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 116

[Docket No. 00–071–2]

RIN 0579–AB90

Viruses, Serums, Toxins, and Analogous Products; Records and Reports

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Proposed rule; withdrawal and reproposal.

SUMMARY: We are proposing to amend the Virus-Serum-Toxin Act regulations concerning records and reports to require veterinary biologics licensees and permittees to record specific information concerning adverse events associated with the use of biological products that they produce or distribute and to compile and submit those records in a summary report to the Animal and Plant Health Inspection Service (APHIS) every 12 months for products licensed for 1 year or more; for newly licensed products, a summary report would have to be submitted at 6-month intervals during the first year of the product license and at 12-month intervals thereafter. The summary report would also have to identify the number of doses, or the average number of doses, of the product in distribution channels, if available. These records and reports would help ensure that APHIS will be able to provide complete and accurate information to consumers regarding adverse reactions or other problems associated with the use of licensed biological products. This proposed rule replaces a previously published proposed rule, which we are withdrawing as part of this document, that contained fewer specifics concerning the information that would have to be recorded in adverse event reports associated with the use of veterinary biologics that are submitted to the Agency.

DATES: We will consider all comments that we receive on or before October 17, 2005.

ADDRESSES: You may submit comments by any of the following methods:

- EDOCKET: Go to *http://www.epa.gov/feddocket* to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Once you have entered EDOCKET, click on the ''View Open APHIS Dockets'' link to locate this document.
- Postal Mail/Commercial Delivery: Please send four copies of your comment (an original and three copies) to Docket No. 00–071–2, Regulatory Analysis and Development, PPD, APHIS, Station 3C71, 4700 River Road Unit 118, Riverdale, MD 20737–1238. Please state that your comment refers to Docket No. 00–071–2.
- Federal eRulemaking Portal: Go to *http://www.regulations.gov* and follow the instructions for locating this docket and submitting comments.

Reading Room: You may read any comments that we receive on this docket in our reading room. The reading room is located in room 1141 of the USDA South Building, 14th Street and Independence Avenue SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 690–2817 before coming.

Other Information: You may view APHIS documents published in the **Federal Register** and related information on the Internet at *http://www.aphis.usda.gov/ppd/rad/webrepor.html.*

FOR FURTHER INFORMATION CONTACT: Dr. Albert P. Morgan, Section Leader, Operational Support Section, Policy, Evaluation, and Licensing, Center for Veterinary Biologics, VS, APHIS, 4700 River Road Unit 148, Riverdale, MD 20737–1231; (301) 734–8245.

SUPPLEMENTARY INFORMATION:

Background

The Virus-Serum-Toxin Act regulations in 9 CFR part 116 (referred to below as the regulations) contain requirements for maintaining detailed records of information necessary to give a complete accounting of all the activities within a veterinary biologics establishment. In § 116.1, paragraph (a) states that such reports must include, but are not limited to, the items enumerated in the regulations, including inventory and disposition records (§ 116.2), information concerning product development and preparation and market suspension and recalls (§ 116.5), animal records (§ 116.6), and test records (§ 116.7).

In § 116.5, paragraph (b) states that if at any time there are indications that raise questions regarding the purity, safety, potency, or efficacy of a product, or if it appears that there may be a problem regarding the preparation, testing, or distribution of a product, the licensee, permittee, or foreign manufacturer must immediately notify the Animal and Plant Health Inspection Service (APHIS) concerning the circumstances and the action taken, if any.

However, the regulations in § 116.1 do not explicitly require licensees and permittees to maintain records of adverse events associated with the use of veterinary biologics, nor do the regulations in § 116.5 provide specific guidance in determining whether an adverse event should be considered an indication that raises questions regarding the purity, safety, potency, efficacy, preparation, testing, or distribution (PSPEPTD) of such product. Consequently, each veterinary biologics manufacturer makes an independent determination concerning (1) whether an adverse event report raises PSPEPTD questions and (2) when and in what manner such report of the adverse event will be provided to APHIS.

To limit the harm to animals posed by unsatisfactory veterinary biologics, APHIS must rely on adverse event reports provided by veterinary biologics licensees and permittees. However, without any explicit guidance in the regulations as to the form those reports should take, licensees and permittees are using nonstandardized methods to record and submit reports regarding adverse events to APHIS. Similarly, without explicit reporting requirements concerning adverse events, reports that may signal problems concerning the use of veterinary biological products are not all being submitted to APHIS in a timely manner.

