RULEMAKING ISSUE
AFFIRMATION

December 10, 2010 SECY-10-0161

FOR: The Commissioners

FROM: R. W. Borchardt
Executive Director for Operations

SUBJECT: FINAL RULE: RISK-INFORMED CHANGES TO LOSS-OF-COOLANT ACCIDENT TECHNICAL REQUIREMENTS (10 CFR 50.46a) (RIN 3150-AH29)

PURPOSE:

To obtain Commission approval to publish a final rule providing alternative risk-informed emergency core cooling system (ECCS) requirements.

SUMMARY:

The U.S. Nuclear Regulatory Commission (NRC) staff is seeking Commission approval of the enclosed rule that would establish an alternative, risk-informed set of ECCS requirements applicable to the current fleet of operating reactors and certain new light water reactors whose designs are similar to currently operating plants. The rule would reduce some ECCS analysis requirements for larger, less likely pipe breaks and provide some plants with additional design flexibility. Facility changes made possible by the new ECCS requirements would also have to meet risk-informed acceptance criteria specified in the rule to ensure adequate protection of public health and safety.

BACKGROUND:

This rulemaking effort was initiated by the Staff Requirements Memorandum (SRM) of March 31, 2003, (Agencywide Documents Access and Management System (ADAMS)

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Accession No. ML030910476), on SECY-02-0057, “Update to SECY-01-0133, ‘Fourth Status Report on Study of Risk-Informed Changes to the Technical Requirements of 10 CFR Part 50 (Option 3) and Recommendations on Risk-Informed Changes to 10 CFR 50.46 (ECCS Acceptance Criteria)’," dated March 29, 2002, (ADAMS Accession No. ML020660607). This SRM directed the staff to prepare a proposed rule that would provide a risk-informed alternative maximum loss-of-coolant accident (LOCA) break size. Since receiving the initial SRM, the NRC staff has resolved a closely-related petition for rulemaking submitted by the Nuclear Energy Institute (NEI) and held over a dozen public meetings to discuss this rulemaking with members of the public, industry stakeholders, and with the Advisory Committee on Reactor Safeguards (ACRS). On two occasions, the staff has summarized various issues affecting this rulemaking and requested additional guidance from the Commission on specific policy issues. The NRC has published a proposed and a supplemental proposed rule and has addressed all associated public comments submitted on these proposals. The staff has now completed and is seeking Commission approval of the enclosed final rule. A detailed history of staff activities on this rulemaking effort is provided in Enclosure 1.

DISCUSSION:

The final rule will establish an alternative set of risk-informed ECCS requirements in Title 10 of the *Code of Federal Regulations* (10 CFR) Part 50.46a with which licensees may choose to comply in lieu of meeting the current requirements in 10 CFR 50.46, “Acceptance Criteria for Emergency Core Cooling Systems for Light-Water Nuclear Power Reactors.” The rule divides the current spectrum of LOCA break sizes into two regions. The division between the two regions is delineated by the transition break size (TBS). The first region includes small-size breaks, up to and including the TBS. The second region includes breaks larger than the TBS, up to and including the double-ended guillotine break (DEGB) of the largest reactor coolant system pipe. These larger breaks are considered to have a much lower likelihood than the smaller breaks in the first region. Under the new rule, the ECCS design requirements for pipe breaks less than the TBS are the same as the requirements for all breaks under the current 10 CFR 50.46 ECCS rule. By contrast, under the new rule, the ECCS design requirements for pipe breaks larger than the TBS may be analyzed using less conservative assumptions based on their lower likelihood. Although LOCAs for break sizes larger than the transition break would become beyond design-basis accidents, these breaks will still be subject to regulatory control. The final rule will require that licensees maintain the ability to mitigate all LOCAs, up to and including the DEGB of the largest reactor coolant system pipe. However, mitigation analyses for LOCAs larger than the TBS need not assume the loss-of-offsite power or the occurrence of a single failure. Licensees will be allowed to credit the use of non-safety-related equipment and will be permitted to operate the facility for a short time (up to 14 days in a 12-month period or an NRC-approved alternative) with certain equipment inoperable that is needed to mitigate the larger breaks.

After performing LOCA analyses under the alternative ECCS requirements in the final rule, some licensees may find that their plant designs are no longer limited by certain parameters associated with previous DEGB analyses. Reducing the DEGB limitations will allow some licensees to propose a wide scope of design or operational changes, up to the point where operation is limited by some other parameter associated with the required accident analyses. Potential design changes include containment spray system set point changes; fuel management improvements; optimization of plant modifications and operator actions to address

postulated sump blockage issues; power uprates; and changes to the required number of accumulators, diesel start times, sequencing of equipment, and valve stroke times.

