(STP-02-029, April 2002, Program, Medical Use Licenses)

April 9, 2002

ALL AGREEMENT STATES
PENNSYLVANIA, MINNESOTA, WISCONSIN

PROGRAM MANAGEMENT INFORMATION: NRC RE-ISSUES, FOR COMMENT, DRAFT CONSOLIDATED GUIDANCE ABOUT MEDICAL USE LICENSES (STP-02-029)

The U.S. Nuclear Regulatory Commission (NRC) has re-issued, for comment, Draft NUREG-1556, Volume 9 entitled, "Program Specific Guidance About Medical Use Licenses" (Federal Register Notice enclosed).

The Draft Consolidated Guidance was developed for use with the revised 10 CFR Part 35. NRC is seeking public comment in order to receive feedback from the widest range of interested parties and to ensure that all information relevant to developing the final document is available to the staff. You may access this draft document on the NRC's web site at: http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/v9/index.html. A hard copy of this document has been forwarded to you by regular mail.

A 1-day public workshop will be held on Thursday, April 25, 2002, from 9 a.m. to 5 p.m. at NRC's Headquarters. The emphasis of this workshop will be on guidance related to therapeutic applications of byproduct materials. A second 1-day public workshop will be held on Tuesday, April 30, 2002, from 9 a.m. to 5 p.m. at NRC's headquarters. The emphasis of this workshop will be on guidance related to diagnostic applications of byproduct materials. Further information on these workshops, may be found in the enclosed Federal Register Notice.

Written comments on NUREG-1556, Volume 9 may be submitted to the Chief, Rules and Directives Branch, Division of Administrative Services, U.S. Nuclear Regulatory Commission, Washington, DC 20555.

Comments* on this draft document should be submitted by c.o.b. June 4, 2002. Comments received after that date will be considered to the extent practicable. If you have any questions regarding this correspondence, please contact the individual named below.

POINT OF CONTACT:	Roger W. Broseus	Internet:	RWB@NRC.GOV
TELEPHONE:	(301) 415-7608	FAX:	(301) 415-5385

/RA Josephine M. Piccone Acting for/
Paul H. Lohaus, Director
Office of State and Tribal Programs

Enclosure:
As stated

*This information request has been approved by OMB 3150-0029, expiration 06/30/04. The estimated burden per response to comply with this voluntary collection is approximately 6 hours. Forward any comments regarding the burden estimate to the Information and Records Branch (T-6F33), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, and to the Paperwork Reduction Project (3150-0029), Office of Management and Budget, Washington, DC 20503. If a document does not display a currently valid OMB control number, the NRC may not conduct or sponsor, and a person is not required to respond to, a collection of information.

[Federal Register: April 5, 2002 (Volume 67, Number 66)]
[Notices]
[Page 16467-16468]
From the Federal Register Online via GPO Access [wais.access.gpo.gov]
[DOCID:fr05ap02-127]

NUCLEAR REGULATORY COMMISSION

Issuance, Availability of Draft NUREG; Announcements of Public Workshops

AGENCY: Nuclear Regulatory Commission.

ACTION: Issuance of draft NUREG for comment and announcements of public workshops.

SUMMARY: The Nuclear Regulatory Commission (NRC) is re-issuing for comment a draft of NUREG-1556, Volume 9, “Consolidated Guidance About Materials Licenses; Program- Specific Guidance About Medical Use Licenses.'' This licensing guide is a companion to the recently published revision to 10 CFR part 35, “Medical Use of Byproduct Material.'' The NRC is also developing additional guidance for medical use licensees and will be holding public workshops to obtain stakeholder input on content of this guidance. The NRC is especially interested in stakeholder comments that will improve the guidance to make it useful to applicants for medical use licenses, including licensees in Agreement States. The NRC is focusing on making the guidance more risk-informed and performance-based.

DATES: Commenters should submit comments on Draft NUREG-1556, Volume 9 by June 4, 2002. Comments received after this date will be considered if it is practical to do so, but the Commission is able to assure consideration only for comments received on or before this date. A 1-day public workshop will be held on Thursday, April 25, 2002, from 9 a.m. to 5 p.m. at NRC's headquarters; the workshop will be preceded by an open house from 8 a.m. to 9 a.m. The emphasis in this workshop will be on guidance related to therapeutic applications of byproduct materials. To ensure that adequate copies of handouts are available, persons planning to attend the workshop should contact the person designated below by April 18, 2002. A second 1-day public workshop will be held at the same location on April 30, 2002, from 9 a.m. to 5 p.m.; the workshop will be preceded by an open house from 8 a.m. to 9 a.m. The emphasis of this workshop will be on guidance related to diagnostic applications of byproduct material. To ensure that adequate copies of handouts are available, persons planning to attend the workshop should contact the person designated below by April 23, 2002. The intent of the open houses is to present the opportunity for informal interactions between attendees, both NRC staff and members of the public. A third workshop, relating to guidance for inspection of entities licensed under 10 CFR part 35, is planned for late May and will be announced in the Federal Register as well as on the NRC's web site (see ADDRESSES, below). It is also planned to post draft inspection guidance on the NRC's web site for comment.

