact those licensees and the public.

In closing, I encourage you, our licensees, to provide us feedback at any time. We welcome and value your input. With much appreciation and gratitude, we congratulate you on your important and continued contribution to the safe and secure use of radioactive materials across the nation.

Charles L. Miller
Charles L. Miller, Director

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the University of Pittsburgh's School of Engineering. In addition, he graduated from the NRC Senior Executive Service and received an NRC Meritorious Service Award for Management Excellence.

The FSME staff will miss Mr. Pangburn, and we wish him well in his future endeavors.

EXEMPTION ISSUED DUE TO MEDICAL ISOTOPE SHORTAGES

The United States, along with other countries throughout the world, has experienced shortages

of molybdenum-99 (Mo-99)/technetium-99m (Tc-99m). The regulators of radioactive materials attributed these shortages to reactor shutdowns.

In 10 CFR 32.72, "Manufacture, Preparation, or Transfer for Commercial Distribution of Radioactive Drugs Containing Byproduct Material for Medical Use under Part 35," 10 CFR 35.60(b), 10 CFR 35.100(a)(1), and 10 CFR 35.200(a)(1), the NRC requires medical licensees to conduct calibration tests on



instruments that use Tc-99m and governs the distribution of Mo-99/Tc-99m generators and the transportation of Tc-99m in radioactive drugs to and from medical use licensees. The NRC determined that an exemption from these regulations was needed to ensure the availability of Tc-99m for patient care. On July 16, 2009, the NRC issued such an exemption, stating that it would be in effect only during the time of the Mo-99/Tc-99m shortages in the United States. The exemption also stated that the shortage had to be caused by production shortages of Mo-99/Tc-99m, which the supplier of Mo-99/Tc-99m generators or Tc-99m in radioactive drugs had to document in writing. Under the exemption, the licensee would not be required to perform instrument calibration tests at the maximum activity level or time interval specified in the national standard if the licensee needed the Tc-99m for patient dosages. The licensee would be required to perform the calibration when adequate supplies became available. On a case-by-case basis, the exemption made possible the transfer of Tc-99m from a medical use licensee with a surplus of Tc-99m (or Tc-99m in a radioactive drug) whose supplier was not affected by the shortage to another medical use licensee whose supplier was affected. The NRC conducted an environmental assessment and found that the exemption would not have a significant environmental impact.

To help medical licensees with the Mo-99/Tc-99m shortages, the NRC decided to expedite license amendment requests related to the shortage. The NRC encouraged State regulators to do

THE CHAIRMAN'S AWARD



Chairman Gregory Jaczko; Solomon Sahle, 2009 FSME CFC coordinator; and Commissioner Kristine Svinicki

Congratulations to the FSME staff for their thoughtfulness and generosity in these turbulent economic times. During the 2009 Combined Federal Campaign kickoff meeting, FSME was

awarded the "Chairman's Award" for its 2008 contributions. The award was given to the office that had the most employee participation.

the same. For example, a licensee might need an expedited license amendment to add thallium-201 to continue cardiac imaging during the Mo-99/Tc-99m shortage.

The NRC posted the exemption to the requirements of 10 CFR Part 32 and 10 CFR Part 35 on its public Web site at <http://www.nrc.gov/materials/miau/med-use-toolkit.html>.

(Contact: Glenda Villamar, FSME, 301-415-8022 or e-mail: Glenda.Villamar@nrc.gov)

SIGNIFICANT ENFORCEMENT ACTIONS



The NRC issued significant actions to licensees, individual and non-licensees for failure to comply with a regulation.

Medical

Ohio Valley Medical Center (EA-09-182)

On September 17, 2009, the NRC issued a Notice of Violation to Ohio Valley Medical Center for a Severity Level III violation involving the failure to meet the physical presence requirements of 10 CFR 35.615(f)(2) during high-dose radiation (HDR) treatments. Specifically, on June 17, 2009, and other occasions before that date, the Medical Center failed to have an authorized medical physicist or either an authorized user (AU) or a physician, under the supervision of an AU, who had been trained in the operation of and emergency response for the HDR unit, physically present during the continuation of all patient treatments involving the unit.

Individual Actions

Martin Ferenc (IA-09-028)

On July 2, 2009, the NRC issued a Notice of Violation to Martin Ferenc for a Severity Level III violation involving the individual's deliberate misconduct that caused his employer, Advex Corporation, to be in violation of 10 CFR 34.47(d) and the company's operating and emergency procedure for failing to report an off-scale pocket dosimeter. Specifically, on January 22, 2008, after the assistant radiographer's pocket dosimeter went off scale, Mr. Ferenc, the lead radiographer, deliberately continued to work and did not notify the radiation safety officer, as required.

