UNITED STATES
NUCLEAR REGULATORY COMMISSION
OFFICE OF NUCLEAR REACTOR REGULATION
OFFICE OF NUCLEAR MATERIALS SAFETY AND SAFEGUARDS
WASHINGTON, DC 20555-0001

November 13, 2007

NRC INFORMATION NOTICE 2007-31: U.S. FOOD AND DRUG ADMINISTRATION ANNOUNCEMENT RELATED TO CERTAIN SLEEP DISORDER DRUGS

ADDRESSEES

All holders of operating licenses for nuclear power reactors and Category I fuel cycle facilities, except licensees for reactors who have permanently ceased operations and have certified that fuel has been permanently removed from the reactor vessel.

PURPOSE

The U.S. Nuclear Regulatory Commission (NRC) is issuing this information notice (IN) to provide information regarding a March 14, 2007, U.S. Food and Drug Administration (FDA) announcement related to certain sleep disorder drugs. The information described in the announcement could be applicable to a licensee's Fitness-for-Duty Program (FFD), Behavioral Observation Program (BOP), and Employee Assistance Program (EAP). The NRC expects that recipients will review this information for applicability to their facilities and consider actions, as appropriate. However, this IN contains no new NRC requirements, and, therefore, no specific action or written response is required.

DESCRIPTION OF CIRCUMSTANCES

On March 14, 2007, the FDA[1] requested that manufacturers of sleep disorder, or "sedative-hypnotic" drugs strengthen their product labeling to include stronger language concerning potential risks. These risks included "complex sleep-related behaviors, which may include sleep-driving." The FDA announcement listed the name of the drugs and manufacturers. This class of drugs is widely advertised in both television and print media.

In addition to the complex sleep-related behaviors noted above, there are other potential side-effects. For example, one drug cited in the FDA announcement had the following side-effects (taken from the manufacturer's web site): more outgoing or aggressive behavior than normal, confusion, strange behavior, agitation, and hallucinations.

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[1] http://www.fda.gov/bbs/topics/NEWS/2007/NEW01587.html

BACKGROUND

Title 10 of the *Code of Federal Regulations* (10 CFR) Part 26, "Fitness for Duty Programs," Section 26.10, "General Performance Objectives," states that FFD programs must "provide reasonable assurance that nuclear power plant personnel...and personnel of licensees authorized to possess or use formula quantities of [strategic special nuclear material] SSNM...will perform their tasks in a reliable and trustworthy manner and are not under the influence of any substance, legal or illegal, or mentally or physically impaired from any cause, which in any way adversely affects their ability to safely and competently perform their duties." The BOP is the primary method of ensuring the continued trustworthiness and reliability of personnel after unescorted access has been granted. The BOP looks for behavior that indicates impairment. The Implementing Guidance for Access Authorization in Current Threat Environment dated January 7, 2003 (Safeguards Information, EA 02-261, Enclosure 4), provides criteria for determining trustworthiness and reliability related to meeting the requirements of 10 CFR 26.10. EAP staff are required to inform licensee management when a determination has been made that any individual's condition constitutes a hazard to himself, herself, or others. The behaviors identified (e.g., aggressive behavior) in the FDA announcement and the potential side-effects noted by manufacturers may influence an EAP provider's determination and subsequent report.

DISCUSSION

There is no regulatory requirement that prohibits licensee personnel from taking the properly prescribed sleep disorder drugs listed in the March 14, 2007, FDA announcement. This IN serves to make licensees aware of the FDA announcement that describes potential side-effects of these commonly prescribed sleep disorder drugs. The BOP plays an important part in satisfying the FFD requirements of 10 CFR Part 26 by looking for behavior that would indicate impairment by any cause, that would adversely affect an individual's ability to safely and competently perform his or her duties.

CONTACT

This information notice requires no specific action or written response. Please direct any questions about this matter to the technical contact listed below.

/RA/

Robert C. Pierson, Director
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Enclosure: Recently Issued FSME/NMSS
Generic Communications

Note: NRC generic communications may be found on the NRC public Web site, http://www.nrc.gov, under Electronic Reading Room/Document Collections.

