

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

fundamentally misconstrues the decision NRC reached in 1990 and because the information provided in the petition does not meet the criteria NRC set in 1999 for reopening the Waste Confidence findings. Further, the Commission's commitment to a fair and comprehensive adjudication on a potential license application for Yucca Mountain is not jeopardized by the 2025 date for repository availability. Under these circumstances, the Commission finds no reason to undertake the burden of reopening the Waste Confidence decision.

**ADDRESSES:** Copies of the petition for rulemaking and the NRC's letter to the petitioner are available for public inspection or copying in the NRC Public Document Room, 11555 Rockville Pike, Room 01-F21, Rockville, Maryland.

**FOR FURTHER INFORMATION CONTACT:** Keith I. McConnell, Office of the General Counsel, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, telephone (301) 415-1743, e-mail: [kim@nrc.gov](mailto:kim@nrc.gov); or E. Neil Jensen, Office of the General Counsel, U.S. Nuclear Regulatory Commission, Washington, DC 20555-00001, telephone (301) 415-1537, e-mail: [enj@nrc.gov](mailto:enj@nrc.gov).

#### SUPPLEMENTARY INFORMATION:

##### Introduction

On March 1, 2005, the State of Nevada (Petitioner or the State) submitted a "State of Nevada Petition for Rulemaking to Amend the Commission's Waste Confidence Decision and Rule to Avoid Prejudging Yucca Mountain" (Petition) which was docketed as a petition for rulemaking under 10 CFR 2.802 of the Commission's regulations (PRM-51-8). Petitioner asserts that the NRC must amend a decision reached in a 1990 rulemaking, termed the "Waste Confidence" decision,<sup>1</sup> that "at least one mined geologic repository will be available within the first quarter of the twenty-first century" as well as a regulation, 10 CFR 51.23(a), which incorporates this decision.<sup>2</sup> 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 (DOE) for a construction authorization for a geologic repository at the Yucca

Mountain, Nevada site (Yucca Mountain).

The Commission sees no need to revisit its Waste Confidence decision at this time. We have carefully considered the State's assertions that changed circumstances warrant reopening of its Waste Confidence findings but, for the reasons described in this decision, we remain unconvinced that there is any present need to resurrect Waste Confidence issues.<sup>3</sup>

##### Background

To provide context for the petition, some background information on the Commission's Waste Confidence proceedings is useful. In 1984, the Commission concluded a generic rulemaking proceeding, which has become known as the "Waste Confidence Rulemaking," designed to assess its degree of confidence that radioactive wastes produced by nuclear facilities could be safely disposed of, to determine when any such disposal would be available, and whether such wastes could be safely stored until safe disposal was available.<sup>4</sup> The 1984 rulemaking proceeding enabled the Commission to make the following five findings:

- (1) that there is reasonable assurance that safe disposal of high-level radioactive waste (HLW) and spent nuclear fuel (SNF) in a mined geologic repository is technically feasible;
- (2) that there is reasonable assurance that one or more mined geologic repositories for commercial HLW and SNF will be available by the years 2007-2009, and that sufficient repository capacity will be available within 30 years beyond expiration of any reactor operating license to dispose of existing commercial HLW and SNF originating in such reactor and generated up to that time;
- (3) that there is reasonable assurance that HLW and SNF will be managed in a safe manner until sufficient repository capacity is available to assure the safe disposal of all HLW and SNF;
- (4) that there is reasonable assurance that, if necessary, spent fuel generated in any reactor can be stored safely and without significant environmental

<sup>3</sup> The NRC did not seek public comment on the instant petition. In this case, the NRC viewed Nevada's petition as involving a straightforward application of the Commission's threshold criterion ("significant and pertinent unexpected events occur, raising substantial doubt about the continuing validity of the 1990 Waste Confidence finding" 64 FR 68005; December 6, 1999) for considering a comprehensive reopening of the 1990 Waste Confidence decision, and did not see a need for public comment on such application.

<sup>4</sup> See "Waste Confidence Decision," 49 FR 34658; August 31, 1984.

impacts for at least 30 years beyond the expiration of that reactor's operating licenses at that reactor's spent fuel storage basin, or at either onsite or offsite independent spent fuel storage installations (ISFSIs); and

(5) that there is reasonable assurance that safe independent onsite or offsite spent fuel storage will be made available if such storage capacity is needed.