To address this situation, on January 15, 2002, we published in the **Federal Register** (67 FR 1910–1913, Docket No. 00–071–1) a proposed rule to amend the regulations concerning records and reports to require veterinary biologics licensees and permittees to record and submit reports to APHIS concerning adverse events associated with the use of veterinary biological products that they produce or distribute. The proposed rule would have required veterinary biologics licensees and permittees to report to APHIS the number of doses of each licensed product that they distribute. The proposed rule also would have amended the regulations in 9 CFR part 101 to provide definitions for the terms *adverse event* and *adverse event report.*

We solicited comments on our proposal for 60 days ending on March 18, 2002. We received 13 comments by that date. The comments were from 10 veterinary biologics manufacturers, 2 trade associations representing veterinary biologics manufacturers, and a veterinary association. Six commenters expressed conceptual support for the proposed rule, but were concerned that parts of the proposed regulations were overly broad or ambiguous and would increase the regulatory burden on the industry and possibly compromise confidential business information. Four commenters were opposed to the rule, stating that it was unnecessary and that APHIS had underestimated the regulatory burden that would be imposed on the industry. The remaining three commenters neither supported nor opposed the rule, but instead either asked for clarification of certain aspects of the proposed rule or suggested alternative wording that they believed would provide greater clarity.

In response to these comments, we believe it is necessary to clarify those provisions that could be subject to multiple interpretations and to provide more specifics concerning the information that should be included in adverse event reports associated with the use of veterinary biologics that are submitted to the Agency. Therefore, we are withdrawing the January 15, 2002, proposed rule referenced above and are replacing it with the proposed changes described in this document. The proposed recordkeeping and reporting requirements regarding adverse events that would apply to each licensee, permittee, and foreign establishment that prepares and distributes biological products are described below.

Definitions

The regulations in 9 CFR part 101 contain definitions of terms used in the regulations concerning veterinary biologics. The proposed changes to part 116 of the regulations would make it necessary for us to add definitions in § 101.2 for two terms used in the proposed regulations: *Adverse event* and *adverse event report.* We would define *adverse event* as any observation in animals, whether or not the cause of the event is known, that is unfavorable and unintended and that occurs after any use (on or off label) of a biological product. For products administered to animals, this would include events related to a suspected lack of expected efficacy. For products intended to diagnose disease, adverse events would refer to anything that hinders discovery of the correct diagnosis. We would define *adverse event report* as a communication concerning the occurrence of an adverse event from an identifiable first-hand reporter that includes at least the following information: An identifiable reporter; an identifiable animal; an identifiable biological product; and one or more adverse events.

Adverse Event Records

In this document we are proposing to add to the regulations a new § 116.9 for adverse event records, reports, and summary reports. New § 116.9 would require licensees and permittees to record reports of all adverse events that they receive concerning the use of biological products they produce or distribute and to submit a summary of such reports to APHIS on an annual (for products licensed for more than 1 year) or semiannual (for products licensed less than 1 year) basis. For each event, licensees and permittees would be required to record the following information: (1) The date of the report; (2) the identification of the person initiating the report; (3) the product code number as it appears on the product license or permit and the product trade name; (4) the product serial number(s), if available; (5) a description of the adverse event; (6) a description of the animal(s) involved in the event, including the number dead, number affected, number exposed to the product, species, breed, age, sex, and physiological status; (7) the opinion of the person reporting the event as to whether the event is product-related (*i.e.*, probable, possible, unknown, unlikely, no assessment); (8) route and site of vaccination for products administered parenterally; (9) identity of the person administering the product (veterinarian, animal owner, other, unknown); (10) the date the event occurred; and (11) the outcome of the event (recovered, death, euthanized, alive with side effects, ongoing event).

