

# Proposed Rules

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This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

## DEPARTMENT OF AGRICULTURE

### Animal and Plant Health Inspection Service

#### 9 CFR Parts 101 and 113

[Docket No. 94-051-2]

RIN 0579-AA66

#### Viruses, Serums, Toxins, and Analogous Products; In Vitro Potency Testing for Serial Release

**AGENCY:** Animal and Plant Health Inspection Service, USDA.

**ACTION:** Proposed rule; extension of comment period and notice of public hearing.

**SUMMARY:** We are extending by 30 days the comment period for our proposed rule that would amend the regulations regarding the use of in vitro potency testing for serial release. The regulations pertaining to in vitro testing for serial release would require that such immunoassays be parallel line assays based upon unexpired reference preparations and would specify procedures and requirements for qualifying reference preparations for inactivated products. This extension will provide interested persons with additional time to prepare comments on the proposed rule.

We are also advising the producers of veterinary biologics and other interested persons that the Animal and Plant Health Inspection Service will be holding a public hearing in Ames, IA, at our Veterinary Biologics Public Meeting to discuss issues related to in vitro potency testing.

**DATES:** Consideration will be given only to comments received on or before September 14, 1995. We will also consider comments made at a public hearing to be held in Ames, IA, on Tuesday, August 1, 1995, from 3:00 p.m. to 5:00 p.m.

**ADDRESSES:** Please send an original and three copies of your comments to Docket No. 94-051-1, Regulatory Analysis and Development, PPD,

APHIS, Suite 3C03, 4700 River Road Unit 118, Riverdale, MD 20737-1238. Please state that your comments refer to Docket No. 94-051-1. Comments received may be inspected at USDA, room 1141, South Building, 14th Street and Independence Avenue SW., Washington, DC, between 8 a.m. and 4:30 p.m., Monday through Friday, except holidays. Persons wishing to inspect comments are requested to call ahead on (202) 690-2817 to facilitate entry into the comment reading room. The public hearing will be held at the Scheman Building, Iowa State Center, Ames, IA, on Tuesday, August 1, 1995. **FOR FURTHER INFORMATION CONTACT:** Dr. David A. Espeseth, Deputy Director, Veterinary Biologics, BBEP, APHIS, 4700 River Road Unit 148, Riverdale, MD 20737-1237, telephone (301) 734-8245, fax (301) 734-8669.

**SUPPLEMENTARY INFORMATION:** On May 17, 1995, the Animal and Plant Health Inspection Service (APHIS) published in the **Federal Register** (60 FR 26381-26384, Docket No. 94-051-1) a proposed rule to amend the regulations regarding the use of in vitro tests for serial release. The proposed rule would, among other things, prescribe requirements for in vitro immunoassays used to determine the relative antigen content of inactivated biological products; require that such immunoassays be parallel line assays based upon unexpired reference preparations; and specify procedures and requirements for qualifying or requalifying reference preparations for inactivated products. Comments on the proposed rule were required to be received on or before August 15, 1995.

So that we may consider comments received after that date, we are extending the public comment period on Docket No. 94-051-1 until September 14, 1995. During this period, interested persons may submit their comments for our consideration.

APHIS is also conducting a public hearing to discuss in vitro potency testing on August 1, 1995, at the Scheman Building, Iowa State Center, Ames, IA. The public hearing is scheduled as part of the public meeting on veterinary biologics that is being held at the Scheman Building on August 1 and 2, 1995, in Ames, IA. The agenda for the public hearing will be limited to issues related to in vitro potency testing. The purpose of the hearing is to have

further discussion of this topic by interested persons. We may also hold a second hearing on August 15, 1995, from 8:30 a.m. to 11 a.m. at the Holiday Inn Gateway Center, Ames, IA, in the event that additional time is needed for further discussion of the topic. We shall announce at the conclusion of the first hearing whether the second hearing shall be held. We will publish a notice in the **Federal Register** if we decide to hold the hearing on August 15, 1995. Interested persons may also call the person listed under **FOR FURTHER INFORMATION CONTACT** after August 1, 1995, to find out whether the second hearing will be held.

Persons wishing either to attend or participate in the public hearing are requested to notify the person listed under **FOR FURTHER INFORMATION CONTACT** at least two business days before the public hearing. Please indicate whether you wish to make a prepared statement at the public hearing, the subject of your remarks, and the approximate amount of time you would like to speak. APHIS welcomes and encourages the presentation of comments at the public hearing.

A representative of APHIS will preside at the public hearing. Any interested person may appear and be heard in person, by attorney, or by other representative. Persons who wish to speak at the public hearing will be asked to sign in with their name and organization, to establish a record for the hearing.

The public hearing is scheduled for the times specified under "**DATES.**" The hearing, however, may be terminated at any time after it begins if all persons desiring to speak have been heard. We ask that anyone who reads a statement provide two copies to the presiding officer at the hearing. If the number of speakers at the hearing warrants it, the presiding officer may limit the time for each presentation so that everyone wishing to speak has the opportunity.

The purpose of the hearing is to give interested persons an opportunity for oral presentation of data, views, and arguments. Questions about the content of the proposed rule may be part of the commenters' oral presentations. Neither the presiding officer nor any other representative of APHIS, however, will respond to comments at the hearing,

except to clarify or explain provisions of the proposed rule.

