

upon demonstration by Mr. Poling of good cause.

## VI

Any person adversely affected by this Confirmatory Order, other than Mr. Douglas Poling, may request a hearing within 20 days of the Order's publication in the **Federal Register**.

Where good cause is shown, consideration will be given to extending the time to request a hearing. A request for extension of time must be directed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, and include a statement of good cause for the extension.

A request for a hearing must be filed in accordance with the NRC E-Filing rule, which the NRC promulgated in the August 28, 2007, **Federal Register** (72 FR 49139). The E-Filing process requires participants to submit and serve documents over the Internet or, in some cases, to mail copies on electronic optical storage media. Participants may not submit paper copies of their filings unless they seek a waiver in accordance with the procedures described below.

To comply with the procedural requirements associated with E-Filing, at least five days prior to the filing deadline the requestor must contact the Office of the Secretary by e-mail at [hearingdocket@nrc.gov](mailto:hearingdocket@nrc.gov), or by calling (301) 415-1677, to request: (1) A digital ID certificate, which allows the participant (or its counsel or representative) to digitally sign documents and access the E-Submittal server for any NRC proceeding in which it is participating; and/or (2) creation of an electronic docket for the proceeding (even in instances when the requestor (or its counsel or representative) already holds an NRC-issued digital ID certificate). Each requestor will need to download the Workplace Forms Viewer™ to access the Electronic Information Exchange (EIE), a component of the E-Filing system. The Workplace Forms Viewer™ is free and is available at <http://www.nrc.gov/site-help/e-submittals/install-viewer.html>. Information about applying for a digital ID certificate also is available on NRC's public Web site at <http://www.nrc.gov/site-help/e-submittals/apply-certificates.html>.

Once a requestor has obtained a digital ID certificate, had a docket created, and downloaded the EIE viewer, it can then submit a request for a hearing through EIE. Submissions should be in Portable Document Format (PDF) in accordance with NRC guidance available on the NRC public Web site at

<http://www.nrc.gov/site-help/e-submittals.html>. A filing is considered complete at the time the filer submits its document through EIE. To be timely, electronic filings must be submitted to the EIE system no later than 11:59 p.m. Eastern Time on the due date. Upon receipt of a transmission, the E-Filing system time-stamps the document and sends the submitter an e-mail notice confirming receipt of the document. The EIE system also distributes an e-mail notice that provides access to the document to the NRC Office of the General Counsel and any others who have advised the Office of the Secretary that they wish to participate in the proceeding, so that the filer need not serve the document on those participants separately. Therefore, any others who wish to participate in the proceeding (or their counsel or representative) must apply for and receive a digital ID certificate before a hearing request is filed so that they may obtain access to the document via the E-Filing system.

A person filing electronically using the agency's adjudicatory E-Filing system may seek assistance through the "Contact Us" link located on the NRC Web site at <http://www.nrc.gov/site-help/e-submittals.html> or by calling the NRC Meta-System Help Desk, which is available between 8 a.m. and 8 p.m., Eastern Time, Monday through Friday, excluding government holidays. The Meta-System Help Desk can be contacted by telephone at 1-866-672-7640 or by e-mail at [MSHD.Resource@nrc.gov](mailto:MSHD.Resource@nrc.gov).

Participants who believe that they have good cause for not submitting documents electronically must file a motion, in accordance with 10 CFR 2.302(g), with their initial paper filing requesting authorization to continue to submit documents in paper format. Such filings must be submitted by: (1) First class mail addressed to the Office of the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, Attention: Rulemaking and Adjudications Staff; or (2) courier, express mail, or expedited delivery service to the Office of the Secretary, Sixteenth Floor, One White Flint North, 11555 Rockville, Pike, Rockville, Maryland, 20852, Attention: Rulemaking and Adjudications Staff. Participants filing a document in this manner are responsible for serving the document on all other participants. Filing is considered complete by first-class mail as of the time of deposit in the mail, or by courier, express mail, or expedited delivery service upon depositing the document with the provider of the service.