Summary Reports

We are proposing to require that licensees and permittees submit to APHIS a summary report of all adverse event reports received during the reporting period. For products licensed for 1 year or more, the summary report would have to be submitted at 12-month intervals; for newly licensed products, a summary report would have to be submitted at 6-month intervals during the first year of the product license and at 12-month intervals thereafter. For new products, we had considered an alternative proposal that would also have allowed summary reports for new products to also be submitted every 12 months. However, we believe that more frequent reporting for new products will enable us to identify trends more quickly and thereby resolve any problems sooner. We specifically request that you comment on the merit of 6-month as compared to 12-month reporting of adverse events concerning new products.

The summary report would have to include the following information: (1) The name, address, and U.S. Veterinary License or Permit number of the producer or permittee; (2) copies of any individual adverse event report record(s); and (3) the number of doses, or the average number of doses, of the product in distribution channels, if available. For products licensed for 1 year or more, firms would be allowed 1 year after the effective date of the final rule to come into compliance with the proposed amendment and submit their first summary report, with subsequent summary reports being submitted at 12-month intervals thereafter. For the reasons explained above, the first summary report for newly licensed products would have to be submitted 6 months after the effective date of the final rule and a second report submitted 6 months later, after which summary reports would have to be submitted at 12-month intervals. We would require all summary reports to be received by APHIS within 60 days after the reporting date (semiannual or annual, as the case may be) that would be established by the licensee or permittee and approved by APHIS.

We would require the submission of summary reports at 12-month intervals (6-month intervals for new products) because we believe that frequent reporting of adverse events concerning veterinary biologicals would ensure that

we have adequate data to support a decision, if necessary, to take regulatory action against products that are associated with an unusual number of adverse event reports.

In order to provide an objective measure of when it may be necessary to take action against a veterinary biologic to limit harm in animals, and as a component of the adverse event reporting system, we would use the number of doses of product distributed or the average number of doses of the product in distribution channels, if available, instead of the number of doses of product administered to animals to calculate the incidence of adverse events associated with a particular product. Typically, the number of doses of product administered to animals would be used to calculate incidence. However, because we must take timely action and may not know precisely how many animals have been treated with a product, we would use the number of distributed doses of a product as representative of the number of doses that were administered to animals.

Completion of Records

The regulations in §§ 116.1(a)(3) and 116.8 provide that all records (other than disposition records) required under part 116 shall be completed by the licensee, permittee, or foreign manufacturer before any portion of a serial of any product may be marketed in the United States or exported. We are proposing to amend those provisions to also allow adverse event records to be excluded from the list of records that must be completed before a product may be marketed or exported. Like disposition records, adverse event records could not be expected to have been completed prior to the marketing or exportation of a product.

Miscellaneous

We would also make several minor, nonsubstantive editorial changes to the regulations to improve their clarity.

Executive Order 12866 and Regulatory Flexibility Act

This rule has been reviewed under Executive Order 12866. The rule has been determined to be significant for purposes of Executive Order 12866, and, therefore, has been reviewed by the Office of Management and Budget.

We are proposing to amend the Virus-Serum-Toxin Act regulations for records and reports to require veterinary biologics licensees and permittees to record and submit reports to APHIS concerning adverse events associated with the use of veterinary biologics that they produce or distribute. The proposed regulations would specify the information to be included in adverse event records and would require the submission, at 12-month intervals (6-month intervals for new products), of summary reports that would include, among other things, compilations of individual adverse event records and information concerning the number of doses, or the average number of doses, of the product in distribution channels, if available. These proposed requirements would assist us in providing complete and accurate information concerning adverse reactions or other problems associated with the use of licensed veterinary biologics.

For this rule, we have prepared an economic analysis. The economic analysis provides a cost-benefit analysis as required by Executive Order 12866, as well as an analysis of the potential economic effects of this proposed rule on small entities, as required under the Regulatory Flexibility Act. The economic analysis is set forth below.

We do not expect that the proposed recordkeeping requirements would have a significant economic impact on most veterinary biologics manufacturers. This is because most manufacturers already maintain recordkeeping systems for adverse event reports that capture most, if not all, of the information that would be required to be recorded under the proposal. The information that would be required is basic in nature; it is the type of information that most manufacturers record anyway, in order to improve their product or reduce their potential legal liability. Furthermore, the proposed regulations would not restrict manufacturers from using their discretion to choose the most appropriate recordkeeping system for maintaining records of these reports; the proposal, therefore, should not result in veterinary biologics manufacturers having to alter their current recordkeeping systems or create new recordkeeping systems. It should also be noted that the vast majority of licensed products are not likely to be associated with adverse events. It is estimated, for example, that reports of adverse events are received for no more than 10 percent of the approximately 2,000 currently licensed products.