Some of these design and operational changes could increase plant safety because a licensee could modify its systems to better mitigate the more likely LOCAs. Other changes, such as increasing power, could increase overall risk to the public. Thus, the 10 CFR 50.46a option includes risk acceptance criteria for evaluating future design changes to ensure that any risk increases "enabled" by this rule are acceptably small. These acceptance criteria (i.e., very small increase in risk) are consistent with the guidelines for risk-informed license amendments in Regulatory Guide 1.174, "An Approach for Using Probabilistic Risk Assessment in Risk-Informed Decisions on Plant-Specific Changes to the Licensing Basis," that can be used at all facilities unless the facility's total risk is unacceptably high. Satisfying these guidelines will ensure both the acceptability of the changes from a risk perspective and the retention of sufficient defense-in-depth, safety margins, and performance monitoring.

The NRC staff will periodically evaluate LOCA frequencies. Should estimated LOCA frequencies increase, causing a significant increase in the risk associated with breaks larger than the TBS, the NRC staff will recommend to the Commission that the agency undertake rulemaking (or issue orders, if appropriate) to change the TBS. The new rule also includes changes to the backfit rule, 10 CFR 50.109, providing that a backfitting analysis need not be prepared for changes the NRC may make to the TBS. If previous plant changes made under 10 CFR 50.46a are invalidated because of a change made to the TBS, licensees will have to modify or restore components or systems or make offsetting changes to other parts of the plant so that the facility will continue to comply with the rule's acceptance criteria. Paragraph (d)(4) of the rule states that the backfit rule and applicable finality provisions in Part 52 will also not apply to such licensee actions. The NRC staff believes that these exclusions from the backfit rule and Part 52 finality provisions are appropriate as a regulatory policy matter because the technical requirement is a voluntary alternative and the technical basis supporting the regulatory acceptance criterion is subject to evolving understanding as more is learned about the frequency of loss-of-coolant events. The "Backfit Analysis" section in the enclosed *Federal Register* Notice (FRN) provides a more detailed discussion of the reasons for these exclusions from the backfit rule.

Public Comments

The NRC received 15 comment letters on the initial proposed rule, nearly all of which were from nuclear industry stakeholders. Although comments were related to a number of issues, several industry commenters were concerned that the significant implementation burden of the rule could prevent it from being widely adopted by licensees. The staff discussed these comments with stakeholders in two public meetings and addressed them in the supplemental proposed rule published in Volume 74 of the *Federal Register* (FR), page 40,006 (74 FR 40006). The NRC received five comment letters on the supplemental proposed rule, two from nuclear industry stakeholders, and three from public citizens. The nuclear industry comments addressed various technical aspects of the supplemental proposed rule, but several were again concerned with potential implementation burden. The public commenters expressed the view that the NRC should resolve the issues raised in several petitions for rulemaking before publishing the final 10 CFR 50.46a rule. Section IV of the enclosed FRN addresses these public comments categorized according to the various issues that were raised.

Recommendations Provided by the ACRS on Applying 10 CFR 50.46a to New Reactor Designs

In a letter on October 20, 2010, (ADAMS Accession No. ML102850279), the ACRS concluded that the staff's draft final rule was an acceptable risk-informed alternative to the current requirements in 10 CFR 50.46 for operating reactors. The ACRS then concluded that it is premature to extend 10 CFR 50.46a to new reactors at this time. The Committee's recommendation was primarily based on the concern that new reactors are expected to have significantly different risk profiles from the current operating reactor fleet and that development of appropriate risk metrics and risk acceptance criteria for these designs is still in the conceptual stage. But the ACRS also recommended that if the NRC staff decides to include new reactors in the final rule, the short time during which a facility may operate without all equipment needed to mitigate beyond-TBS LOCAs should be subject to an additional limitation to preclude a significant relative decrease in the level of safety provided by the new design. The NRC staff agrees with this ACRS recommendation and has modified the rule to include the additional requirement. A detailed discussion of the staff's response to the ACRS recommendations on new reactors is included in Enclosure 2.