The NRC's enforcement program can be accessed at <http://www.nrc.gov/about-nrc/regulatory/enforcement/current.html>, under Recently Issued Significant Enforcement Actions. Documents related to cases can be accessed through the NRC's Agencywide Documents Access and Management System (ADAMS) at <http://www.nrc.gov/reading-rm/adams.html>. Help in using ADAMS is available by contacting the NRC Public Document Room staff at 301-415-4737 or 1-800-397-4209 or by sending an e-mail to PDR.Resource@nrc.gov.

(Contact: Michele Burgess, FSME, 301-415-5868 or e-mail: Michele.Burgess@nrc.gov)

GENERIC COMMUNICATIONS ISSUED

The following are summaries of NRC generic communications issued by FSME. If one of these

documents appears relevant to your needs and you have not received it, please call one of the technical contacts listed below. The Internet address for the NRC library of generic communications is <http://www.nrc.gov/reading-rm/doc-collections/gen-comm>.

Bulletins

None

Generic Letters

None

Information Notices (INs)

Information Notices are issued to addressees to provide significant recently identified information about safety, safeguards, or environmental issues. Addressees are expected to review the information for applicability to their facilities and consider actions, as appropriate, to avoid similar problems.

The NRC issued IN 2009-12, "Exempt Distribution Licensing Requirements for Irradiated Gemstones," on July 27, 2009, to all NRC exempt distribution licenses authorized to distribute irradiated gemstones; organizations associated with importing, distributing, or selling irradiated gemstones or jewelry containing irradiated gemstones; and Agreement State Radiation Control Program Directors and State Liaison Officers.

(Technical Contact: Lisa Dimmick, FSME, 301-415-0694 or e-mail: Lisa.Dimmick@nrc.gov)

The NRC issued IN 2009-15, "Varian Medical Systems Varisource High Dose-Rate Remote Afterloader Events: Source Retraction Problems," on August 28, 2009, to all NRC

medical use and master materials licensees authorized to possess or use a Varian Medical Systems VariSource high dose-rate remote afterloader, as well as Agreement State Radiation Control Program Directors and State Liaison Officers.

(Technical Contact: Stephen Poy, FSME, 301-415-7135 or e-mail: Stephen.Poy@nrc.gov)

The NRC issued IN 2009-17, "Reportable Medical Events Involving Treatment Delivery Errors Caused by Confusion of Units for the Specification of Brachytherapy Sources," on August 28, 2009, to all NRC medical use and master materials licensees and Agreement State Radiation Control Program Directors and State Liaison Officers.

(Technical Contact: Cindy Flannery, FSME, 301-415-0223 or e-mail: Cindy.Flannery@nrc.gov)

The NRC issued IN 2009-18, "Performance of Required Shutter Checks And Reporting of Gauge Shutter Failures," on September 18, 2009, to all NRC specific and renewal fixed gauge materials licensees and Agreement State Radiation Control Program Directors and State Liaison Officers.

(Technical Contacts: J. Bruce Carrico, FSME, 301-415-7826 or e-mail: Jbruce.Carrico@nrc.gov and Jim Lynch, Region III, 630-829-9661 or e-mail: James.Lynch@nrc.gov)

Regulatory Issue Summaries (RIS)

The NRC issued RIS 2009-09, "Use of Multiple Dosimetry and Compartment Factors in Determining Effective Dose

Equivalent from External Radiation Exposures," on July 13, 2009. The NRC issued this RIS to all NRC licensees, Agreement State Radiation Control Program Directors, and State Liaison Officers.

(Technical Contacts: Joshua Palotay, 301-415-6231 or e-mail: Joshua.Palotay@nrc.gov and Roger Pedersen, 301-415-3162 or e-mail: Roger.Pedersen@nrc.gov)

The NRC issued RIS 2009-12, "Uranium Recovery Policy Regarding Site Preparation Activities At Proposed, Unlicensed Uranium Recovery Facilities," on September 23, 2009. The NRC issued this RIS to all holders of operating licenses for uranium recovery facilities and companies that submitted applications to construct all types of new uranium recovery facilities (conventional mills, heap leach facilities, and in situ recovery facilities) or letters of intent to submit such applications.

