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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.

NUCLEAR REGULATORY COMMISSION

10 CFR Part 50

[Docket Nos. PRM-50-93 and PRM-50-95; NRC-2009-0554]

Calculated Maximum Fuel Element Cladding Temperature

AGENCY: Nuclear Regulatory Commission.

ACTION: Petitions for rulemaking; denial.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is denying two related petitions for rulemaking (PRMs), PRM-50-93 and PRM-50-95, submitted by Mark Edward Leyse. The petitioner requested that the NRC amend its regulations for the domestic licensing of production and utilization facilities. The petitioner asserted that data from multirod (assembly) severe fuel damage experiments indicate that specific aspects of the NRC's regulations on emergency core cooling systems acceptance criteria and evaluation models are not conservative and that additional regulations are necessary. The NRC is denying these petitions because existing NRC regulations provide reasonable assurance of adequate protection of public health and safety. The petitioner did not present sufficient new information or arguments to support the requested changes.

DATES: The dockets for the petitions for rulemaking, PRM-50-93 and PRM-50-95, are closed on January 7, 2021.

ADDRESSES: Please refer to Docket ID NRC-2009-0554 when contacting the NRC about the availability of information for this action. You may obtain publicly-available information related to this action by any of the following methods:

- *Federal Rulemaking Website:* Go to <https://www.regulations.gov> and search for Docket ID NRC-2009-0554. Address questions about NRC dockets to Dawn Forder; telephone: 301-415-3407; email: Dawn.Forder@nrc.gov. For technical questions, contact the

individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.

- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly-available documents online in the ADAMS Public Documents collection at <https://www.nrc.gov/reading-rm/adams.html>. To begin the search, select "ADAMS Public Documents" and then select "Begin Web-based ADAMS Search." For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1-800-397-4209, 301-415-4737, or by email to pdr.resource@nrc.gov. For the convenience of the reader, instructions about obtaining materials referenced in this document are provided in Section IV, "Availability of Documents."

- *Attention:* The PDR, where you may examine and order copies of public documents, is currently closed. You may submit your request to the PDR via email at pdr.resource@nrc.gov or call 1-800-397-4209 between 8:00 a.m. and 4:00 p.m. (EST), Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION:

- I. Background and Summary of the Petitions
- II. Public Comments on the Petitions
- III. NRC Technical Evaluation and Reasons for Denial
- IV. Availability of Documents
- V. Conclusion

I. Background and Summary of the Petitions

Section 2.802 of title 10 of the *Code of Federal Regulations* (10 CFR), "Petition for Rulemaking—Requirements for Filing," provides an opportunity for any interested person to petition the Commission to issue, amend, or rescind any regulation. On November 17, 2009, Mark Edward Leyse submitted a PRM under § 2.802. The NRC assigned docket number PRM-50-93 to this petition and published a notice of receipt and request for public comment in the **Federal Register** on January 25, 2010 (75 FR 3876).

The petitioner asserted that data from multirod (assembly) severe fuel damage experiments indicate that specific

aspects of the NRC's regulations and associated regulatory guidance on Emergency Core Cooling Systems (ECCS) acceptance criteria and evaluation models are not conservative and that additional regulations are necessary. Therefore, the petitioner requested that the NRC: (1) Amend its regulations to require that the calculated maximum fuel element cladding temperature not exceed a limit based on data from cited experiments; (2) amend its regulations and associated regulatory guidance to require that the rates of energy release, hydrogen generation, and Zircaloy cladding oxidation from the metal-water reaction of zirconium with steam considered in the evaluation models used to calculate ECCS cooling performance be based on data from cited experiments; and (3) issue a new regulation that requires minimum allowable core reflood rates in the event of a loss-of-coolant accident (LOCA).

On June 7, 2010, Mark Edward Leyse, on behalf of the New England Coalition, submitted a petition for enforcement action under § 2.206, "Requests for action under this subpart." The petitioner requested that the NRC order the Vermont Yankee Nuclear Power Station to lower its licensing basis peak cladding temperature to provide an adequate margin of safety in the event of a LOCA. The NRC staff concluded that this petition did not meet the criteria for review under § 2.206 because it identified generic issues that could require revisions to existing NRC regulations. Therefore, the NRC decided to review it as a PRM under § 2.802 and assigned it docket number PRM-50-95. Because PRM-50-93 and PRM-50-95 address similar issues, the NRC staff consolidated its review into a single activity. On October 27, 2010, the NRC published a notice of consolidation of PRM-50-93 and PRM-50-95 in the **Federal Register** (75 FR 66007) and requested public comment.

The NRC identified three main issues in the two petitions. The remaining paragraphs of Section I summarize the following information for each main issue: (1) Relevant background information; (2) arguments in the petitions; and (3) specific requests the petitioner made to address each issue.

Issue 1: Calculated Maximum Fuel Element Cladding Temperature Limit

Background for Issue 1

Under § 50.46, “Acceptance criteria for emergency core cooling systems for light-water nuclear power reactors,” of 10 CFR, light-water nuclear power reactors fueled with uranium oxide pellets within cylindrical Zircaloy cladding must be provided with an ECCS that must be designed so that its calculated cooling performance following postulated loss of coolant accidents (LOCAs)¹ conforms to the criteria specified in § 50.46(b).² Under § 50.46(b)(1), the calculated maximum fuel element cladding temperature shall not exceed 2,200 °F. In addition, § 50.46(b)(2) through (5), respectively, contain requirements for calculations involving: Maximum cladding oxidation, maximum hydrogen generation, changes in core geometry, and long-term cooling.

Petitioner’s Arguments and Requests Related to Issue 1

The petitioner asserted that data from multirod (assembly) severe fuel damage experiments indicate that the calculated maximum fuel element cladding temperature limit of 2,200 °F specified in § 50.46(b)(1) is not conservative. Although not its intended purpose, the NRC previously determined that this limit provides a conservative safety margin from an area of Zircaloy cladding oxidation behavior known as the autocatalytic regime. An autocatalytic condition occurs when the heat released by the metal-water reaction of zirconium with steam is greater than the heat that can be transferred away from the Zircaloy cladding. This causes the Zircaloy cladding temperature to rise, thereby increasing the diffusion of oxygen into the metal, which in turn raises the rate at which the zirconium-steam oxidation reaction occurs. As the metal-water reaction rate continues to increase, the temperature of the Zircaloy cladding continues to rise, eventually resulting in an uncontrolled reaction and

temperature excursion. The petitioner asserted that data from cited experiments indicate that such autocatalytic metal-water oxidation reactions and uncontrolled temperature excursions involving Zircaloy cladding have occurred at temperatures below 2,200 °F. The petitioner provided this assertion as evidence that the 2,200 °F limit is not conservative, and requested that the NRC amend § 50.46 to require that the calculated maximum fuel element cladding temperature not exceed a limit based on data from cited experiments, instead of the 2,200 °F limit specified in § 50.46(b)(1).