Implementation Burden

Because the use of this rule is voluntary, the NRC staff expects that each licensee would do its own plant-specific cost-benefit analysis to decide whether to adopt the rule. But for those licensees who do apply for approval to use 10 CFR 50.46a, the NRC staff agrees with comments made by industry stakeholders that the implementation burden of this rule is potentially significant. The staff held four public stakeholder meetings to consider alternatives to reduce the burden incurred by licensees who adopt the rule. The staff believes that all requirements now included in the rule are necessary to ensure adequate protection of the public. For those licensees who do adopt the rule, potential net benefits are expected to be large. If 18 plants implement the rule, cumulative net benefits have been estimated to range from $279 million up to $5,656 million, depending upon the assumed scenario (see pages 34 and 35 of the regulatory analysis provided in Enclosure 3).

The staff is preparing implementation guidance in the form of two regulatory guides. The agency published one guide, DG-1216, ''Plant-Specific Applicability of the Transition Break Size Specified in 10 CFR 50.46a," for public comment in June 2010. This guide describes the evaluation that a licensee must perform to ensure that the TBS is applicable to its plant. But this draft guide does not reflect the changes recently made to the rule in response to the ACRS recommendations received in October 2010. The staff may need to revise this guide and seek additional public comments on the changes. To evaluate the regulatory burden associated with this applicability review guidance, the NRC plans to conduct a pilot plant study with industry. The goal of this study is to ensure that the final guidance provides reasonable assurance that plant safety is not impacted by proposed facility changes under 10 CFR 50.46a while minimizing licensee implementation costs. The second regulatory guide will provide process guidance for implementing the rule. The staff expects to publish the second guide for public comment approximately 12 months after the Commission makes its decision on the enclosed rule. With the possible exception of the pilot plant study, all final regulatory guidance is expected to be completed approximately 19 - 22 months after the Commission makes its decision on the final rule. The staff typically would prefer to publish regulatory guides concurrently with the issuance of a final rule; however, since this rule is voluntary the staff believes it will be acceptable to complete these regulatory guides after the rule is promulgated. The staff also believes

collaboration on the development of the final guidance will be more effective once the final rule is approved. Additionally, given the options currently associated with the resolution of GSI-191, the Commission may benefit from the availability of this proposed final rule for review, and the industry would also likely benefit from an earlier issuance of the final rule than the time required developing the regulatory guides would allow.

Major Rule

As previously noted, one scenario considered in the regulatory analysis resulted in net cumulative benefits of $5,656 million. These benefits would accrue over the remaining lifetimes of a group of plants from 2011 until 2054, when the license of the last plant would expire. Because the average annual benefit over this 43-year period is over $100 million, the staff plans to identify this action as a major rule. As required by the Congressional Review Act, the effective date of the rule will be extended from 30 days until 60 days to allow for possible Congressional review.

Petition for Rulemaking

In February 2002, NEI submitted a petition for rulemaking (PRM-50-75) requesting the NRC to revise the ECCS requirements by redefining the large break LOCA (ADAMS Accession no. ML020630082). Specifically, NEI requested that the NRC amend § 50.46 to allow licensees to use as an alternative to the DEGB of the largest pipe in the reactor coolant system, an alternate maximum break size that would be approved by the Director of the Office of Nuclear Reactor Regulation (NRR). Notice of the petition was published for public comment (67 FR 16654) and 18 sets of public comments were received. Comments were mostly from the power reactor industry in favor of granting the petition, but two commenters were concerned about potential impacts on defense-in-depth and safety margins if significant changes were made to reactor designs based upon a smaller break size. The NRC staff addressed the petition on November 6, 2008, by publishing a notice in the FR stating that the petitioner's recommendation would be considered in the rulemaking process (See 73 FR 66000). The NRC staff considered all PRM-50-75 public comments during the 10 CFR 50.46a rulemaking, but formally addressed only the comments that did not support the petition. After considering the petition and the public comments, the NRC staff concluded that the Director of NRR should not specify maximum LOCA break sizes in a case-by-case fashion because of potential problems with determining the level of adequate protection on a design-specific basis and associated difficulties in maintaining fairness and regulatory stability. The staff concluded that the maximum LOCA break size should be determined during a rulemaking in which all stakeholders could participate. This approach resulted in the transition break size concept upon which the enclosed final rule is based. The final rule addresses the petitioner's rulemaking request by specifying the TBS for currently operating reactors and establishing the process and criteria for evaluating applicants' proposals for a TBS applicable to a new reactor design. However, because the rule does not reflect the rule language submitted in PRM-50-75, the petitioner's request is accepted in part and denied in part.