ADDRESSES: Written comments on NUREG-1556, Volume 9 may be submitted to the Chief, Rules and Directives Branch, Division of Administrative Services, U.S. Nuclear Regulatory Commission, Washington, DC 20555. You may also provide comments through the NRC's

rulemaking forum / web site at: http://ruleforum.llnl.gov/cgi-bin/rulemake?source=MU–PRULE The NRC also plans to post draft inspection guidance at this web site for public viewing prior to the public meeting on inspection guidance planned for late May. Provisions are available at this site to upload comments as files (any format) if your web browser supports that function. For information about the web site, contact Carol Gallagher via E-mail at CAG@nrc.gov.

The public workshops will be held at the NRC Auditorium, Two White Flint North, 11545 Rockville Pike, Rockville, Maryland. Information about the workshops will also be posted at NRC's web site at http://www.nrc.gov; click on “Public Meeting Schedule."

FOR FURTHER INFORMATION CONTACT: Roger W. Broseus, Office of Nuclear Material Safety and Safeguards, Office of Industrial and Medical Nuclear Safety, Rulemaking and Guidance Branch, Mail Stop T9-C24, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; telephone: (301) 415-7608; E-mail: RWB@nrc.gov. Questions about the public meeting process should be directed to Francis Cameron; Office of the General Counsel, USNRC, Washington DC 20555-000; E-mail: FXC@nrc.gov; telephone: (301) 415-1642.

SUPPLEMENTARY INFORMATION:

Draft NUREG-1556, Consolidated Guidance About Materials Licenses--Volume 9, Program--Specific Guidance About Medical Use Licenses

The NRC is issuing a draft of NUREG-1556, Volume 9, for public comment for a 60-day period. In addition to obtaining written comments, the staff will be conducting a public workshop on April 25, 2002, to obtain stakeholder comments on this Volume, with emphasis on therapeutic applications of byproduct materials. A second public workshop will be held on April 30, 2002, to receive stakeholder input on guidance, with emphasis on diagnostic applications of byproduct materials. Both workshops will be held in the Auditorium at NRC Headquarters in Rockville, MD.

The NRC staff is seeking input on the guidance contained in the draft NUREG, previously published for public comment in August 1998, in order to make the guidance as useful as possible to those who may seek NRC licensure under 10 CFR part 35, “Medical Use of Byproduct Material." Comments received since publication of the 1998 draft have been considered by staff; these comments and NRC's responses appear in Appendix Z of the current draft. Comments about any of the guidance in Volume 9 are welcome; staff is especially interested in receiving comments on the following questions:

1. Level of Detail and Format: Is the format and level of detail in the guidance appropriate for first-time applicants? Should the guidance be more general in describing acceptable methods of meeting 10 CFR part 35 requirements? If so, please provide suggestions for revisions. Discussion about the pros and cons of providing extensive detail about safety and other procedures would be especially helpful.

2. Model Procedures: Are the model procedures helpful as written? Should they be retained or rewritten? If so, please provide suggestions for revisions.

3. Licensing Guidance Specific to Diagnostic Nuclear Medicine: The staff is considering development of a summary of the licensing requirements for diagnostic medical use of byproduct materials? Is such a document desirable? What should be provided in the guidance? How long should it be?

4. Other Guidance: Are there additional voluntary industry consensus standards or other publically available documents that should be considered for reference in NUREG-1556, Volume 9?

To facilitate the NRC's handling of comments, we request that commenters relate their comments to specific sections and/or appendices in the NUREG. This will help place the comments in context and aid in understanding how they relate to the guidance.

The NRC is placing added emphasis on conducting its regulatory activities in a risk-informed and performance-based manner. This approach is intended to be less prescriptive and allow for the implementation of programs by licensees that may be specific to their needs while meeting the regulatory requirements. In the past, applicants have requested guidance from the NRC staff on what procedures are acceptable, with the expectation that licensing process delays would thereby be avoided. Others have expressed the view that the provision of specific guidance results in the perception that the only way to receive a license is to adhere to the guidance. The NRC staff seeks to meet the needs of applicants for licensure, while not suggesting that details in the guidance are prescriptive. Comments on Volume 9 will help NRC staff to provide guidance that is helpful while not providing too much detail.

Dated at Rockville, Maryland, this 28th day of March, 2002.

For The Nuclear Regulatory Commission
Patricia K. Holahan,
Chief, Rulemaking and Guidance Branch, Division of Industrial and Medical Nuclear Safety, Office of Nuclear Materials Safety and Safeguards.
[FR Doc. 02-8243 Filed 4-4-02; 8:45 am]
BILLING CODE 7590-01-P