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](http://ehd.nrc.gov/EHD_Proceeding/home.asp), unless excluded pursuant to an order or policy 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. 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 works.

If a person other than Mr. Douglas Poling requests a hearing, that person shall set forth with particularity the manner in which his interest is adversely affected by this Order and shall address the criteria set forth in 10 CFR 2.309(d) and (f).

If the hearing is requested by a person whose interest is adversely affected, the Commission will issue an Order designating the time and place of any hearing. If a hearing is held, the issue to be considered at such hearing shall be whether this Confirmatory Order should be sustained.

In the absence of any request for hearing, or written approval of an extension of time in which to request a hearing, the provisions specified in Section V above shall be final 20 days from the date this Order is published in the **Federal Register** without further order or proceedings. If an extension of time for requesting a hearing has been approved, the provisions specified in Section V shall be final when the extension expires, if a hearing request has not been received. A request for hearing shall not stay the immediate effectiveness of this order.

Dated this 16th day of September 2009.

For the U.S. Nuclear Regulatory Commission.

**Mark A. Satorius,**

*Regional Administrator, Region III.*

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## NUCLEAR REGULATORY COMMISSION

[NRC-2009-0418]

### Draft Regulatory Guide: Issuance, Availability

AGENCY: Nuclear Regulatory Commission.

**ACTION:** Notice of Issuance and Availability of Draft Regulatory Guide, DG-6007.

**FOR FURTHER INFORMATION CONTACT:** Jack Foster, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, telephone: (301) 415-6250 or e-mail to [Jack.Foster@nrc.gov](mailto:Jack.Foster@nrc.gov).

**SUPPLEMENTARY INFORMATION:**

**I. Introduction**

The U.S. Nuclear Regulatory Commission (NRC) is issuing for public comment a draft guide in the agency's "Regulatory Guide" series. This series was developed to describe and make available to the public such information as methods that are acceptable to the NRC staff for implementing specific parts of the NRC's regulations, techniques that the staff uses in evaluating specific problems or postulated accidents, and data that the staff needs in its review of applications for permits and licenses.

The draft regulatory guide (DG), entitled, "Establishing Quality Assurance Programs for the Manufacture and Distribution of Sealed Sources and Devices Containing Byproduct Material," is temporarily identified by its task number, DG-6007, which should be mentioned in all related correspondence. DG-6007 is a proposed Revision 1 of Regulatory Guide 6.9, dated February 1995.

This regulatory guide directs the reader to the type of quality assurance (QA) and quality control (QC) program acceptable to the staff of the NRC during the review of an application to manufacture or distribute sealed sources and devices containing byproduct materials.

Title 10 of the *Code of Federal Regulations* (10 CFR) Part 32, "Specific Domestic Licenses to Manufacture or Transfer Certain Items Containing Byproduct Material," regulates the manufacture and distribution of sealed sources or devices containing byproduct material. Regulations in 10 CFR 32.210(c) require the applicant or registrant to submit information about the QC program in sufficient detail to allow the NRC reviewers to ensure that the product is manufactured and distributed in a manner that is adequate to protect health and minimize danger to life and property.

This regulatory guide endorses the methods and procedures for a QA/QC program described in Section 10.7, "Quality Assurance and Quality Control" of NUREG-1556, Volume 3, "Consolidated Guidance About Materials Licenses: Applications for Sealed Source and Device Evaluation

and Registration," issued April 2004, as a process that the NRC finds acceptable. As described in Volume 3 of NUREG-1556, the applicant must provide details of the QA program that ensure that the product is manufactured and distributed in accordance with the representations made in the application and the statements contained in the registration certificate for the product.

**II. Further Information**

The NRC staff is soliciting comments on DG-6007. Comments may be accompanied by relevant information or supporting data and should mention DG-6007 in the subject line. Comments submitted in writing or in electronic form will be made available to the public in their entirety through the NRC's Agencywide Documents Access and Management System (ADAMS).