The proposed requirement for the submission of summary reports to APHIS should not have a significant economic impact on most veterinary biologics manufacturers. As indicated above, most manufacturers already maintain recordkeeping systems for adverse event reports that capture most, if not all, of the information that would be required to be recorded under the proposal. For most manufacturers that receive adverse reports, therefore, the proposed requirement for the submission of annual summary reports to APHIS should involve no more than packaging and assembling information that has already been captured, a task that should have only minimal economic consequences. The current regulations do not require veterinary biologics licensees or permittees to report to APHIS on the number of doses of each licensed or permitted product that has been distributed, but that information, too, is currently being captured by most manufacturers.

Effect on Small Entities

The proposed rule would affect all of the approximately 125 U.S. veterinary biologics manufacturers, including permittees. This is because, at the present time, none of the licensees and permittees is in full compliance with the proposed requirements on a voluntary basis; they would all have to take at least some additional action, even if that additional action simply involved establishing a formal system for recording adverse event reports that they receive.

We do not have definitive information on the size of all potentially affected entities. However, it is reasonable to assume that most are small in size, under the U.S. Small Business Administration's (SBA) standards. This assumption is based on composite data for providers of the same and similar services in the United States. In 2002, there were 296 U.S. establishments in North American Industry Classification System (NAICS) subsector 325414, a classification comprised of establishments primarily engaged in manufacturing vaccines, toxoids, blood fractions, and culture media of plant or animal origin (except diagnostic). Of the 296 establishments, 285 (or 96 percent) had fewer than 500 employees, the SBA's small entity threshold for establishments in that NAICS category. Similarly, in 2002, there were 236 U.S. establishments in NAICS 325413, a classification comprised of establishments primarily engaged in manufacturing in-vitro diagnostic substances, including biological substances. Of the 236 establishments, 223 (or 95 percent) had fewer than 500 employees, the SBA's small entity threshold for establishments in NAICS 325413.

Alternatives

Alternatives to the proposed rule would be to either leave the regulations unchanged, or to require a different set

of criteria than is proposed. Leaving the regulations unchanged would be unsatisfactory, because it would perpetuate the current situation, *i.e.*, one that may not allow APHIS to take expeditious action to limit the harm to animals caused by harmful or dangerous veterinary biologics. The current regulations have resulted in licensees and permittees using non-standardized methods to record and submit reports regarding adverse events to APHIS. In addition, adverse event reports that may signal problems concerning the use of veterinary biological products are not all being submitted to APHIS in a timely manner. Without complete information and timely reports, APHIS may not be able to take prompt action to limit the harm to animals posed by unsatisfactory veterinary biologics.

APHIS considers the proposed set of criteria to be the minimum necessary to accomplish the rule's objectives. The submission of reports to APHIS at longer than 12-month intervals was considered but rejected; we believe that longer reporting intervals would not ensure that we have adequate data to support a decision to take regulatory action against products that are associated with an unusual number of adverse event reports.

Costs and Benefits

The proposed rule has the potential to benefit animals and their owners, to the extent that it allows APHIS to act quickly to limit the harm to animals posed by unsatisfactory veterinary biologics. For animal owners, the monetary benefits are difficult to estimate, because they would depend on several factors that are currently unknown—the significance, or gravity, of the harm that would be avoided with the rule in effect, and the number, and value, of animals that would avoid harm with the rule in effect. For some animal owners, especially those with large numbers of high-value animals, the potential monetary benefits of avoided harm could be large. For the reasons discussed above, manufacturer costs to comply with the rule should be minimal in most cases. Thus, we expect that the benefits of this proposed action would outweigh its costs.

Under these circumstances, the Administrator of the Animal and Plant Health Inspection Service has determined that this action would not have a significant economic impact on a substantial number of small entities.

Executive Order 12372

This program/activity is listed in the category of Federal Domestic Assistance under No. 10.025 and is subject to Executive Order 12372, which requires intergovernmental consultation with State and local officials. (See 7 CFR part 3015, subpart V.)