49 FR 34659-34960. The Commission incorporated the second and fourth findings into a new regulation at 10 CFR 51.23 which, among other things, established a generic determination of no significant environmental impact from the temporary storage of spent fuel after the cessation of reactor operation and which also found reasonable assurance that one or more mined geologic repositories for commercial HLW and SNF would be available by the years 2007-2009.<sup>5</sup> The Commission also committed to reviewing its Waste Confidence findings should significant and pertinent unexpected events occur or at 5-year intervals until a repository was available. 49 FR 34660.

In 1989-1990, the Commission conducted a second Waste Confidence proceeding to review its 1984 findings. As a result, the Commission decided to modify findings two and four as follows:

- (2) the Commission finds reasonable assurance that at least one mined geologic repository will be available within the first quarter of the twenty-first century, and that sufficient repository capacity will be available within 30 years beyond the licensed life for operation (which may include the term of a revised or renewed license) of any reactor to dispose of the commercial HLW and SNF originating in such reactor and generated up to that time;
- (4) the Commission finds reasonable assurance that, if necessary, spent fuel generated in any reactor can be stored safely and without significant environmental impacts for at least 30 years beyond the licensed life for operation (which may include the term of a revised or renewed license) of that reactor at its spent fuel storage basin, or at either onsite or offsite ISFSIs.

55 FR 38474 (emphasis added). Thus, the Commission, in 1990, decided to extend the time-frame of its assurance of the availability of a repository from the 2007-2009 period to 2025, and also expanded on the minimal amount of time for which it had confidence that SNF could be safely stored. Further, "believ[ing] that predictions of

<sup>5</sup> See "Requirements for Licensee Actions Regarding the Disposition of Spent Fuel Upon Expiration of Reactor Operating Licenses," 49 FR 34688, 34694; August 31, 1984.

<sup>1</sup> See "Waste Confidence Decision Review," 55 FR 38474; September 18, 1990.

<sup>2</sup> See "Consideration of Environmental Impacts of Temporary Storage of Spent Fuel After Cessation of Reactor Operation," 55 FR 38472; September 18, 1990.

repository availability are best expressed in terms of decades rather than years," the Commission decided to change its review period to 10 years or "whenever significant and pertinent unexpected changes occur [ , e.g. ] such events as a major shift in national policy, a major unexpected institutional development, and/or new technical information \* \* \* ." 55 FR 38475.

In 1999, as the 10 year review period approached, the Commission considered the need for a further Waste Confidence review in the context of events that had occurred since 1990. 64 FR 68005; December 6, 1999. These considerations "confirm[ed] and strengthen[ed] the Commission's 1990 findings and le[d] the Commission to conclude that no significant and unexpected events ha[d] occurred—no major shifts in national policy, no major unexpected institutional developments, no unexpected technical information—that would cast doubt on the Commission's Waste Confidence findings or warrant a detailed reevaluation \* \* \* ." 64 FR 68007. For that reason, the Commission determined not to conduct another Waste Confidence review at that time but did state that "the Commission would consider undertaking a comprehensive reevaluation of the Waste Confidence findings when the impending repository development and regulatory activities run their course or if significant and pertinent unexpected events occur, raising substantial doubt about the continuing validity of the Waste Confidence findings." *Id.*

#### The Petition

The State's petition focuses on the second Waste Confidence finding and, in particular, on that aspect of the finding that there is reasonable assurance that a repository will be available by 2025. The petitioner believes that this finding must be revised because it is now evident that a repository can only be available by this date if NRC grants DOE's anticipated application for a license at the Yucca Mountain site at the completion of the adjudicatory proceeding because it would be too late, if NRC were to deny the license application, for DOE to have a repository available at a different site by this date. Petition at 2–3. This situation, in petitioner's view, impermissibly amounts to prejudging the result of the Yucca Mountain licensing proceeding. *Id.*

In support of its position, petitioner reviews the 1990 Waste Confidence decision and concludes that it relies on three "critical determinations" which petitioner describes as follows:

(1) The acceptability of the Yucca Mountain site should not be presumed, for to do so would prejudice the outcome of the NRC's licensing review and proceeding;

(2) Notwithstanding the twenty-five year lead time required, a second repository site will be available if necessary by the year 2025 because a final decision on the acceptability of the Yucca Mountain site will surely be made by the year 2000, leaving sufficient time (twenty five years) to develop another repository if Yucca Mountain fails; and (3) spent fuel can be stored safely and in an environmentally sound manner until either Yucca Mountain or a second repository becomes available beginning in the year 2025.