RESOURCES:

The following staff full-time equivalent and contractor support resources are required to complete this rulemaking and prepare the associated regulatory guidance. These resources

have been allocated in the fiscal year (FY) 2011 and FY 2012 budgets for NRR, for the Office of New Reactors (NRO) and the Office of Nuclear Regulatory Research (RES).

Office	Description	FY 2011		FY 2012	
		CS&T	FTE	CS&T	FTE
NRR	Risk-Informed Rulemaking and Regulatory Guidance	0	1.1	0	0.1
NRO	Risk-Informed Regulatory Guidance	0	0.3	0	0.1
RES	Final Rule: Risk Informed Changes to Loss-of-Coolant Accident Technical requirements	150K	0	0	0
RES	Final Rule: Risk Informed Changes to Loss-of-Coolant Accident Technical requirements	0	0.6	0	0.25
Total:		150K	2.0	0	0.45

RECOMMENDATIONS:

The staff recommends that the Commission take the following four actions:

(1) Approve the enclosed final rule (Enclosure 4) for publication in the FR.

(2) Certify that this rule, if promulgated, will not have a significant impact on a substantial number of small entities. This certification is included in the enclosed FRN and satisfies the requirement of the Regulatory Flexibility Act of 1980 (5 U.S.C. 605(b)).

(3) Note the following:

a. The staff has prepared a final regulatory analysis for this rulemaking (Enclosure 3).

b. The final rule contains amended information collection requirements subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501, et seq.) that must be submitted to the Office of Management and Budget (OMB) for its review and approval before the final rule can be published in the FR.

c. The staff has determined that this action is a “major rule,” as defined in the Congressional Review Act of 1996 (5 U.S.C. 804(2)), and has confirmed this determination with OMB. The staff will inform the appropriate Congressional and U.S. Government Accountability Office contacts.

d. The staff will inform the appropriate Congressional committees.

e. The Office of Public Affairs will issue a press release when the NRC publishes the final rule in the FR.

(4) Approve the staff recommendation to partially accept and partially deny PRM-50-75.

COORDINATION:

The staff conducted its final briefings of the ACRS subcommittee and full committee on September 22 and October 7, 2010, respectively. The ACRS concluded that the rule was an acceptable alternative for operating reactors. The staff's response to the ACRS recommendations on applying the rule to new reactor designs is provided in Enclosure 2. The staff coordinated this paper with NRR, RES, NRO, the Office of Administration, the Office of Information Services, the Office of the Chief Financial Officer, and the Office of Enforcement. The Office of the General Counsel has no legal objection to this paper.

/RA Martin Virgilio for/

R. W. Borchardt
Executive Director
for Operations

Enclosures:
1. History of § 50.46a Rulemaking
2. Staff Evaluation of ACRS Recommendations
3. Regulatory Analysis
4. *Federal Register* Notice

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History of § 50.46a Risk-Informed ECCS Rulemaking Activities

The Commission's Staff Requirements Memorandum (SRM) of March 31, 2003 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML030910476), on SECY-02-0057, "Update to SECY-01-0133, 'Fourth Status Report on Study of Risk-Informed Changes to the Technical Requirements of 10 CFR Part 50 (Option 3) and Recommendations on Risk-Informed Changes to 10 CFR 50.46 (ECCS Acceptance Criteria)'," dated March 29, 2002 (ADAMS Accession No. ML020660607) directed the staff to prepare a proposed rule that would provide a risk-informed alternative maximum loss-of-coolant accident (LOCA) break size. The Nuclear Regulatory Commission (NRC) staff began to prepare a proposed rule in response to the SRM direction. However, after holding two public stakeholder meetings (June 9, 2003 and July 24, 2003; ADAMS Accession Nos. ML031810178 and ML032130059, respectively) the NRC staff found differences between stated Commission objectives and industry stakeholder interests.

To reach a common understanding about the objectives of the rulemaking, the NRC staff requested additional Commission guidance in SECY-04-0037, "Issues Related to Proposed Rulemaking to Risk-Inform Requirements Related to Large Break Loss-of-Coolant Accident (LOCA) Break Size and Plans for Rulemaking on LOCA with Coincident Loss-of-Offsite Power," dated March 3, 2004 (ADAMS Accession No. ML040490133). The Commission stated in an SRM dated July 1, 2004 (ADAMS Accession No. ML041830412), that the NRC staff should determine an appropriate risk-informed alternative break size and remove breaks larger than this size from the design-basis event category. The Commission indicated that the proposed rule should be structured to allow operational as well as design changes and should include requirements for licensees to maintain capability to mitigate the full spectrum of LOCAs, up to the double-ended guillotine break (DEGB) of the largest reactor coolant system pipe. The Commission stated that the mitigation capabilities for beyond-design-basis events should be controlled by NRC requirements commensurate with the safety significance of these capabilities. The Commission also stated that LOCA frequencies should be periodically reevaluated and if LOCA frequencies increase, licensees may be required to restore the facility to its original design basis or make other compensating changes. For plant changes made in this manner, the backfit rule (10 CFR 50.109, "Backfitting") would not apply.