Issue 2: Metal-Water Reaction Rate Equations for ECCS Evaluation Models

Background for Issue 2

To evaluate conformance with the criteria specified in § 50.46(b), ECCS cooling performance must be calculated using an acceptable evaluation model³ for a range of postulated LOCAs of different sizes, locations, and other properties sufficient to provide assurance that the most severe postulated LOCAs are evaluated. On September 16, 1988, the NRC amended the requirements of § 50.46 and appendix K, “ECCS Evaluation Models,” to 10 CFR part 50 to reflect an improved understanding of ECCS performance during reactor transients that was obtained through extensive research performed after promulgation of the original requirements (53 FR 35996). Under § 50.46(a)(1), licensees or applicants may use one of two acceptable ECCS evaluation model options: (1) A best-estimate or realistic evaluation model⁴ or (2) a conservative evaluation model option is summarized below.

Option 1: Best-Estimate or Realistic ECCS Evaluation Model

Section 50.46(a)(1)(i) of 10 CFR specifies that a best-estimate evaluation model must include sufficient supporting justification to show that the analytical technique realistically describes the behavior of the reactor system during a LOCA. Comparisons to

applicable experimental data must be made and uncertainties must be identified and assessed so that the uncertainty in the calculated results can be estimated to (1) account for the uncertainty in comparing the calculated ECCS cooling performance to the criteria specified in § 50.46(b); and (2) assure that there is a high probability of not exceeding these criteria.

RG 1.157 describes models,⁵ correlations,⁶ data, model evaluation procedures, and methods that are acceptable to the NRC staff for meeting the requirements for: (1) A realistic or best-estimate calculation of ECCS cooling performance during a LOCA; (2) estimating the uncertainty in that calculation; and (3) including uncertainty in the comparisons of the calculated results to the criteria of § 50.46(b) to assure a high probability that the criteria would not be exceeded. Other models, data, model evaluation procedures, and methods can be considered if they are supported by appropriate experimental data and technical justification.

To be considered acceptable under RG 1.157, evaluation models should account for identified sources of heat—including the metal-water reaction rate—in performing best-estimate calculations. In particular, the rates of energy release, hydrogen generation, and Zircaloy cladding oxidation from the metal-water reaction of zirconium with steam should be calculated in a best-estimate manner using one of two procedures, depending on the cladding temperature:

(1) If the cladding temperature is less than or equal to 1,900 °F, correlations to be used to calculate metal-water reaction rates should: (a) Be checked against a set of relevant data and (b) recognize the effects of steam pressure, pre-oxidation of the cladding, deformation during oxidation, and internal oxidation from both steam and uranium oxide fuel.

(2) If the cladding temperature is greater than 1,900 °F, the Cathcart-Pawel equation and the underlying empirical data used to derive it are considered acceptable for calculating the rates of energy release, hydrogen generation, and cladding oxidation.

¹ Under § 50.46(c), LOCAs are hypothetical accidents that would result from the loss of reactor coolant, at a rate that exceeds the capability of the reactor coolant makeup system, from breaks in pipes in the reactor coolant pressure boundary.

² Criterion 35 of appendix A to 10 CFR part 50, “General Design Criteria for Nuclear Power Plants,” further requires that a system to provide abundant emergency core cooling shall be provided and that the system safety function shall be to transfer heat from the reactor core following any loss of reactor coolant at a rate such that: (1) Fuel and cladding damage that could interfere with continued effective core cooling is prevented and (2) the cladding metal-water reaction is limited to negligible amounts.

³ Regulatory Guide (RG) 1.157, “Best-Estimate Calculations of Emergency Core Cooling System Performance,” issued May 1989, states that “the term ‘evaluation model’ refers to a nuclear plant system computer code or any other analysis tool designed to predict the aggregate behavior of a reactor during a loss of coolant accident. It can be either best-estimate or conservative and may contain many correlations or models.”

⁴ RG 1.157 states that “the terms ‘best-estimate’ and ‘realistic’ have the same meaning. Both terms are used to indicate that the techniques attempt to predict realistic reactor system thermal-hydraulic response.”

⁵ RG 1.157 states that “the term ‘model’ refers to a set of equations derived from fundamental physical laws that is designed to predict the details of a specific phenomenon.”

⁶ RG 1.157 states that “the term ‘correlation’ refers to an equation having empirically determined constants such that it can predict some details of a specific phenomenon for a limited range of conditions.”

Option 2: Conservative ECCS Evaluation Model

Alternatively, a conservative evaluation model may be developed in conformance with the required and acceptable features of appendix K, "ECCS Evaluation Models," to 10 CFR part 50. Under appendix K, section I.A., evaluation models must account for various sources of heat during LOCA conditions including the metal-water reaction rate. In particular, section I.A.5, "Metal-Water Reaction Rate," of appendix K requires use of the Baker-Just equation to calculate the rates of energy release, hydrogen generation, and Zircaloy cladding oxidation from the metal-water reaction of zirconium with steam, assuming that the reaction is not steam limited.

Petitioner's Arguments and Requests Related to Issue 2

The petitioner argued that data from multirod (assembly) severe fuel damage experiments indicate that the equations used to calculate the metal-water reaction rate in ECCS evaluation models that the NRC has determined to be acceptable for use in evaluating ECCS cooling performance are not conservative. In particular, the petitioner asserted that data from cited experiments indicate that use of the Cathcart-Pawel equation in realistic evaluation models or use of the Baker-Just equation in conservative evaluation models would: (1) Overestimate the temperature at which autocatalytic metal-water oxidation reactions would

occur during a LOCA; and (2) underestimate the rate of Zircaloy cladding oxidation from the metal-water reaction of zirconium with steam and, therefore, underestimate the heatup, heatup rate, and maximum temperature of the Zircaloy cladding during a LOCA. Therefore, the petitioner requested that the NRC amend RG 1.157 and appendix K to 10 CFR part 50 to require that the rates of energy release, hydrogen generation, and Zircaloy cladding oxidation from the metal-water reaction of zirconium with steam considered in evaluation models used to calculate ECCS cooling performance be calculated based on data from cited experiments, instead of using the Cathcart-Pawel or Baker-Just equations.