**Authority:** 21 U.S.C. 151-159, 7 CFR 2.17, 2.51, and 371.2(d).

**Lonnie J. King,**

*Administrator, Animal and Plant Health Inspection Service.*

[FR Doc. 95-17738 Filed 7-17-95; 8:45 am]

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## NUCLEAR REGULATORY COMMISSION

### 10 CFR Part 61

RIN 3150-AE88

#### Land Ownership Requirements for Low-Level Waste Sites

**AGENCY:** Nuclear Regulatory Commission.

**ACTION:** Advance notice of proposed rulemaking; withdrawal.

**SUMMARY:** The Nuclear Regulatory Commission (NRC or Commission) is withdrawing an advance notice of proposed rulemaking that presented a possible change to the NRC Federal or State land ownership requirements for low-level waste (LLW) facility sites. The Commission has decided that a rule change to allow private ownership of a LLW site is not warranted or needed. The basis for this decision is that States and compacts have generally indicated that they do not need, nor would they allow, private ownership, and that this rule change could be potentially disruptive to the current LLW program.

**FOR FURTHER INFORMATION CONTACT:**

Mark Haisfield, Office of Nuclear Regulatory Research, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, telephone (301) 415-6196.

**SUPPLEMENTARY INFORMATION:** On August 3, 1994 (59 FR 39485), the Commission published an advance notice of proposed rulemaking (ANPRM) to consider amending its regulations to allow private ownership of LLW facility sites as an alternative to the current requirement for Federal or State ownership. In the ANPRM, the Commission requested information on specific questions that dealt with (1) the potential use of this alternative, (2) impacts to public health and safety or the environment, and (3) liability considerations.

The 60-day comment period was extended another 60 days at the request of the Nuclear Information and Resource Service (October 20, 1994; 59 FR 52941). The comment period expired on December 2, 1994. The Commission

received 49 comment letters: 19 commenters were from States, compacts, or their representatives; 12 were from public organizations; 11 were from commercial/industrial organizations or their representative; 4 were from individuals; and 1 each were from a Federal agency, a national laboratory, and a professional organization. Most of the commenters took a definitive position regarding whether to initiate a proposed rule. For the most part the commenters, at a ratio of about 4 to 1, were against developing a generic rule. The Commission prepared a detailed summary of the comments received. Copies of the summary are available for inspection or copying for a fee from the NRC Public Document Room at 2120 L Street NW. (Lower Level), Washington DC; the PDR's mailing address is US NRC, Mail Stop LL-6, Washington, DC 20555-0001; telephone (202)634-3273; fax (202)634-3343.

As noted in the ANPRM, the purpose for making a generic rule change would be to facilitate the objectives of the Low-Level Radioactive Waste Policy Act of 1980, as amended. Therefore, as noted in the ANPRM, the NRC was particularly interested in determining whether Agreement States or compacts would use a provision allowing private ownership of the land for a LLW facility. The Commission believes that if there did not seem to be a significant interest or need for such a provision, addressing private ownership issues through appropriate exercise of exemption authority would be sufficient.

The Agreement State and compact commenters generally indicated that they would not allow private land ownership, and in many cases, State ownership of the land is required by State law or regulation. Of the 19 comments from States, compacts, or their representatives, only Nebraska indicated a desire to actively consider changes permitting private ownership. Nebraska and the Cortland County, New York, Low-Level Radioactive Waste Office stated that there is not an adequate basis for requiring Federal or State land ownership, which therefore would support private ownership. The Commission believes there is adequate statutory authority for the NRC to require Federal or State land ownership. Moreover, because Nebraska is the only additional State considering changes permitting private ownership, the Commission believes assisting Nebraska on a case-specific basis, if requested and appropriate, is preferable to developing a generic rule change.

Many commenters, including States and compacts, also believe that this type of change to 10 CFR part 61 is not only unnecessary but would be a significant disruption to the current siting and licensing process. As one commenter noted, this would have a negative impact on public health and safety because it would affect the timely development of new LLW disposal facilities needed to reduce on-site storage at thousands of licensee sites throughout the country. The Commission believes that these comments have merit. The Commission believes that the potential negative impact of disrupting the current process far outweighs any potential benefits that might be derived from making a generic rule change at this time.

This change could also generate significant public misunderstanding and unwarranted public concern about the potential rollback of other LLW disposal requirements. The Idaho National Engineering Laboratory's National Low-Level Waste Management Program summarized this issue, stating:

For over three decades the public has been led to believe that all LLW disposal sites would necessarily be owned and controlled by either a Federal or State government. This, we believe, has been an important factor in convincing many proponent groups and State and local LLW advisory groups that LLW can and will be disposed of in a safe manner. To now try and convince these groups that Federal or State ownership of LLW disposal sites is not required, may be difficult and generate a significant credibility problem.

The Commission has not objected to private ownership of the Envirocare site under Agreement State authority in the State of Utah because of special reasons and provisions applicable to that site. The Commission believes that if any other State desires to use an exemption provision, a case-specific evaluation would be conducted, as was done for the State of Utah. Any evaluation would consider whether the underlying purpose of governmental ownership, assuring the existence of a responsible entity for long-term care and monitoring of the site, can be achieved.

For the reasons discussed, the Commission is withdrawing the ANPRM.

Dated at Rockville, Maryland this 12th day of July, 1995.

For the Nuclear Regulatory Commission.

**John C. Hoyle,**

*Secretary of the Commission.*

[FR Doc. 95-17562 Filed 7-17-95; 8:45 am]

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