Petition at 7. Petitioner says that the second "critical determination" has proved to be incorrect, thus requiring the Commission to revise its second Waste Confidence finding.

In its 1990 Waste Confidence decision, the Commission concluded that SNF can be safely stored without significant environmental impact for at least 100 years, if necessary. 55 FR 38513 (1990). Petitioner cites recent documents and events which have corroborated and even extended this conclusion such as DOE's Final Environmental Impact Statement for Yucca Mountain and the increased licensing of independent spent fuel storage installations. Petition at 11–13. Petitioner concludes that these developments support extending the second part of the second Waste Confidence finding (that sufficient repository capacity will be available within 30 years beyond the licensed life for operation (which may include the term of a revised or renewed license) of any reactor to dispose of the commercial HLW and SNF originating in such reactor and generated up to that time) to a longer or even indefinite period. Petition at 13. Thus, petitioner proposes that the regulation which encapsulates the second Waste Confidence finding, 10 CFR 51.23(a), be amended to provide:

The Commission has made a generic determination that there is reasonable assurance all licensed reactor spent fuel will be removed from storage sites to some acceptable disposal site well before storage causes any significant safety or environmental impacts.

This generic finding does not apply to a reactor or storage site if the Commission has found, in the 10 CFR part 50, part 52, part 54 or part 72 specific licensing proceeding, that storage of spent fuel during the term requested in the license application will

cause significant safety or environmental impacts.

Petition at 14.

#### Reasons for Denial

In 1999, the Commission stated that it would consider undertaking a comprehensive reevaluation of the Waste Confidence findings if either of two criteria were met: (1) "When the impending repository development and regulatory activities run their course;" or (2) "if significant and pertinent unexpected events occur, raising substantial doubt about the continuing validity of the Waste Confidence findings." 64 FR 68007. Petitioner states that it is not asking NRC to reopen its general finding that one or more safe geologic repositories can be made available on a timely basis. Petition at 7. Nevertheless, because the findings are interrelated, reopening the Waste Confidence inquiry, even if somehow limited in this manner, could be expected to become a large endeavor covering most of the questions considered in the 1990 findings; e.g., multiple questions concerning the timeliness of repository availability and conditions for the extended safe storage of SNF. In 1999, the Commission was reluctant to expend agency resources on such a far-reaching endeavor absent developments which might cast doubt on the Commission's findings. Barring developments or information meeting the 1999 criteria, the Commission remains unwilling to initiate a reevaluation, even a severely limited one assuming that would be possible, because that would not be a prudent use of the agency's limited resources. As noted below, the Commission does not believe that petitioner has demonstrated that significant and pertinent unexpected events have occurred, meeting the Commission's reopening criteria.

Petitioner seeks to meet the second prong of these criteria by arguing that two pieces of information constitute the "significant and pertinent unexpected events" which should trigger the Waste Confidence review process. First, petitioner asserts that NRC's determination that a repository would be available by 2025 was based on the "express finding" that the "acceptability" of Yucca Mountain as a geologic repository would be decided by the year 2000, but that "we now know that the acceptability of Yucca Mountain will not be decided before 2010 at the earliest (completion of the construction authorization stage)." Petition at 7–8. Second, petitioner asserts that the availability of a repository by 2025 assumed a 25-year

period would be needed between a possible finding of unacceptability of the Yucca Mountain site in 2000 and the availability of a repository at a different site, but we “now know that if Yucca Mountain fails on or about the year 2010, fifteen years \* \* \* will not nearly be sufficient time to accomplish all of the steps needed to make another repository actually available.” Petition at 8–10.