Issue 3: Minimum Allowable Core Reflood Rate

Background for Issue 3

Section 50.46(b) of 10 CFR does not include criteria for calculated ECCS cooling performance pertaining to the core reflood rate following postulated LOCAs.

Petitioner's Arguments and Requests Related to Issue 3

The petitioner asserted that a constant core reflood rate of approximately 1 inch per second or lower would not, with high probability, prevent Zircaloy cladding from exceeding the 2,200 °F limit in § 50.46(b)(1) if, at the onset of reflood, the cladding temperature was greater than or equal to 1,200 °F. In particular, the petitioner asserted that:

(1) Although reflood rates would vary throughout the reactor core during a LOCA, local reflood rates could be approximately 1 inch per second or lower; and (2) extrapolation of data from the cited experiments indicates that a constant core reflood rate of approximately 1 inch per second or lower would not, with high probability, prevent Zircaloy cladding from exceeding the 2,200 °F limit, if the cladding temperature was greater than or equal to 1,200 °F at the onset of reflood.⁷ Therefore, the petitioner requested that the NRC issue a new regulation that would require minimum allowable core reflood rates in the event of a LOCA.

II. Public Comments on the Petitions

II.A. Overview of Public Comments

The NRC received a total of 33 comment submissions that collectively included 125 individual comments. The NRC reviewed and considered all 125 comments in its evaluation of the petitions. Table I identifies the number of comment submissions and individual comments submitted, grouped by three main categories of comments. These categories are used only to facilitate presenting a high-level summary and totals for the comments that different stakeholder groups submitted; the NRC staff used the same approach for addressing all submitted comments, regardless of category or who submitted them. The paragraphs that follow provide a high-level overview of each category of comments.

TABLE I—NUMBER OF COMMENT SUBMISSIONS AND INDIVIDUAL COMMENTS BY CATEGORY

Category	Number of comment submissions	Number of individual comments
Comments from the Petitioner	^a 13	^a 97
Comments from Nuclear Industry Representatives	3	9
Comments from Public Interest Groups or Other Interested Individuals	17	19
Total	33	125

^a The petitioner provided nine comment submissions after the public comment period that closed on November 26, 2010. Although not required to do so, the NRC also considered all the comment submissions that were submitted after the public comment period closed.

Category 1: Comments From the Petitioner

Petitioner Mark Edward Leyse provided 13 comment submissions in support of PRM-50-93 and PRM-50-95. He provided nine of these comment submissions after the comment period closed. The NRC considered all 13 comment submissions in its evaluation.

In general, the petitioner's comments further supported the petitions by either: (1) Repeating information that had already been provided; (2) providing additional details to clarify specific issues; or (3) citing other references that the petitioner believed further substantiated the arguments in the petitions. In some comments, the

petitioner identified additional technical issues that were relevant to the subject matter, but were not directly related to the requested changes to the NRC's regulations. As discussed in Section III, the NRC staff addressed these additional technical issues in its final technical safety analysis report.

⁷ Extrapolation of the experimental data was necessary because the referenced tests were started with relatively low initial cladding temperatures.

The petitioner hypothesized that, if these tests had started with higher initial cladding temperatures, autocatalytic oxidation and failure of the Zircaloy

cladding would have occurred with high probability.

Category 2: Comments From Nuclear Industry Representatives

The Nuclear Energy Institute (NEI) provided two comment submissions that oppose PRM-50-93 and PRM-50-95. Overall, NEI recommended that the NRC deny PRM-50-93 and PRM-50-95 because the experiments identified in the petitions—whether considered individually or in conjunction with other experiments—do not substantiate the assertions or requests made in the petitions. NEI further provided additional experimental evidence that indicates the NRC's regulations and associated regulatory guidance on ECCS acceptance criteria and evaluation models are adequate.

Exelon Corporation provided one comment submission that opposes PRM-50-93 and PRM-50-95, stating that: (1) It did not consider the proposed amendments to the NRC's regulations or associated regulatory guidance to be necessary and (2) it agreed with the comments that NEI submitted.

Category 3: Comments From Public Interest Groups or Other Interested Individuals

Three public interest groups (Don't Waste Michigan, Beyond Nuclear, and Union of Concerned Scientists (UCS)) each provided one comment submission in support of PRM-50-93 and PRM-50-95. In general, these comments provided high-level statements of support for the petitions but did not cite relevant evidence to substantiate the petitions.

Other interested individuals provided a total of 10 comment submissions on PRM-50-93 and PRM-50-95. In general, these individual comments also provided high-level statements of support for the petitions but did not cite relevant evidence to substantiate the petitions. In addition, several comments identified unrelated concerns about the NRC's regulations or practices that the NRC staff determined to be outside the scope of PRM-50-93 and PRM-50-95.

Robert Leyse, a relative of petitioner Mark Edward Leyse, provided four comment submissions in support of PRM-50-93 and PRM-50-95. Robert Leyse had previously submitted a related petition for rulemaking (PRM-50-76) that the NRC denied on September 6, 2005.⁸ In general, his

⁸ Robert Leyse petitioned the NRC on May 1, 2002, requesting the NRC to amend Appendix K of 10 CFR part 50 and RG 1.157 to correct asserted technical deficiencies in the Baker-Just and Cathcart-Pawel equations used to calculate the metal-water reaction rate in ECCS evaluation models. The NRC denied PRM-50-76, determining that: (1) None of the specific technical issues raised by the petitioner showed safety-significant deficiencies in the research, calculation methods, or

comments either repeated information provided in the petitions or expressed his view that the NRC did not appropriately consider all relevant information in its denial of PRM-50-76.

II.B. NRC Response to Public Comments

Two main factors influenced the NRC's approach to developing and documenting its response to public comments submitted on PRM-50-93 and PRM-50-95: (1) The substantial number, length, and complexity of the comments that were submitted; and (2) the limited availability of NRC resources due to competing, higher-priority work. In this approach, individual comments that addressed similar subject categories were grouped into one of 16 high-level comment bins. The following paragraphs provide for each bin of comments: (1) A high-level summary of the main subject category addressed in the grouped comments, including a listing in parentheses of the unique identifiers for individual comments that were assigned to the bin; and (2) the NRC's response to the grouped comments, including—if appropriate—a high-level summary of the basis for the response and reference to the relevant section(s) of the NRC's final technical safety analysis report that provide(s) additional details to support the NRC's position. A separate document consolidates all 33 comment submissions and 125 individual comments, and provides the following information: (1) A table that lists the unique identifier and ADAMS accession number assigned to each comment submission document and (2) markings that clearly assign unique identifiers to portions of each comment submission that were identified as distinct individual comments. Information about how to access this consolidated document is provided in Section IV.