Executive Order 12988

This proposed rule has been reviewed under Executive Order 12988, Civil Justice Reform. It is not intended to have retroactive effect. This rule would not preempt any State or local laws, regulations, or policies unless they present an irreconcilable conflict with this rule. The Virus-Serum-Toxin Act does not provide administrative procedures which must be exhausted prior to a judicial challenge to the provisions of this rule.

Paperwork Reduction Act

In accordance with section 3507(d) of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the information collection or recordkeeping requirements included in this proposed rule have been submitted for approval to the Office of Management and Budget (OMB). The information collection and recordkeeping requirements described in the January 2002 proposed rule withdrawn by this document were approved by OMB under control number 0579–0209, and we will request that OMB approve the information collection or recordkeeping requirements included in this proposed rule under that same number. Please send written comments to the Office of Information and Regulatory Affairs, OMB, Attention: Desk Officer for APHIS, Washington, DC 20503. Please state that your comments refer to Docket No. 00–071–2. Please send a copy of your comments to: (1) Docket No. 00–071–2, Regulatory Analysis and Development, PPD, APHIS, Suite 3C03, 4700 River Road Unit 118, Riverdale, MD 20737–1238, and (2) Clearance Officer, OCIO, USDA, room 404–W, 14th Street and Independence Avenue SW., Washington, DC 20250. A comment to OMB is best assured of having its full effect if OMB receives it within 30 days of publication of this proposed rule.

This proposed rule would require manufacturers of veterinary biological products to maintain records of adverse event reports that they receive concerning the use of veterinary biological products that they produce or distribute for 2 years. In addition, licensees and permittees would have to submit summary reports of adverse events to APHIS every 12 months for products licensed for 1 year or more; for newly licensed products, a summary report would have to be submitted at 6-month intervals during the first year of the product license and at 12-month intervals thereafter. These information collection and recordkeeping requirements would allow us to monitor and provide the appropriate level of regulatory oversight.

We are soliciting comments from the public (as well as affected agencies) concerning our proposed information collection and recordkeeping requirements. These comments will help us:

(1) Evaluate whether the proposed information collection is necessary for the proper performance of our agency's functions, including whether the information will have practical utility;

(2) Evaluate the accuracy of our estimate of the burden of the proposed information collection, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the information collection on those who are to respond (such as through the use of appropriate automated, electronic, mechanical or other technological collection techniques or other forms of information technology, *e.g.*, permitting electronic submission of responses).

Estimate of burden: The public reporting burden for this collection of information is estimated to average 0.5 hour per response.

Respondents: Veterinary biologics licensees and permittees.

Estimated annual number of respondents: 125.

Estimated annual number of responses per respondent: 4.

Estimated annual number of responses: 1,000.

Estimated total annual burden on respondents: 500 hours. (Due to averaging, the total annual burden hours may not equal the product of the annual number of responses multiplied by the reporting burden per response.)

Copies of this information collection can be obtained from Mrs. Celeste Sickles, APHIS' Information Collection Coordinator, at (301) 734–7477.

Government Paperwork Elimination Act Compliance

The Animal and Plant Health Inspection Service is committed to compliance with the Government Paperwork Elimination Act (GPEA), which requires Government agencies in general to provide the public the option of submitting information or transacting business electronically to the maximum extent possible. For information pertinent to GPEA compliance related to this proposed rule, please contact Mrs.

Celeste Sickles, APHIS' Information Collection Coordinator, at (301) 734–7477.

List of Subjects

9 CFR Part 101

Animal biologics.

9 CFR Part 116

Animal biologics, Reporting and recordkeeping requirements.

Accordingly, we propose to amend 9 CFR parts 101 and 116 as follows:

PART 101—DEFINITIONS

1. The authority citation for part 101 would continue to read as follows:

Authority: 21 U.S.C. 151–159; 7 CFR 2.22, 2.80, and 371.4.

2. In § 101.2, definitions of *adverse event* and *adverse event report* would be added in alphabetical order to read as follows:

§ 101.2 Administrative terminology.

* * * * *

Adverse event. Any observation in animals, whether or not the cause of the event is known, that is unfavorable and unintended and that occurs after any use (off label or on label) of a biological product. Included are events related to a suspected lack of expected efficacy. For products intended to diagnose disease, adverse events refer to anything that hinders discovery of the correct diagnosis.