First, we consider petitioner's assertion that the Commission's 1990 determination that a repository would be available by 2025 was based on an “express finding” that the acceptability of Yucca Mountain as a geologic repository would be decided by the year 2000. The Commission made no such finding, express or otherwise. What the Commission did state in the 1990 decision was that “NRC continues to believe that if DOE determines that the Yucca Mountain site is unsuitable, it will make this determination by about the year 2000.” 55 FR 38477 (emphasis added). There is a significant difference, in the Waste Confidence decision, between the concept of the “suitability” of Yucca Mountain and the concept of the “acceptability” of Yucca Mountain.

“Suitability” refers to the decision the Secretary of Energy must make, on the basis of site characterization activities and other factors, that a particular site is suitable for submission of an application for a construction authorization for a repository. See section 113 of the Nuclear Waste Policy Act of 1982, as amended (NWPAA), 42 U.S.C. 10133. Upon finding a particular site to be suitable, the Secretary is required to make a recommendation to the President that the President approve the recommended site for the development of a repository. See section 114 of NWPAA, 42 U.S.C. 10134.<sup>6</sup>

“Acceptability” refers to the decisions NRC must make concerning the licenseability of the site. There are three NRC decision points on a determination of the acceptability (or license-ability) of Yucca Mountain: the first will be the decision of the NRC staff in the licensing proceeding on whether to

recommend approval of the license application; the second will be when the Commission, acting in its adjudicatory capacity, determines whether to issue a construction authorization for the repository, see 10 CFR 63.31; and the third will be when the Commission determines whether to issue a license for the receipt and possession of high-level waste, see 10 CFR 63.41. But, to be clear, these considerations as to a site's “acceptability” were not the basis for deciding on the 2025 date.

It is important to examine what NRC actually said in the 1990 Waste Confidence decision with respect to its revision of the second finding because petitioner confuses the concepts of “suitability” and “acceptability” and fundamentally misperceives the second finding. The Nuclear Waste Policy Amendments Act of 1987 (NWPAA) had limited DOE's site characterization activities to the Yucca Mountain site. In the Commission's view, “the possible scheduler benefits to single-site characterization \* \* \* must be weighed for the purposes of this Finding against the potential for additional delays in repository availability if the Yucca Mountain site is found to be unsuitable [because by focusing DOE site characterization activities on Yucca Mountain, the NWPAA ha[d] essentially made it necessary for that site to be found suitable if the 2007–2009 timeframe for repository availability in the Commission's 1984 decision is to be met” (emphasis added). 55 FR 38494. This was because DOE had estimated conservatively that “it would require approximately 25 years to begin site screening for a second repository, perform site characterization, submit an EIS and license applications, and await authorizations before the repository could be ready to receive waste.” *Id.* Obviously, any DOE finding of unsuitability made after 1990 would not allow an alternative repository site to be available in the 2007–2009 timeframe if 25 years were to be required for this purpose. Moreover, in addition to reliance on a single site, other factors raised doubts that a repository would be available in that time period: the probability that site characterization activities would not proceed entirely without problems; the history of DOE's scheduler slippages; and DOE's own then-current schedule calling for submittal of a license application in 2001 and for repository availability in 2010. *Id.*

In light of these considerations, it no longer seemed prudent to the Commission in 1990 to reaffirm NRC's 1984 finding of reasonable assurance

that the 2007–2009 timetable would be met. Instead, the Commission decided to take DOE's estimate of the time it would take to make another repository available if Yucca Mountain were to be found unsuitable (25 years) and then, for the sake of conservatism, make the assumption that Yucca Mountain would not be found suitable. The Commission thought it “reasonable to expect that DOE would be able to reach this conclusion by the year 2000 [which] would leave 25 years for the attainment of repository operations at another site.” 55 FR 38495. Thus, the “express finding” that the Commission made in 1990 was that the suitability (not the acceptability) of Yucca Mountain would be decided by the year 2000, leaving 25 years for the availability of a different repository if DOE found Yucca Mountain to be unsuitable.

That DOE in fact found the Yucca Mountain site to be suitable—in early 2002—buttresses the 1990 finding of reasonable assurance that a repository will be available in 2025, within the meaning of our 1990 Waste Confidence decision. That decision rested on a DOE suitability determination by “about” 2000. See 55 FR 38477. DOE made such a determination in early 2002, and thus substantially met our expectation.