1. General Support for Petitions Without Providing Rationale

Comment: The NRC should initiate rulemaking to address the issues raised in the petitions. (5-1, 6-1, 7-1, 8-1, 9-1, 10-1, 11-1, 12-1, 15-1, 19-1, 23-1)

NRC response: Because these comments generally supported the petitions without providing a rationale to substantiate this support, the NRC's overall response to the petitions applies to this bin of comments. The final technical safety analysis report provides additional details to support the NRC staff's position.

data used to support ECCS cooling performance evaluations; and (2) the NRC's regulations and regulatory guidance on ECCS cooling performance evaluations were based on sound science and did not need to be amended (70 FR 52893).

2. General Opposition to Petitions Without Providing Rationale

Comment: The requested amendments to NRC's regulations are not necessary. (18-1)

NRC response: Because this comment generally opposed the petitions without providing a rationale to substantiate this opposition, the NRC's overall response to the petitions applies to this bin of comments. The final technical safety analysis report provides additional details to support the NRC staff's position.

3. Comments Related to PRM-50-76

Comment: As stated in PRM-50-76, the Cathcart-Pawel and Baker-Just equations are not conservative because they were not developed to consider how complex thermal-hydraulic phenomena would affect the metal-water reaction rate in the event of a LOCA. (2-1, 17-2)

NRC response: The NRC disagrees with these comments. Consistent with the technical safety analysis that was performed for PRM-50-76, the NRC staff determined that—for the development of metal-water reaction rate equations—well-characterized isothermal tests are more important than considering the effects of complex thermal-hydraulic phenomena. The suggested use of complex thermal-hydraulic conditions would be counterproductive in tests that experimentally derive reaction rate correlations because temperature control is required to develop a consistent set of data for correlation derivation. Isothermal tests provide this needed temperature control. Section 1.1, "Similar Petition Previously Considered by NRC (ML041210109)," of the final technical safety analysis report provides additional details to support the NRC staff's position.

4. Peak Cladding Temperature Limit Is Not Conservative

Comment: Data from cited experiments indicate that autocatalytic metal-water oxidation reactions and uncontrolled temperature excursions involving Zircaloy cladding have occurred at temperatures below 2,200 °F, indicating the regulatory limit of 2,200 °F is not conservative. (2-6, 2-10, 3-1, 4-1, 14-5, 14-7, 14-11, 16-2, 16-4, 20-1, 20-5, 20-6, 20-10, 20-14, 20-15, 21-4, 21-14, 23-2, 24-1, 25-1, 26-11, 32-1, 32-7)

NRC response: The NRC disagrees with these comments. The NRC staff reviewed experimental data and information from the cited experiments and found no evidence of temperature

escalation rates that demonstrated the occurrence of autocatalytic or runaway oxidation reactions below 2,200 °F under LOCA conditions. Section 2.1, “Peak Cladding Temperature Limit is Nonconservative,” of the final technical safety analysis report provides additional details to support the NRC staff’s position.

5. Baker-Just and Cathcart-Pawel Equations Are Not Conservative

Comment: Data from cited experiments indicate that the Baker-Just and Cathcart-Pawel equations used to calculate the metal-water reaction rate in ECCS evaluation models that the NRC has determined to be acceptable for use in evaluating ECCS cooling performance are not conservative. (1–1, 2–5, 14–1, 14–8, 14–9, 14–10, 14–12, 14–13, 14–14, 16–1, 20–4, 20–7, 20–8, 20–9, 20–11, 20–12, 20–16, 20–17, 21–3, 21–10, 21–13, 24–2, 26–1, 27–1, 27–3, 28–2, 29–3, 29–5, 29–6, 30–1, 30–2, 32–2, 32–9)

NRC response: The NRC agrees in part and disagrees in part with these comments. The NRC agrees that the Cathcart-Pawel equation is generally not conservative. However, consistent with its intended use, the NRC staff has determined that use of the Cathcart-Pawel equation generally results in sufficiently accurate calculations of the metal-water reaction rate that are appropriate for realistic ECCS evaluation models. The NRC disagrees that the Baker-Just equation is not conservative. Consistent with its intended use, the NRC staff has determined that use of the Baker-Just equation results in sufficiently conservative calculations of the metal-water reaction rate that are appropriate for conservative ECCS evaluation models. Section 2.2, “Baker-Just and Cathcart-Pawel Equations are Nonconservative,” of the final technical safety analysis report provides additional details to support the NRC staff’s position.

6. Need for a Minimum Allowable Reflood Rate

Comment: Extrapolation of data from cited experiments indicates that a new regulation that requires minimum allowable core reflood rates in the event of a LOCA is necessary to prevent Zircaloy cladding from exceeding the regulatory limit of 2,200 °F under certain conditions. (2–2, 2–3, 2–4, 16–3, 20–2, 20–3, 20–13, 20–18, 21–2, 24–3, 26–2, 26–7, 26–9, 32–6)

NRC response: The NRC disagrees with these comments. The NRC staff has determined—using simulations of a Zircaloy cladding bundle with the geometry and design that was used for

the cited experiments—that steam cooling would be sufficient to maintain Zircaloy cladding temperatures below the 2,200 °F limit. Section 2.3, “Need for a Minimum Allowable Reflood Rate,” of the final technical safety analysis report provides additional details to support the NRC staff’s position.

7. Issues Related to National Research Universal Full-Length High-Temperature (FLHT) In-Reactor Tests

Comment: In the FLHT–1 test, the test conductors were unable to prevent a temperature excursion and runaway oxidation by increasing the coolant flow rate when peak cladding temperatures reached approximately 2,200 °F. This provides additional evidence indicating that the regulatory limit of 2,200 °F is not conservative. (21–5, 26–4, 26–8, 28–3, 29–1, 29–4)

NRC response: The NRC disagrees with these comments. The NRC staff determined that excessive heatup rates were not experienced during the FLHT–1 experiment until temperatures exceeded 2,420 °F. Section 3.1, “Issues Related to National Research Universal (NRU) full-length high-temperature (FLHT) In-reactor Tests,” of the final technical safety analysis report provides additional details to support the NRC staff’s position.