Adverse event report. Any communication concerning the occurrence of an adverse event from an identifiable first-hand reporter which includes at least the following information:

(1) An identifiable reporter;

(2) An identifiable animal;

(3) An identifiable biological product; and

(4) One or more adverse events.

* * * * *

PART 116—RECORDS AND REPORTS

3. The authority citation for part 116 would continue to read as follows:

Authority: 21 U.S.C. 151–159; 7 CFR 2.22, 2.80, and 371.4.

4. In § 116.1, paragraph (a)(3) would be revised to read as follows:

§ 116.1 Applicability and general considerations.

(a) * * *

(3) Records (other than disposition records and adverse event records) required by this part must be completed by the licensee, permittee, or foreign manufacturer, as the case may be, before any portion of a serial of any product may be marketed in the United States or exported.

* * * * *

5. Section 116.8 would be revised to read as follows:

§ 116.8 Completion and retention of records.

All records (other than disposition records and adverse event records) required by this part must be completed by the licensee, permittee, or foreign manufacturer before any portion of a serial of any product may be marketed in the United States or exported. All records must be retained at the licensed or foreign establishment or permittee's place of business for a period of 2 years after the expiration date of a product or longer as may be required by the Administrator. (Approved by the Office of Management and Budget under control number 0579–0013)

6. A new § 116.9 would be added to read as follows:

§ 116.9 Adverse event report records and summary reports.

(a) A detailed record must be maintained for every adverse event report the licensee or permittee receives for any biological product it produces or distributes. Each record must include:

(1) The date of the report;

(2) The identification of the person initiating the report;

(3) The product code number as it appears on the product license or permit, and product trade name;

(4) The serial number(s) of the product, if available;

(5) A description of the adverse event;

(6) A description of the animal(s) involved, including the number dead, number affected, number exposed to the product, species, breed, age, sex, and physiological status;

(7) The opinion (probable, possible, unknown, unlikely, no assessment) of the person initiating the report as to whether the event is product-related;

(8) The route and site of vaccination for products administered parenterally;

(9) The identity of the person administering the product (veterinarian, animal owner, other, unknown);

(10) The date of the event; and

(11) The outcome of the event (recovered, death, euthanized, alive with side effects, ongoing event).

(b) A summary report of all adverse event reports received by a licensee or permittee must be compiled and submitted to the Animal and Plant Health Inspection Service. For products licensed for 1 year or more, such summary reports must cover intervals of 12 months; for products licensed for less than 1 year, the summary reports must be submitted at 6-month intervals. All summary reports must be received within 60 days after the end of the reporting date that will be determined by the licensee or permittee and approved by the Animal and Plant Health Inspection Service. Each summary report must include:

(1) The name, address, and U.S. Veterinary License or Permit number of the producer, permittee, or foreign manufacturer;

(2) Copies of any individual adverse event reports for the product maintained as prescribed in paragraph (a) of this section; and

(3) The number of doses, or the average number of doses, of the product in distribution channels, if available.

Done in Washington, DC, this 11th day of August 2005.

Bill Hawks,

Under Secretary for Marketing and Regulatory Programs.

[FR Doc. 05–16266 Filed 8–16–05; 8:45 am]

BILLING CODE 3410–34–P

NUCLEAR REGULATORY COMMISSION

10 CFR Part 51

[Docket No. PRM–51–8]

State of Nevada; Denial of a Petition for Rulemaking

AGENCY: Nuclear Regulatory Commission.

ACTION: Petition for rulemaking: denial.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC or Commission) is denying a petition for rulemaking submitted by the State of Nevada (PRM–51–8). The petitioner requests that NRC amend a decision reached in a 1990 rulemaking, referred to as the ''Waste Confidence'' decision, that at least one mined geologic repository will be available within the first quarter of the twenty-first century as well as a regulation making a generic determination of no significant environmental impact from the temporary storage of spent fuel after cessation of reactor operation which incorporates this decision. Petitioner believes that the decision and rule must be amended to avoid ''prejudging'' the outcome of the anticipated licensing proceeding on a potential application from the Department of Energy for a construction authorization for a geologic repository at the Yucca Mountain, Nevada site. The NRC is denying the petition because the petition