Given what the Commission actually said in its 1990 Waste Confidence finding, it is easy to see that the significant new information regarding the timing of a repository proffered by petitioner; *i.e.*, that the acceptability (defined in the petition as completion of the construction authorization stage) of Yucca Mountain will not be decided before 2010 at the earliest and that if Yucca Mountain is found to be unacceptable around the year 2010, 15 years will not be sufficient time for DOE to make another repository available, petition at 8, is not the type of information that would meet the Commission's criteria for reopening. The Commission did not speculate in 1990 as to a date by which it might make a decision on construction authorization; its finding was based solely on its estimate of when DOE might make a suitability determination.

The petition assumes that the NRC, in 1990, abandoned its expectation that a repository would become available in the 2007–2009 time frame and selected a new date, 2025, out of a concern that the continued use of the 2007–2009 period for repository availability would “prejudge” its construction authorization decision. Petition at 10. This, too, is an error.

“Availability,” as used in the 1990 decision, begins with a DOE projection of when a repository is targeted for

<sup>6</sup> On February 14, 2002, the Secretary of Energy recommended the Yucca Mountain site for the development of a repository to the President, thereby setting in motion the approval process set forth in sections 114 and 115 of the NWPAA. See 42 U.S.C. 10134(a)(1); 10134(a)(2); 10135(b), 10136(b)(2). On February 15, 2002, the President recommended the site to Congress. On April 8, 2002, the State of Nevada submitted a notice of disapproval of the site recommendation to which Congress responded, on July 9, 2002, by passing a joint resolution approving the development of a repository at Yucca Mountain which the President signed on July 23, 2002. See Pub. L. No. 107–200, 116 Stat. 735 (2002) (codified at 42 U.S.C. 10135 note (Supp. IV 2004)).

availability based on DOE's estimates of the timing of the suitability determination. 55 FR 38494. These DOE projections were used by the Commission as a starting point for determining "availability." But, because of DOE's need to focus exclusively on Yucca Mountain, the probability that site characterization activities would not proceed entirely without problems, and the chronic delays in the program, the Commission was unwilling to accept DOE's then current projection of repository availability in 2010. Instead, the Commission chose to take a "conservative" approach to the timing of "availability" by setting a conservative upper bound of 2025. See 55 FR 38494, 38595 and 38500. This would allow for DOE's estimate of a 25-year time period needed for the availability of a repository at an alternative site if DOE found the Yucca Mountain site to be unsuitable and had to start over from scratch.

If in 1990 the Commission had been thinking in terms of 25 years being needed for an alternate repository site following an adverse Commission finding of acceptability, obviously it could not have chosen 2025 as the date for which it had reasonable confidence that a repository would be available. DOE's submission of a license application was at that time scheduled to be in 2001, meaning that any Commission rejection of the license could not have been the basis for computing the 25 years needed for evaluation of an alternative site. In fact, the use of a Commission acceptability finding as the basis for repository availability is impossible to implement because it would require the Commission to prejudge the acceptability of any alternative to Yucca Mountain in order to establish a reasonably supported outer date for the Waste Confidence finding. That is, if the Commission were to assume that a license for the Yucca Mountain site might be denied in 2015 and establish a date 25 years hence for the "availability" of an alternative repository (i.e., 2040), it would still need to presume the "acceptability" of the alternate site to meet that date.

Because it was untenable to presume the "acceptability" of any site, including Yucca Mountain, the Commission, in 1990, chose instead to take a two pronged approach to determining "availability." First, it would use DOE's statutorily mandated suitability determination as a basis for providing assurance that a repository would be available in 2025. Specifically, the Commission stated that it believed that DOE's site suitability determination

process should provide a " \* \* \* strong basis for evaluating the likelihood of meeting the 2025 estimate of repository availability." 55 FR 38495. Second, the Commission allowed for reconsideration of its findings pending significant and unexpected events. Certainly, the denial of a license for the Yucca Mountain site would meet these criteria and the Commission would need to reevaluate its findings at that time.

The State would recast the approach the Commission took to defining "availability" by presuming that "some acceptable disposal site" would be available at some undefined time in the future. We find this approach inconsistent with that taken in the 1984 Waste Confidence Decision because it provides neither the basis for assessing the degree of assurance that radioactive waste can be disposed of safely nor the basis for determining when such disposal will be available.