8. Eutectic Behavior at Temperatures Below 2,200 °F

Comment: In a design-basis LOCA, eutectic reactions⁹ between various fuel assembly components (the Zircaloy cladding, control rods, and spacer grids) at temperatures below 2,200 °F could significantly reduce the safety margins for the following types of materials interactions: (1) Degradation of boiling-water reactor (BWR) control blades due to the eutectic reaction of boron carbide (B₄C), stainless steel, and Zircaloy; (2) degradation of pressurized-water reactor (PWR) cladding due to the eutectic reaction between Inconel grids and Zircaloy cladding; and (3) degradation of PWR control rods that contain silver, indium, and cadmium. (21–1, 21–6, 21–7, 21–8, 21–9, 24–4, 26–10)

NRC response: The NRC disagrees with these comments. These assertions are not supported by available experimental evidence. In its review of available information, the NRC staff was unable to find any evidence that loss of a coolable geometry had occurred at temperatures below 2,200 °F. Test results and analyses have shown that

⁹ In this context, a eutectic reaction is a reaction in which two materials in contact with one another at relatively high temperatures can liquefy at a temperature that is lower than the melting temperatures of the two individual materials.

insignificant eutectic reactions occur for times and maximum temperatures assumed in a design-basis LOCA. Section 3.2, “Eutectic Behavior at Temperatures below 2,200 °F (1,204 °C),” of the final technical safety analysis report provides additional details to support the NRC staff’s position.

9. TRAC/RELAP¹⁰ Advanced Computational Engine (TRACE) Code Simulation of (Full Length Emergency Cooling Heat Transfer) FLECHT Run 9573

Comment: NRC’s TRACE simulations of FLECHT Run 9573 are invalid because they did not simulate the section of the test bundle that incurred runaway oxidation. Therefore, since NRC’s conclusions regarding the reflood rate are based on its TRACE simulations of FLECHT Run 9573, these conclusions are also invalid. (31–4, 32–3, 32–5, 33–1)

NRC response: The NRC disagrees with these comments. The NRC staff determined that the experimental data from FLECHT run 9573 do not show evidence of runaway oxidation below 2,200 °F, despite its low reflood rate. In addition, FLECHT run 9573 was a low-reflood-rate experiment in which thermocouple measurements were taken at five elevations. All five elevations were included in the NRC’s TRACE simulation of FLECHT run 9573. Section 3.3, “TRACE simulation of FLECHT run 9573,” of the final technical safety analysis report provides additional details to support the NRC staff’s position.

10. Stainless Steel and Zircaloy Heat Transfer Coefficients

Comment: The heat transfer coefficients used in appendix K ECCS evaluation models are based on data from thermal-hydraulic experiments conducted with stainless steel rod bundles and therefore should not be used to infer what would happen in a reactor core with Zircaloy bundles in the event of a LOCA. (2–9, 22–1, 26–3, 26–5, 26–6, 32–4)

NRC response: The NRC disagrees with these comments. The NRC staff determined that models for convective heat transfer are dependent upon the properties of the fluid—not the material properties of the heat transfer surface. Therefore, the heater rod material used in the experiments is irrelevant to developing correlations based on the experimental data. Section 3.5,

¹⁰ TRAC: Transient Reactor Analysis Code. RELAP: Reactor Excursion and Leak Analysis Program.

“Stainless Steel and Zircaloy Heat Transfer Coefficients,” of the final technical safety analysis report provides additional details to support the NRC staff’s position.

11. Issues Related to the PHEBUS B9R Test

Comment: Oxidation models are unable to predict autocatalytic oxidation reactions that occurred below 2,200 °F in the PHEBUS B9R-2 test. (32-8, 32-10)

NRC response: The NRC disagrees with these comments. The NRC staff determined that data from the cited PHEBUS B9R test does not demonstrate that an autocatalytic oxidation reaction occurred at temperatures below 2,200 °F. Section 3.6, “Issues Related to the PHEBUS B9R Test,” of the final technical safety analysis report provides additional details to support the NRC staff’s position.

12. Whether Runaway Oxidation Begins at 2,012 °F

Comment: Information in a report about degraded core quench experiments¹¹ indicates that temperatures at which temperature excursions associated with runaway oxidation occur range from 1,922 °F to 2,012 °F. (2-7)

NRC response: The NRC disagrees with this comment. The NRC staff examined the cited report and found no data to support a determination that runaway oxidation occurs at cladding temperatures less than 2,200 °F for experiments simulating conditions for design-basis accidents. Section 3.7, “Issue Related to Whether Runaway Oxidation Temperatures Start at 1100 °C (2012 °F),” of the final technical safety analysis report provides additional details to support the NRC staff’s position.

13. Experimental Methods Used To Derive the Baker-Just Metal-Water Oxidation Reaction Correlation

Comment: The Baker-Just equation is not conservative because it is partly derived using experimental data from inductive heating experiments that included radiative heat losses. These radiative heat losses would affect the oxidation behavior such that the experiment is not representative of reactor behavior in the event of a LOCA

¹¹ Committee on the Safety of Nuclear Installations, Nuclear Energy Agency, Organisation for Economic Co-operation and Development. *Degraded Core Quench: Summary of Progress 1996-1999. NEA/CSNI/R(99)23*. Paris, France: Organisation for Economic Co-operation and Development; 2000. Available at: <http://www.oecd-nea.org/nsd/docs/1999/csni-r99-23.pdf>.

and would cause the Baker-Just equation to be not conservative. (13-1, 14-2, 14-3, 14-4, 14-6, 17-1, 27-2)

NRC response: The NRC disagrees with these comments. The NRC staff determined that the subject experimental data are consistent with data obtained using other methods and concluded that radiative heat losses are not relevant in correlating the data to develop the metal-water reaction rate equation. The NRC staff further concluded that use of the Baker-Just equation results in sufficiently conservative calculations of the metal-water reaction rate that are appropriate for conservative ECCS evaluation models. Section 3.9, “Experimental Methods Used to Derive the Baker-Just Metal-Water Oxidation Reaction Correlation,” of the final technical safety analysis report provides additional details to support the NRC staff’s position.

14. Issues Related To Cladding Oxidation and Hydrogen Production

Comment: The Cathcart-Pawel and Baker-Just equations are unable to determine the increased hydrogen production that occurred in the CORA and LOFT LP-FP-2 experiments. (29-2, 31-3)

NRC response: The NRC neither agrees nor disagrees with these comments. The cited experiments were performed to better understand reactor behavior under severe accident conditions. Increased hydrogen production under such beyond-design-basis conditions is not relevant in determining the suitability of the Cathcart-Pawel or Baker-Just equations when used in evaluations of ECCS cooling performance for design-basis LOCAs. Section 3.10, “Issues Related to Cladding Oxidation and Hydrogen Production,” of the final technical safety analysis report provides additional details to support the NRC staff’s position.