Personal information will not be removed from your comments. You may submit comments by any of the following methods:

1. *Mail comments to:* Rulemaking and Directives Branch, Mail Stop: TWB-05-B01M, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

2. *Federal e-Rulemaking Portal:* Go to <http://www.regulations.gov> and search for documents filed under Docket ID [NRC-2009-0418]. Address questions about NRC dockets to Carol Gallagher, 301-492-3668; e-mail [Carol.Gallagher@nrc.gov](mailto:Carol.Gallagher@nrc.gov).

3. *Fax comments to:* Rulemaking and Directives Branch, Office of Administration, U.S. Nuclear Regulatory Commission at (301) 492-3446. Requests for technical information about DG-6007 may be directed to the NRC contact, Jack Foster at (301) 415-6250 or e-mail to [Jack.Foster@nrc.gov](mailto:Jack.Foster@nrc.gov).

Comments would be most helpful if received by November 21, 2009. Comments received after that date will be considered if it is practical to do so, but the NRC is able to ensure consideration only for comments received on or before this date. Although a time limit is given, comments and suggestions in connection with items for inclusion in guides currently being developed or improvements in all published guides are encouraged at any time.

Electronic copies of DG-6007 are available through the NRC's public Web site under Draft Regulatory Guides in the "Regulatory Guides" collection of the NRC's Electronic Reading Room at <http://www.nrc.gov/reading-rm/doc-collections/>. Electronic copies are also available in ADAMS (<http://www.nrc.gov/reading-rm/adams.html>), under Accession No. ML091670485.

In addition, regulatory guides are available for inspection at the NRC's Public Document Room (PDR) located at 11555 Rockville Pike, Rockville, Maryland. The PDR's mailing address is USNRC PDR, Washington, DC 20555-0001. The PDR can also be reached by telephone at (301) 415-4737 or (800) 397-4205, by fax at (301) 415-3548, and by e-mail to [pdr.resource@nrc.gov](mailto:pdr.resource@nrc.gov).

Regulatory guides are not copyrighted, and Commission approval is not required to reproduce them.

Dated at Rockville, Maryland, this 17th day of September 2009.

For the Nuclear Regulatory Commission.

**Andrea D. Valentin,**

*Chief, Regulatory Guide Development Branch, Division of Engineering, Office of Nuclear Regulatory Research.*

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**BILLING CODE 7590-01-P**

**NUCLEAR REGULATORY COMMISSION**

[NRC-2009-0410; Docket No. 030-35904]

**Notice of Availability of Environmental Assessment and Finding of No Significant Impact for License Amendment to Byproduct Materials License No. 29-30707-01, for Termination of the License and Unrestricted Release of the Memory Pharmaceuticals Corporation Facility Located in Montvale, NJ**

**AGENCY:** Nuclear Regulatory Commission.

**ACTION:** Issuance of Environmental Assessment and Finding of No Significant Impact for License Amendment.

**FOR FURTHER INFORMATION CONTACT:**

Dennis Lawyer, Health Physicist, Commercial and R&D Branch, Division of Nuclear Materials Safety, Region I, 475 Allendale Road, King of Prussia, Pennsylvania; telephone 610-337-5366; fax number 610-337-5269 or by e-mail: [dennis.lawyer@nrc.gov](mailto:dennis.lawyer@nrc.gov).

**SUPPLEMENTARY INFORMATION:**

**I. Introduction**

The U.S. Nuclear Regulatory Commission (NRC) is considering the issuance of a license amendment to Byproduct Materials License No. 29-30707-01. This license is held by Memory Pharmaceuticals Corporation (the Licensee) for its facility located at 100 Philips Parkway in Montvale, New Jersey (the Facility). Issuance of the amendment would authorize release of the Facility for unrestricted use and termination of the NRC license. The