(Technical Contact: Stephen J. Cohen, FSME, 301-415-7182 or e-mail: Stephen.Cohen@nrc.gov)

(Contact: Angela R. McIntosh, FSME, 301-415-5030 or e-mail: Angela.McIntosh@nrc.gov)

SIGNIFICANT EVENTS

Event 1: Use of Wrong Collimator Size Results in Medical Event with Gamma Stereotactic Radiosurgery Unit

Date and Place: July 2, 2009, Honolulu, HI

Nature and Probable Causes:
On July 2, 2009, the licensee reported that a patient received a

gamma stereotactic radiosurgery treatment to two metastatic sites using an 18-millimeter (mm) collimator instead of the prescribed 8-mm collimator. The treatment was prescribed for seven discrete brain metastatic sites using the 8-mm collimator. The prescribed dose was 2,400 cGy (rad). After the second discrete site had been treated, it was determined that an 18-mm collimator had been used instead of the 8-mm collimator. Following the discovery, the collimator was changed to the 8-mm collimator. The treatment to the remaining five discrete sites was administered with the 8-mm collimator. The use of the 18-mm collimator instead of the 8-mm collimator increased the treatment site dose by 3 percent. The 18-mm collimator caused the volume of each of the two treatment areas to increase by 2.35 cm³. The additional tissue received a dose of 2,400 cGy (rad). If the 8-mm collimator was originally used, the target tissue would have received a dose of approximately 430 cGy (rad). Both the physician and patient were notified of the incident. It was discovered that the previous patient had been treated with the 18-mm collimator as prescribed. The medical physicist neglected to change the collimator before the next treatment. The corrective actions included sending a notice to all neurosurgeons and radiation oncologists stressing that they each must independently check collimator size before each treatment.

Event 2: Positioning Error Causes Delivery of Dose to Wrong Site during High Dose Afterloader Treatment

*Date and Place: July 21, 2009,
Colorado Springs, CO*

Nature and Probable Causes: On July 21, 2009, the licensee reported that a patient received 700 cGy (rad) approximately 10 cm from the intended location during an HDR afterloader procedure performed with a Varian model VariSource. The iridium-192 source (Varian model VS2000) contained an activity of 339.18 GBq (9.167 curies). A positioning error resulted in the incident. The dose was delivered to the entrance of the vagina rather than inside the uterus. The applicator used in the procedure had a collet to hold a 3-mm source tube in place. The subsequent investigation revealed that the collet on the applicator had not been tightened sufficiently to prevent movement of the source tube within the applicator. The patient and physician were notified. The patient was retreated with the prescribed dose 3 days later without incident. The corrective actions included generating a new procedure to measure the distance from the end of the source tube to the cylinder before patient treatment and providing additional training to all staff involved in HDR treatments.

**Event 3: Therapeutic Dose
Delivered Instead of Intended
Diagnostic Dose**

*Date and Place: September 30, 2009,
Charlottesville, VA*

Nature and Probable Causes: On September 30, 2009, the licensee reported that a patient was administered a therapeutic dose of 3.7 GBq (100 mCi) of iodine-131 instead of the prescribed diagnostic dose of

0.15 GBq (4 mCi). The patient received a therapeutic dose in August 2008 and was scheduled for the diagnostic followup on September 30, 2009. When the followup was scheduled, the dose was incorrectly entered as therapeutic instead of diagnostic. The hospital notified the patient's physician and consulted with the patient. The hospital also notified its risk management group and began an investigation into the incident.

(Contact: Angela R. McIntosh, FSME, 301-415-5030 or e-mail: Angela.McIntosh@nrc.gov)

SELECTED FEDERAL REGISTER NOTICES



Final Regulatory Guide:
Issuance, Availability (RG 5.74)
(NRC-2009-0280), 74 FR 32197,
July 7, 2009.

(Contact: Bonnie Schnetzler, NSIR,
301-415-7883 or e-mail:
Bonnie.Schnetzler@nrc.gov)

Solicitation for Public Comment on
Potential Changes to the Agency's
Radiation Protection Regulations
(NRC-2009-0279), 74 FR 32198,
July 7, 2009.

(Contact: Dr. Donald Cool, FSME,
301-415-6347 or e-mail:
Donald.Cool@nrc.gov or
Dr. Kimyata Morgan Butler, FSME,
301-415-0733 or e-mail:
Kimyata.MorganButler@nrc.gov)

Medical Use of Byproduct Material:
Authorized User Clarification
(RIN AI59) (NRC-2009-0098),
74 FR 33925, July 14, 2009.

(Contact: Edward M. Lohr, FSME,
301-415-0253 or e-mail:
Edward.Lohr@nrc.gov)

Governors' Designees Receiving
Advance Notification of
Transportation of Nuclear Waste
(NRC-2009-0302), 74 FR 34053,
July 14, 2009.

(Contact: Stephen N. Salomon,
FSME, 301-415-3781 or e-mail:
Stephen.Salomon@nrc.gov)

Draft Regulatory Guide:
Issuance, Availability (DG-3038)
(NRC-2009-0323), 74 FR 36780,
July 24, 2009.