15. Issues Related to the Fuel Rod Failure (FRF) Tests Conducted in the Transient REactor Test (TREAT) Facility Reactor

Comment: Data from the FRF-1 experiment for the TREAT facility indicate that ECCS evaluation models underpredicted the amount of hydrogen produced in that experiment. This means that ECCS evaluation models would underpredict the amount of hydrogen produced in the event of a LOCA and therefore are not conservative. In addition, neither Westinghouse nor the NRC applied the Baker-Just equation to metallurgical data from the locations of FLECHT run 9573

that incurred autocatalytic oxidation in their application of the Baker-Just equation under LOCA conditions to evaluate its suitability. For this reason, it was incorrect for Westinghouse and the NRC to conclude that there is sufficient conservatism in applying the Baker-Just equation to LOCA conditions. (2-8, 21-11, 21-12, 28-1)

NRC response: The NRC disagrees with these comments. The NRC considered the information about the FRF-1 experiment in the TREAT facility in the 1971 Indian Point Unit 2 licensing hearing and determined that the ECCS evaluation models were adequate. In addition, while it is true that the Baker-Just equation has not been applied to metallurgical data from the locations of FLECHT run 9573 that incurred autocatalytic oxidation, these data were not collected at the time of the experiment, and therefore do not exist. However, the NRC staff has determined that the inability to apply the Baker-Just equation to such data is an inadequate basis for asserting that it was incorrect for Westinghouse and the NRC to conclude that there is sufficient conservatism in applying the Baker-Just equation to LOCA conditions. Several independent studies have shown that use of the Baker-Just equation results in sufficiently conservative calculations of the metal-water reaction rate under design-basis LOCA conditions. Section 3.11, “Issues Related to the FRF Tests Conducted in the TREAT Reactor,” of the final technical safety analysis report provides additional details to support the NRC staff’s position.

16. Issues Raised at the Public Commission Meeting in January 2013

Comment: An NRC document¹² states that runaway zirconium oxidation would commence at 1,832 °F in a postulated station blackout scenario at Grand Gulf Nuclear Station, which indicates the regulatory limit of 2,200 °F is not conservative. In addition, a report about best-estimate predictions for the LOFT LP-FP-2 experiments¹³ states that runaway oxidation would commence if fuel-cladding temperatures were to start increasing at a rate of 3.0 kelvins/second (K/s). Since an analysis in support of the NRC staff’s interim evaluation of the petitions showed heatup rates of 10.3 K/s and 11.9 K/s at

¹² Haskin FE, Camp AL. *Perspectives on Reactor Safety. NUREG/CR-6042 (SAND93-0971)*. Washington, DC: U.S. Nuclear Regulatory Commission; 1994. Available at: <https://www.nrc.gov/docs/ML0727/ML072740014.pdf>.

¹³ Guntay S, Carboneau M, Anoda Y. *Best Estimate Prediction for OECD LOFT Project Fission Product Experiment LP-FP-2. OECD LOFT-T-3803*. Idaho Falls, ID: EG&G IDAHO, INC.; 1985. Available at ADAMS accession no. ML071940361.

2,199 °F, this indicates that runaway oxidation has occurred at temperatures below the 2,200 °F limit. (31–1, 31–2)

NRC response: The NRC disagrees with the comments. First, the postulated station blackout scenario discussed in the document is a severe accident that involves conditions that are beyond the design basis, and it is inappropriate to evaluate the regulatory limit of 2,200 °F for design-basis LOCAs using information obtained from models of severe accidents, which model conditions that are more severe than those of design-basis accidents and therefore do not provide information about how fuel cladding would respond to high temperatures under design-basis LOCA conditions. Second, the NRC staff has determined that the runaway oxidation described in the cited LOFT LP–FP–2 report was initiated because of the high temperature (2,870 °F), not because of the heatup rate of 3.0 K/s. Therefore, the NRC staff concluded that there is no basis for the assertion that runaway oxidation has occurred at temperatures below the 2,200 °F limit because heatup rates of more than 3.0 K/s have been observed at lower temperatures. Section 3.12, “Issues Raised at the Public Commission Meeting in January 2013,” of the final technical safety analysis report provides additional details to support the NRC staff’s position.

III. NRC Technical Evaluation and Reasons for Denial

The NRC staff used a special review process to evaluate these petitions. It did this for three main reasons: (1) Additional time and resources were needed to reevaluate more than 40 years of severe accident and thermal-hydraulic experimental data from more than 200 technical references to address all arguments in the petitions; (2) to promptly respond to any significant safety issues, if any were to be identified; and (3) to keep the public informed and to publicly address any stakeholder concerns about the adequacy of the NRC’s regulations following the accident that occurred in 2011 at the Fukushima Dai-ichi Nuclear Power Station in Japan.

As part of this special review process, the NRC made a series of draft interim reports available to the public. These reports informed the public of NRC’s progress in evaluating the petitions and included the NRC staff’s initial evaluation of specific issues and relevant data that were prioritized to determine the order in which they would be evaluated. Information about how to access these draft interim reports is provided in Section IV.

The NRC staff completed its technical evaluation of the petitions and prepared a final technical safety analysis report that documents the official technical basis for the staff’s evaluation. This final technical safety analysis report includes the NRC staff’s evaluation of (1) each of the three main issues raised in the petitions and (2) additional technical issues that are not directly related to the requested changes to the NRC’s regulations that were raised in either the petitions or in subsequent communications (*e.g.*, submitted public comments, email messages, letters, and oral statements in a public meeting with the Commission).

Overall, the NRC is denying the petitions because the petitioner did not present sufficient new information or arguments to support the requested changes. In addition, the NRC disagrees with the arguments in the petitions and concludes that the requested amendments to its regulations and associated regulatory guidance on ECCS acceptance criteria or evaluation models are not necessary. The remaining paragraphs of Section III summarize the staff’s evaluation of each of the three main issues identified in the petitions and identify the relevant section of the staff’s final technical safety analysis report that provides additional details to support the NRC’s position. Information about how to access the final technical safety analysis report is provided in Section IV.

