the Atomic Safety and Licensing Board that the request and/or petition should be granted and/or the contentions should be admitted, based on a balancing of the factors specified in 10 CFR 2.309(c)(1)(i)–(viii).

Documents submitted in adjudicatory proceedings will appear in NRC's electronic hearing docket which is available to the public at *http://ehd.nrc.gov/ehd_proceeding/home.asp,* unless excluded pursuant to an order of the Commission, an Atomic Safety and Licensing Board, or a Presiding Officer. Participants are requested not to include personal privacy information, such as social security numbers, home addresses, or home phone numbers in their filings, unless an NRC regulation or other law requires submission of such information. With respect to copyrighted works, except for limited excerpts that serve the purpose of the adjudicatory filings and would constitute a Fair Use application, participants are requested not to include copyrighted materials in their submissions.

For further details with respect to this license amendment application, see the application for amendment dated June 15, 2009, as supplemented by letters dated June 20 and June 23, 2009, which are available for public inspection at the Commission's PDR, located at One White Flint North, Public File Area O1 F21, 11555 Rockville Pike (first floor), Rockville, Maryland. Publicly available records will be accessible electronically from the ADAMS Public Electronic Reading Room on the Internet at the NRC Web site, *http://www.nrc.gov/reading-rm/adams.html.* Persons who do not have access to ADAMS or who encounter problems in accessing the documents located in ADAMS should contact the NRC PDR Reference staff by telephone at 1–800–397–4209, or 301–415–4737, or by e-mail to *pdr.resource@nrc.gov.*

Attorney for licensee: Mr. Bradley J. Fewell, Associate General Counsel, Exelon Generation Company, LLC, 4300 Winfield Road, Warrenville, IL 60555.

Dated at Rockville, Maryland, this 10th day of July 2009.

For the Nuclear Regulatory Commission.

Stephen P. Sands,

Project Manager, Plant Licensing Branch 3–2, Division of Operating Reactor Licensing, Office of Nuclear Reactor Regulation.

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NUCLEAR REGULATORY COMMISSION

[NRC–2009–0312; Docket No. 030–35985]

Environmental Assessment and Final Finding of No Significant Impact With Regard to Exemption From Certain Regulatory Requirements

Introduction

The U.S. Nuclear Regulatory Commission (NRC) is proposing to exempt all NRC medical use licensees from certain requirements in 10 CFR 35.60(b), 10 CFR 35.100(a)(1) and 35.200(a)(1), and 10 CFR 32.72. These requirements govern calibration tests that use technetium-99m, and distribution of molybdenum-99/technetium-99m generators and technetium-99m radioactive drugs to and from medical use licensees. NRC is issuing these exemptions to ensure that available technetium-99 is being used for patient administrations during any period of United States and worldwide shortages of molybdenum-99, which is used to produce molybdenum-99/technetium-99m generators for medical use.

These exemptions will be effective only when there are United States shortages of technetium-99m caused by production shortages of molybdenum-99, as documented in writing by the supplier of molybedenum-99/technetium-99m generators or technetium-99m.

Environmental Assessment

Identification of the Proposed Action

The NRC proposes to issue exemptions to all NRC medical use licensees from the requirements in 10 CFR 35.60(b) to calibrate the instrumentation required in paragraph (a) of this section in accordance with nationally recognized standards. The licensee will not be required to perform the calibration test at the maximum activity or at the time interval specified in the national standard if the licensee would use technetium-99m needed for a patient administration to perform the calibration test. The exemption will only be in effect when the licensee is receiving reduced quantities of technetium-99m as a result of production shortages of molybdenum-99 affecting their generator or technetium-99m supplier, as documented in writing by the supplier. The licensee must perform the test when adequate supplies, as documented in writing by the technetium-99 supplier, become available, and document results of the test in accordance with 10 CFR 35.2060. Depending on the maximum activity needed to perform the calibration test and the activity of technetium-99m in the radioactive drug, this may make dosages available to 7–15 additional patients at the licensee's facility.

The NRC proposes to issue exemptions to all NRC medical use licensees from the requirements in 10 CFR 35.100(a)(1) and 35.200(a)(1) to obtain unsealed byproduct material prepared for medical use for uptake, dilution, excretion, imaging or localization studies from a manufacturer or preparer licensed under § 32.72 of this chapter or equivalent Agreement State requirements, if the licensee obtains the technetium-99m (or a technetium-99m radioactive drug) from another medical use licensee to administer to patients. This permits medical use licensees that cannot get technetium-99m from their normal supplier because of the shortage to obtain some technetium-99m from a local medical use licensee that has a surplus. This exemption will only be in effect when the licensee is unable to obtain technetium-99m (or a technetium-99m radioactive drug) from its normal supplier as a result of production shortages of molybdenum-99 affecting its generator or technetium-99m supplier, as documented in writing by the supplier. This exemption will give some relief on a case-by-case basis to a medical use licensee if its supplier is severely affected by the shortage but the other medical use licensee's supplier is not.

The NRC proposes to issue exemptions to all NRC medical use licensees from requirements in 10 CFR 32.72, to permit the licensee to transfer surplus molybdenum-99/technetium-99m generators or technetium-99m, or technetium-99m radioactive drugs to other medical use licensees for administration to patients without requiring the licensee to meet the requirements for a commercial distributor of radioactive drugs to medical use licensees. This exemption will only be in effect when the receiving medical use licensee is unable to obtain a generator, or technetium-99m or technetium-99m radioactive drugs from its normal supplier, as a result of production shortages of molybdenum-99 affecting its generator or technetium-99m supplier, as documented in writing by the supplier. This exemption will facilitate and give relief on a case-by-case basis to a medical use licensee with a surplus of technetium-99m (or a technetium-99m radioactive drug) because its supplier is not affected by the shortage in the transfer of the technetium-99m to the other medical use licensee whose supplier is affected.