(Contact: Margie Kotzalas, NMSS,
301-492-3202 or e-mail:
Margie.Kotzalas@nrc.gov)

Limiting the Quantity of Byproduct
Material in a Generally Licensed
Device (AI33) (NRC-2008-0272),
74 FR 38372, August 3, 2009.

(Contact: Solomon Sahle, FSME,
301-415-3781 or e-mail:
Solomon.Sahle@nrc.gov)

Draft Regulatory Guide:
Issuance, Availability (DG-5034)
(NRC-2009-0345), 74 FR 39343,
August 6, 2009.

(Contact: Robert Norman, NSIR,
301-415-2278 or e-mail:
Robert.Norman@nrc.gov)

List of Approved Spent Fuel
Storage Casks: HI-STORM
100 Revision 6, Confirmation
of Effective Date (AI60)
(NRC-2009-0132), 74 FR 40060,
August 11, 2009.

(Contact: Jayne M. McCausland,
FSME, 301-415-6219 or e-mail:
Jayne.McCausland@nrc.gov)

List of Approved Spent Fuel
Storage Casks: Standardized
NUHOMS System Revision 10,
Confirmation of Effective Date
(AI62) (NRC-2009-0162),
74 FR 40060, August 11, 2009.

(Contact: Jayne M. McCausland, FSME, 301-415-6219 or e-mail: Jayne.McCausland@nrc.gov)

Draft Regulatory Guide: Issuance, Availability (DG-5029) (NRC-2009-0353), 74 FR 40854, August 13, 2009.

(Contact: Steven Ward, NMSS, 301-492-3426 or email: Steven.Ward@nrc.gov)

Export and Import of Nuclear Equipment and Material; Updates and Clarifications; Reopening of Comment Period for Information Collection (AI16) (NRC-2008-0567), 74 FR 41096, August 14, 2009.

(Contact: Cinthya Roman Cuevas, NMSS, 301-492-3224 or e-mail: Cinthya.Roman@nrc.gov)

Medical Use of Byproduct Material: Authorized User Clarification, Confirmation of Effective Date (AI59) (NRC-2009-0098), 74 FR 43619, August 27, 2009.

(Contact: Edward M. Lohr, FSME, 301-415-0253 or e-mail: Edward.Lohr@nrc.gov)

Withdrawal of Proposed Regulatory Issue Summary: Implementation of New Final Rule, Protection of Safeguards Information (NRC-2009-0106), 74 FR 46472, September 9, 2009.

(Contact: Robert Norman, NSIR, 301-415-2278 or e-mail: Robert.Norman@nrc.gov)

State of Colorado and the Organization of Agreement States; Consideration of Petition in the Rulemaking Process (NRC-2008-0453), 74 FR 46512, September 10, 2009.

(Contact: Kimyata Morgan Butler, FSME, 301-415-0733 or e-mail: Kimyata.MorganButler@nrc.gov or Gary Comfort, FSME, 301-415-8106 or e-mail: Gary.Comfort@nrc.gov)

Notice of Issuance of Guidelines on Use of Firearms by Security Personnel; Notice of Effective Date of Statute (NRC-2008-0465), 74 FR 46800, September 11, 2009.

(Contact: Philip Brochman, NSIR, 301-415-6557 or e-mail: Phil.Brochman@nrc.gov or Susan Fonner, OGC, 301-415-1629 or e-mail: Susan.Fonner@nrc.gov)

License and Certificate of Compliance Terms (AI09) (NRC-2009-0361), 74 FR 47126, September 15, 2009.

(Contact: Keith McDaniel, FSME, 301-415-5252 or e-mail: Keith.McDaniel@nrc.gov)

Draft Regulatory Guide: Issuance, Availability (DG-6007) (NRC-2009-0418), 74 FR 48783, September 24, 2009.

(Contact: Jack Foster, FSME, 301-415-6250 or e-mail: Jack.Foster@nrc.gov)

TO OUR READERS: In our attempt to keep the FSME Licensee Newsletter relevant, we welcome useful and informative feedback on the contents of the newsletter. If you would like to suggest topics, provide bulletins or Web site postings, or even write an article with pictures or self-explanatory diagrams, please contact Vanessa Cox or Gwendolyn Davis, from FSME Rulemaking Branch A. Ms. Cox may be contacted at 301-415-8342 or Vanessa.Cox@nrc.gov. Ms. Davis may be contacted at 301-415-8165 or Gwendolyn.Davis@nrc.gov. In addition, to ensure proper delivery of the FSME Licensee Newsletter, please report any address changes to Ms. Cox to prevent any interruption of service at FSME_Newsletter@nrc.gov.



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