Issue 1: Calculated Maximum Fuel Element Cladding Temperature Limit

The NRC staff reviewed experimental data and information from the multirod (assembly) severe fuel damage experiments cited in the petitions and found no evidence of temperature escalation rates that demonstrated the occurrence of autocatalytic or runaway oxidation reactions at Zircaloy cladding temperatures less than 2,200 °F. Although some rapid temperature increases were observed in the data from the cited experiments, the NRC staff disagrees with the assertion that these data indicate that (1) autocatalytic metal-water oxidation reactions and uncontrolled temperature excursions involving Zircaloy cladding have occurred at temperatures less than the 2,200 °F limit under LOCA conditions and (2) the 2,200 °F limit is therefore not conservative. The NRC staff has further determined that the 2,200 °F limit in § 50.46(b)(1) provides an adequate margin of safety to preclude autocatalytic metal-water oxidation reactions.

Therefore, the NRC concludes that the petitioner did not provide sufficient

information to support amending 10 CFR 50.46 to require that the calculated maximum fuel element cladding temperature not exceed a limit based on data from cited experiments, instead of the 2,200 °F limit in § 50.46(b)(1). Section 2.1, “Peak Cladding Temperature Limit is Nonconservative,” of the final technical safety analysis report provides additional details to support the staff’s position.

Issue 2: Metal-Water Reaction Rate Equations for ECCS Evaluation Models

The NRC staff has determined that: (1) Use of the Cathcart-Pawel equation generally results in sufficiently accurate calculations of the metal-water reaction rate that are appropriate for realistic ECCS evaluation models and (2) use of the Baker-Just equation results in sufficiently conservative calculations of the metal-water reaction rate that are appropriate for conservative ECCS evaluation models. The final technical safety analysis report also cites several independent studies that provide further support for these findings.

The petitioner relied on two main arguments to support the assertion that the Cathcart-Pawel and Baker-Just equations are not conservative. The first argument was that data from cited multirod (assembly) severe fuel damage experiments indicate both equations are not conservative for use in analyses that calculate the temperature at which an autocatalytic or runaway oxidation reaction involving the Zircaloy cladding would occur in the event of a LOCA. The NRC staff disagrees with this argument for two reasons: (1) Autocatalytic or runaway oxidation does not begin at a specific temperature and (2) the petitioner made invalid comparisons between the results of specific experiments and generic calculations that were not intended to be applied to a specific test facility.

The second argument was that the Cathcart-Pawel and Baker-Just equations were not developed to consider how complex thermal-hydraulic phenomena would affect the metal-water reaction rate in the event of a LOCA. However, consistent with the technical safety analysis that was performed for PRM–50–76, the NRC staff determined that—for the development of metal-water reaction rate equations—well-characterized isothermal tests are more important than the complex thermal hydraulics suggested in the petitions. The suggested use of complex thermal-hydraulic conditions would be counterproductive in tests to experimentally derive reaction rate correlations because temperature control is required to develop a

consistent set of data for correlation derivation. Isothermal tests provide this necessary temperature control. However, previous studies have applied the derived correlations to transients that include complex thermal-hydraulic conditions to verify that the proposed phenomena embodied in the correlations are limiting. These studies showed that (1) use of the Cathcart-Pawel equation results in conservative or best-estimate calculations of the metal-water reaction rate and (2) use of the Baker-Just equation results in conservative calculations of the metal-water reaction rate.

Therefore, the NRC concludes that the petitioner did not provide sufficient information to support revising RG 1.157 and appendix K to 10 CFR part 50 to require that the rates of energy release, hydrogen generation, and Zircaloy cladding oxidation from the metal-water reaction of zirconium with steam considered in evaluation models used to calculate ECCS cooling performance be calculated based on data

from cited experiments, instead of using the Cathcart-Pawel or Baker-Just equations. Section 2.2, “Baker-Just and Cathcart-Pawel Equations are Nonconservative” of the final technical safety analysis report provides additional details to support the NRC staff’s position.

Issue 3: Minimum Allowable Core Reflood Rate

NRC calculations using simulations of a Zircaloy cladding bundle with the geometry and design that was used for the cited multirod (assembly) severe fuel damage experiments disproved the petitioner’s assertions about the reflood rate. In particular, calculations using simulations showed that steam cooling would be sufficient to maintain the Zircaloy cladding temperatures below the 2,200 °F limit specified in § 50.46(b)(1). Moreover, the NRC staff determined that (1) cooling of a fuel rod bundle depends on several parameters and heat transfer mechanisms rather than on the reflood rate alone; (2) linear extrapolation of initial Zircaloy

cladding temperatures to predict final cladding temperature is inappropriate because of increased radiative cooling at higher temperatures; and (3) extrapolation of experimental data does not show “with high probability” that peak cladding temperatures will exceed 2,200 °F.

Therefore, the NRC staff concludes that the petitioner did not provide sufficient information to support issuance of a new regulation that requires minimum allowable core reflood rates in the event of a LOCA. Section 2.3, “Need for a Minimum Allowable Reflood Rate,” of the final technical safety analysis report provides additional details to support the NRC staff’s position.

IV. Availability of Documents

Table II provides information about how to access the documents referenced in this document. The **ADDRESSES** section of this document provides additional information about how to access ADAMS.

TABLE II—INFORMATION ABOUT HOW TO ACCESS REFERENCED DOCUMENTS

Date	Document	ADAMS accession No. or Federal Register citation
Submitted Petitions		
May 1, 2002	Petition for Rulemaking (PRM–50–76)	ML022240009
November 17, 2009	Petition for Rulemaking (PRM–50–93)	ML093290250
June 7, 2010	Petition for Rulemaking (PRM–50–95)	ML102770018
Federal Register Notices		
September 6, 2005	Denial of Petition for Rulemaking (PRM–50–76)	70 FR 52893
January 25, 2010	Notice of Receipt of Petition for Rulemaking (PRM–50–93)	75 FR 3876
October 27, 2010	Notice of Consolidation of Petitions for Rulemaking and Re-Opening of Comment Period (PRM–50–93 and PRM–50–95).	75 FR 66007
Consolidated Public Comments Document		
November 21, 2017	Public Comments on Petitions for Rulemaking: Calculated Maximum Fuel Element Cladding Temperature.	ML17325A007
Draft Interim Reports		
August 23, 2011	Draft Interim Review of PRM–50–93/95 Issues Related to the CORA Tests	ML112290888
September 27, 2011	Draft Interim Review of PRM–50–93/95 Issues Related to the LOFT LP–FP–2 Test	ML112650009
October 16, 2012	Draft Interim Review of PRM–50–93/95 Issues Related to Conservatism of 2200 °F, Metal-Water Reaction Rate Correlations, and “The Impression Left from [FLECHT] Run 9573.”	ML12265A277
March 8, 2013	Draft Interim Review of PRM–50–93/95 Issues Related to Minimum Allowable Core Reflood Rate.	ML13067A261
Final Technical Safety Analysis Report		
August 19, 2016	Technical Safety Analysis of PRM–50–93/95, Petition for Rulemaking on § 50.46	ML16078A318

V. Conclusion

For the reasons cited in this document, the NRC is denying PRM–50–93 and PRM–50–95. The petitioner did not present sufficient new

information or arguments to support the requested changes. In addition, the NRC disagrees with the arguments in the petitions and concludes that the requested amendments to its regulations

and associated regulatory guidance are not necessary. The NRC’s existing regulations provide reasonable assurance of adequate protection of public health and safety.