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Recently Issued FSME/NMSS Generic Communications

Date	GC No.	Subject	Addressees
02/02/07	IN-07-03	Reportable Medical Events Involving Patients Receiving Dosages of Sodium Iodide Iodine-131 less than the Prescribed Dosage Because of Capsules Remaining in Vials after Administration	All U.S. Nuclear Regulatory Commission medical use licensees and NRC Master Materials Licensees. All Agreement State Radiation Control Program Directors and State Liaison Officers.
02/28/07	IN-07-08	Potential Vulnerabilities of Time-reliant Computer-based Systems Due to Change in Daylight Saving Time Dates	All U. S. Nuclear Regulatory Commission licensees and all Agreement State Radiation Control Program Directors and State Liaison Officers.
03/13/07	IN-07-10	Yttrium-90 Theraspheres® and Sirspheres® Impurities	All U.S. Nuclear Regulatory Commission (NRC) Medical Licensees and NRC Master Materials Licensees. All Agreement State Radiation Control Program Directors and State Liaison Officers.
04/04/07	IN-07-13	Use of As-Found Conditions to Evaluate Criticality-related Process Upsets at Fuel Cycle Facilities	All licensees authorized to possess a critical mass of special nuclear material.
05/02/07	IN-07-16	Common Violations of the Increased Controls Requirements and Related Guidance Documents	All licensees who are implementing the U.S. Nuclear Regulatory Commission (NRC) Order Imposing Increased Controls (EA-05-090), issued November 14, 2005 and December 22, 2005.
05/21/07	IN-07-19	Fire Protection Equipment Recalls and Counterfeit Notices	All holders of operating licenses for nuclear power reactors and fuel cycle facilities; except those licensees for reactors that have permanently ceased operations and who have certified that fuel has been permanently removed from the reactor vessel; and except those licensees for decommissioned fuel cycle facilities.
06/11/07	IN-07-20	Use of Blank Ammunition	All power reactors, Category I fuel cycle facilities, independent spent fuel storage installations, conversion facility, and gaseous diffusion plants.

Date	GC No.	Subject	Addressees
08/08/07	IN-07-23	Inadvertent Discharge of Halon 1301Fire-suppression System from Incorrect and/or Out-of-date Procedures	All holders of operating licenses for nuclear power reactors, except those who have permanently ended operations and have certified that fuel has been permanently removed from the reactor vessel. All holders of licenses for fuel cycle facilities.
07/19/07	IN-07-25	Suggestions from the Advisory Committee on the Medical Use of Isotopes For Consideration to Improve Compliance With Sodium Iodide I-131 Written Directive Requirements in 10 CFR 35.40 and Supervision Requirements in 10 CFR 35.27	All U.S. Nuclear Regulatory Commission (NRC) medical-use licensees and NRC Master Materials Licensees. All Agreement State Radiation Control Program Directors and State Liaison Officers.
08/13/07	IN-07-26	Combustibility of Epoxy Floor Coatings at Commercial Nuclear Power Plants	All holders of operating licenses for nuclear power reactors and fuel cycle facilities except licensees for reactors that have permanently ceased operations and who have certified that fuel has been permanently removed from the reactor vessel.
03/01/07	RIS-07-03	Ionizing Radiation Warning Symbol	All U.S. Nuclear Regulatory Commission licensees and certificate holders. All Radiation Control Program Directors and State Liaison Officers
03/09/07	RIS-07-04	Personally Identifiable Information Submitted to the U.S. Nuclear Regulatory Commission	All holders of operating licenses for nuclear power reactors and holders of and applicants for certificates for reactor designs. All licensees, certificate holders, applicants, and other entities subject to regulation by the U.S. Nuclear Regulatory Commission (NRC) of the use of source, byproduct, and special nuclear material
03/20/07	RIS-07-05	Status and Plans for Implementation of NRC Regulatory Authority for Certain Naturally-occurring and Accelerator-produced Radioactive Material	All NRC materials licensees, Radiation Control Program Directors, State Liaison Officers, and NRC's Advisory Committee on the Medical Uses of Isotopes
04/05/07	RIS-07-07	Clarification of Increased Controls for Licensees That Possess Collocated Radioactive Material During Transportation Activities	All U.S. Nuclear Regulatory Commission (NRC) licensees issued NRC's Order Imposing Increased Controls and all Radiation Control Program Directors and State Liaison Officers

Date	GC No.	Subject	Addressees
05/04/07	RIS-07-09	Examples of Recurring Requests for Additional Information (RAIs) for 10 CFR Part 71 and 72 Applications	All holders of, and applicants for, a: (1) 10 CFR Part 71 certificate of compliance (CoC) for a radioactive material transportation package; (2) 10 CFR Part 72 CoC for a spent fuel storage cask; and (3) 10 CFR Part 72 specific license for an independent spent fuel storage installation (ISFSI).
06/27/07	RIS-06-27, Suppl. 1	Availability of NRC 313A Series of Forms and Guidance for Their Completion	All U.S. Nuclear Regulatory Commission (NRC) medical-use licensees and NRC Master Materials licensees. All Radiation Control Program Directors and State Liaison Officers.
05/15/07	RIS-07-10	Subscriptions To New List Server For Automatic Notifications Of Medical-Related Generic Communications, *Federal Register* Notices And Newsletters	All U.S. Nuclear Regulatory Commission (NRC) medical-use licensees and NRC Master Materials licensees. All Radiation Control Program Directors and State Liaison Officers.

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