Need for the Proposed Action

These exemptions are needed in times of molybdenum-99 shortages in the United States to ensure that available technetium-99m is used for patient treatment. On May 14, 2009, the Chalk River National Research Universal reactor in Canada experienced an unexpected shutdown that has resulted in an extended shutdown for safety repairs. The Chalk River reactor produces approximately 50 percent of the United States supply of molybdenum-99 used to produce molybdenum-99/technetium-99m generators. This resulted in a United States and worldwide shortage of molybdenum-99 for generator production and technetium-99m for medical uses. The High Flux Reactor in Petten, the Netherlands, also produces a substantial amount of molybdenum-99 used to produce generators in the United States and the world. The reactor in Petten is currently operating on a temporary operating permit and expected to be shut down in early 2010 for a number of months for repairs. This will also cause molybdenum-99 and technetium-99m shortages in the United States and the world. The supply chain for fission-produced isotopes is fragile and may shrink dramatically at any time when these two, or the other three aging international reactors currently producing these isotopes, are shut down for safety or routine maintenance.

Environmental Impacts of the Proposed Action

During times of supply shortages, there is less molybdenum-99 and technetium-99m available for molybdenum-99/technetium-99 generator production. There are also fewer generators to elute, and fewer technetium-99m radioactive drugs produced. The exemption will: (1) Allow lower quantities of technetium-99m to be used for calibrations and delay the calibration test, making quantities available for patient administrations; (2) allow a licensee to obtain unsealed byproduct material from another licensee other than directly from the manufacturer or commercial nuclear pharmacy; and (3) allow a licensee with sufficient product to transfer excess to another authorized licensee for patient administration. The exemptions do not relieve the licensee from NRC environmental release requirements or worker dose or public dose requirements associated with the elution of molybdenum-99/technetium-99m generators, preparation of technetium-99m radioactive drugs, administration of the technetium-99m radioactive drugs to patients, handling of these radioactive materials, or handling of radioactive waste. All of those protections remain in place. Neither molybdenium-99 nor technetium-99m is a volatile radionuclide. Molybdenum-99 remains attached to the generator resins and technetium-99m stays suspended in the eluent. Both radionuclides have short half-lives. None of the proposed exemptions affects how the licensee handles these radionuclides. Their medical use when there are no shortages results in minimal impact on the environment and public dose exposures. During times of shortage, medical use licensees will have less technetium-99m to use and there will be fewer patients receiving technetium-99m radioactive drugs even when maximizing the medical use of available technetium-99m. Therefore, the proposed action will not result in an increase in the release of radioactive material into the environment or increase public radiation exposure. There will be no impact on the environment as a result of the proposed action.

Alternatives to the Proposed Action

As required by Section 102(2)(E) of NEPA (42 U.S.C. 4322(2)(E)), possible alternatives to the final action have been considered. The NRC identified only one reasonable alternative for consideration: the no action alternative. This no action alternative would not result in any adverse impact on the environment but would negatively impact the medical use licensees' provision of medical care to their patients. During shortages in the United States and the world of molybdenum-99, the supply of technetium-99m available to administer to patients is less than the amount needed to perform important cardiac, cancer, and other imaging procedures. Using technetium-99m to perform calibration tests at maximum activities and at preset intervals instead of for patient administrations would prevent a number of patients from receiving these needed procedures. Temporary relief from the national standards should not result in significantly different patient radiation dosages because most instruments used to measure patient dosages today are stable if not moved and provided with reasonable climate controls. Also, performing the test at lower activity levels will provide confidence that the instrument is still calibrated over the levels of routine technetium-99m dosages. For higher dosages requiring written directives, the licensee can use the activity provided with the radioactive drug to assure patient safety. Not granting an exemption to permit distribution to and receipt of excess generators and technetium-99m by other authorized medical use licensees that do not have any also would reduce the number of patients receiving needed procedures. For these reasons, the NRC did not adopt the no action alternative.

Alternative Use of Resources

No alternative use of resources was considered due to the reasons stated above.

Agencies and Persons Consulted

No other agencies or persons were contacted regarding this proposed action.

Identification of Source Used

None.

Finding of No Significant Impact

Based on the above environmental assessment, the NRC finds that the proposed action will not have a significant effect on the quality of the human environment. Accordingly, the NRC has determined that a Finding of No Significant Impact is appropriate and preparation of an environmental impact statement is not warranted.

Dated at Rockville, Maryland, this 10th day of July 2009.

For the Nuclear Regulatory Commission.

Duane E. White,

Acting Chief, Radioactive Materials Safety Branch, Division of Materials Safety and State Agreements, Office of Federal and State Materials and Environmental Management Programs Safety and Safeguards.

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NUCLEAR REGULATORY COMMISSION

[NRC–2009–0313]

License Renewal Interim Staff Guidance LR–ISG–2006–02: Staff Guidance Regarding the Acceptance Reviews for Environmental Requirements for License Renewal Applications; Notice of Withdrawal

AGENCY: U.S. Nuclear Regulatory Commission (NRC).

ACTION: Notice of withdrawal.

SUMMARY: The NRC is withdrawing its proposed License Renewal Interim Staff Guidance (LR–ISG), LR–ISG–2006–02, ''Staff Guidance on Acceptance Review for Environmental Reports for License Renewal Applications,'' which was noticed in the **Federal Register** (72 FR 7694 on February 16, 2007). This