Dated: December 29, 2020.

For the Nuclear Regulatory Commission.

Annette L. Vietti-Cook,

Secretary of the Commission.

[FR Doc. 2020-29151 Filed 1-6-21; 8:45 am]

BILLING CODE 7590-01-P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Parts 1301, 1309, and 1321

[Docket No. DEA-587]

RIN 1117-AB58

Amending Regulations To Require Online Submission of Applications for and Renewals of DEA Registration

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Notice of proposed rulemaking.

SUMMARY: This rule proposes to amend the Drug Enforcement Administration (DEA) regulations to require all initial and renewal applications for DEA registration to be submitted online.

DATES: Electronic comments must be submitted, and written comments must be postmarked, on or before March 8, 2021. Commenters should be aware that the electronic Federal Docket Management System will not accept any comments after 11:59 p.m. Eastern Time on the last day of the comment period.

All comments concerning collections of information under the Paperwork Reduction Act must be submitted to the Office of Management and Budget on or before March 8, 2021.

ADDRESSES: To ensure proper handling of comments, please reference “Docket No. DEA-587” on all correspondence, including any attachments.

• *Electronic comments:* The Drug Enforcement Administration (DEA) encourages that all comments be submitted electronically through the Federal eRulemaking Portal which provides the ability to type short comments directly into the comment field on the web page or attach a file for lengthier comments. Please go to <http://www.regulations.gov> and follow the online instructions at that site for submitting comments. Upon completion of your submission, you will receive a Comment Tracking Number for your comment. Please be aware that submitted comments are not instantaneously available for public view on [Regulations.gov](http://www.regulations.gov). If you have received a Comment Tracking Number, your comment has been successfully submitted and there is no need to resubmit the same comment.

• *Paper comments:* Paper comments that duplicate electronic submissions are not necessary. Should you wish to mail a paper comment, *in lieu* of an electronic comment, it should be sent via regular or express mail to: Drug Enforcement Administration, Attn: DEA Federal Register Representative/DPW, 8701 Morrisette Drive, Springfield, Virginia 22152.

FOR FURTHER INFORMATION CONTACT: Scott A. Brinks, Regulatory Drafting and Policy Support Section, Diversion Control Division, Drug Enforcement Administration; Mailing Address: 8701 Morrisette Drive, Springfield, Virginia 22152; Telephone: (571) 362-3261.

SUPPLEMENTARY INFORMATION:

Posting of Public Comments

Please note that all comments received are considered part of the public record. They will, unless reasonable cause is given, be made available by the Drug Enforcement Administration (DEA) for public inspection online at <http://www.regulations.gov>. Such information includes personal identifying information (such as your name, address, etc.) voluntarily submitted by the commenter. The Freedom of Information Act applies to all comments received. If you want to submit personal identifying information (such as your name, address, etc.) as part of your comment, but do not want it to be made publicly available, you must include the phrase “PERSONAL IDENTIFYING INFORMATION” in the first paragraph of your comment. You must also place all of the personal identifying information you do not want made publicly available in the first paragraph of your comment and identify what information you want redacted.

If you want to submit confidential business information as part of your comment, but do not want it to be made publicly available, you must include the phrase “CONFIDENTIAL BUSINESS INFORMATION” in the first paragraph of your comment. You must also prominently identify the confidential business information to be redacted within the comment.

Comments containing personal identifying information or confidential business information identified as directed above will be made publicly available in redacted form. If a comment has so much confidential business information that it cannot be effectively redacted, all or part of that comment may not be made publicly available. Comments posted to <http://www.regulations.gov> may include any personal identifying information (such

as name, address, and phone number) included in the text of your electronic submission that is not identified as confidential as directed above.

An electronic copy of this proposed rule is available at <http://www.regulations.gov> for easy reference.

Legal Authority

The Controlled Substances Act (CSA) grants the Attorney General authority to promulgate rules and regulations relating to: The registration and control of the manufacture, distribution, and dispensing of controlled substances and listed chemicals; reporting changes to professional or business addresses; and the efficient execution of his statutory functions. 21 U.S.C. 821, 822(a), 827(h), 871(b), 957(a). The Attorney General is further authorized by the CSA to promulgate rules and regulations relating to the registration and control of importers and exporters of controlled substances and listed chemicals. 21 U.S.C. 958(f). The Attorney General has delegated this authority to the Administrator of DEA. 28 CFR 0.100(b).

DEA Form 224 applies to new registration applications for retail pharmacy, hospital/clinic, practitioner, teaching institution, or mid-level practitioner registrations.¹ DEA Form 225 applies to new registration applications for manufacturer, distributor, researcher, canine handler, analytical laboratory, importer, or exporter registrations.² DEA Form 363 applies to new registration applications for narcotic treatment program registrations.³ DEA Form 510 applies to new registration applications for domestic chemical registrations.⁴ DEA Forms 224a, 225a, 363a, and 510a apply to registration renewal applications.⁵

Purpose of the Proposed Rule

The purpose of this notice of proposed rulemaking is to simplify the form submission process by requiring that all registration and renewal applications be submitted online. Currently, DEA regulations permit DEA Registration Forms (224/224a, 225/225a, 363/363a, and 510/510a) to be submitted either through the secure online database, or by paper forms delivered to DEA Headquarters.⁶ This proposed rule will amend DEA regulations to require that all registration and renewal applications be

¹ 21 CFR 1301.13(e)(1)(iv).

² 21 CFR 1301.13(e)(1)(i)-(iii), (v)-(vi), and (viii)-(x).

³ 21 CFR 1301.13(e)(1)(vii).

⁴ 21 CFR 1309.21.

⁵ 21 CFR 1301.13(e)(1) and 1309.21

⁶ <https://www.deadiversion.usdoj.gov/drugreg/index.html#regapps>.