In sum, petitioner has not submitted any information establishing that significant and pertinent unexpected events have occurred which raise substantial doubt about the continuing validity of the second Waste Confidence finding and, in particular, that reasonable assurance exists that at least one mined geologic repository will be available by 2025. Even if DOE's estimate as to when it will tender a license application should slip further, the 2025 date would still allow for unforeseen delays in characterization and licensing. It also must be recognized that the Commission remains committed to a fair and comprehensive adjudication and, as a result, there is the potential for the Commission to deny a license for the Yucca Mountain site based on the record established in the adjudicatory proceeding. That commitment is not jeopardized by the 2025 date for repository availability. The Commission did not see any threat to its ability to be an impartial adjudicator in 1990 when it selected the 2025 date even though then, as now, a repository could only become available if the Commission's decision is favorable. Should the Commission's decision be unfavorable and should DOE abandon the site, the Commission would need to reevaluate the 2025 availability date, as well as other findings made in 1990. However, that day has not yet come and until it does the Commission finds no reason to undertake the burden of reopening its Waste Confidence findings in the absence of information meeting the criteria it has established for this purpose.

## Conclusion

Petitioner misapprehends the Commission's 1990 Waste Confidence findings and has not shown any significant and pertinent unexpected event that raises substantial doubt about the continuing validity of the 1990 Waste Confidence findings. Accordingly, for the reasons stated above, the NRC denies the petition for rulemaking to amend the Commission's Waste Confidence decision in its entirety.

Dated at Rockville, Maryland, this 10th day of August, 2005.

For the Nuclear Regulatory Commission.

Andrew L. Bates,

Acting Secretary of the Commission.

[FR Doc. 05-16253 Filed 8-16-05; 8:45 am]

BILLING CODE 7590-01-P

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## DEPARTMENT OF TRANSPORTATION

### Federal Aviation Administration

#### 14 CFR Part 39

[Docket No. FAA-2005-21787; Directorate Identifier 2005-CE-34-AD]

RIN 2120-AA64

#### Airworthiness Directives; Shadin ADC-2000 Air Data Computers

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

**SUMMARY:** The FAA proposes to adopt a new airworthiness directive (AD) for certain Shadin ADC-2000 air data computers (ADC) installed on airplanes. This proposed AD would require you to replace affected ADC-2000 units with a modified unit. This proposed AD results from reports that certain ADC-2000 units display incorrect altitude information on the Electronic Flight Information System (EFIS) to the pilot. We are issuing this proposed AD to prevent ADC-2000 units, part numbers (P/Ns) 962830A-1-S-8, 962830A-2-S-8, and 962830A-3-S-8, configurations B, C, and D, from displaying incorrect altitude information. This could cause the flight crew to react to this incorrect flight information and possibly result in an unsafe operating condition.

**DATES:** We must receive any comments on this proposed AD by October 11, 2005.

**ADDRESSES:** Use one of the following to submit comments on this proposed AD:

- DOT Docket Web Site: Go to <http://dms.dot.gov> and follow the instructions

CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the foregoing Underlying Decision, 70 Fed. Reg. 48,329 to 48,333, was served this 6th day of October, 2005 via U.S. First Class Mail, on the following individuals:

Annette L. Vietti-Cook  
Secretary of the Commission  
U.S. Nuclear Regulatory  
Commission  
One White Flint North  
11555 Rockville Pike  
Room 16 H3, Mail Stop 016-C1  
Rockville, MD 20852-2738

Karen D. Cyr, Esq.  
General Counsel  
U.S. Nuclear Regulatory  
Commission  
One White Flint North  
11555 Rockville Pike  
Mail Stop 015-D21  
Rockville, MD 20852-2738

The Hon. Alberto R. Gonzales  
Attorney General of the  
United States  
U.S. Department of Justice  
950 Pennsylvania Avenue, N.W.  
Washington, D.C. 20530-0001

Kenneth L. Wainstein  
United States Attorney  
U.S. Attorney's Office  
District of Columbia  
Judiciary Center Building  
555 Fourth Street, N.W.  
Washington, D.C. 20530

  
Nakita Toliver