On March 29, 2005, in SECY-05-0052, "Proposed Rulemaking for 'Risk-Informed Changes to Loss-of-Coolant Accident Technical Requirements,'" the NRC staff provided a proposed rule to the Commission for its consideration. In an SRM dated July 29, 2005 (ADAMS Accession No. ML052100416), the Commission directed the NRC staff to publish the proposed rule for public comment after making certain changes.

On November 7, 2005, the NRC published the proposed rule in the *Federal Register* (FR) (70 FR 67598), with a comment period of 90 days. In response to two different stakeholder requests, the NRC extended the public comment period by 30 days until March 8, 2006. The NRC held a public workshop on February 16, 2006, to ensure before the comment period closed that stakeholders understood the NRC's intent and interpretation of the proposed rule. The NRC then held public meetings on June 28, 2006 and August 17, 2006 (ADAMS Accession Nos. ML061940138 and ML062360105, respectively), to discuss public comments. After evaluating public comments, the NRC completed draft final rule language that addressed nearly all commenter concerns.

On October 31 and November 1, 2006, the NRC staff met with the Advisory Committee on Reactor Safeguards (ACRS) to discuss the draft final rule. In a letter dated November 16, 2006, (ADAMS Accession No. ML063190465) ACRS provided its evaluation of the draft rule. ACRS recommended that the NRC not issue the rule in its current form and suggested numerous rule changes, primarily to increase the defense-in-depth provided for large pipe breaks.

The NRC staff evaluated the ACRS recommendations and, in SECY-07-0082, "Rulemaking to Make Risk-Informed Changes to Loss-of-Coolant Accident Technical Requirements; 10 CFR 50.46a, 'Alternative Acceptance Criteria for Emergency Core Cooling Systems for Light Water Nuclear Power Reactors,'" dated May 16, 2007 (ADAMS Accession No. ML070180692), sought additional guidance from the Commission on the both the priority of the rule and the issues raised by ACRS. In its SRM dated August 10, 2007 (ADAMS Accession No. ML072220595), the Commission approved NRC staff recommendations for a revised rule priority and its approach for addressing the ACRS concerns and completing the final rule.

Following the ACRS recommendations and the Commission's direction, the NRC staff modified the rule by making numerous substantive changes in the draft final rule. After considering the extent of these changes, the NRC decided to provide an additional opportunity for public stakeholders to review and submit comments on the revised rule language. Thus, the NRC published a supplemental proposed rule on August 10, 2009 (74 FR 40006). In response to an industry stakeholder request, the NRC extended the comment period for all stakeholders until January 22, 2010. The NRC evaluated public comments received on the supplemental proposed rule and prepared a draft final rule. This draft rule language was made publicly available on May 12, 2010, and posted on regulations.gov. The NRC held a public meeting on June 4, 2010, to discuss resolution of public comments and the draft final rule language with stakeholders. The staff prepared the final draft rule and discussed it in meetings with the ACRS subcommittee and full committee on September 22, and October 7, respectively. The ACRS provided its views on the rule to the Commission in a letter on October 20, 2010 (ADAMS Accession No. ML102850279).

ACRS Recommendations on Applying § 50.46a to New Reactor Designs

The NRC staff conducted its final briefings of the Advisory Committee on Reactor Safeguards (ACRS) subcommittee and full committee on September 22 and October 7, 2010, respectively. The ACRS provided a letter with its final recommendations on October 20, 2010. The letter concluded that, for operating reactors, the staff's draft final rule was an acceptable risk-informed alternative to the current regulations in Title 10 of the *Code of Federal Regulations* (10 CFR) Part 50.46. The letter then concluded that it is premature to extend § 50.46a to new reactor designs at this time. This recommendation was primarily based on the concern that new reactors are expected to have significantly different risk profiles from the current operating reactor fleet and that development of appropriate risk metrics and risk acceptance criteria for these designs is still in the conceptual stage. But the ACRS also recommended that if the Nuclear Regulatory Commission staff decides to include new reactors in the final rule, the allowable outage time for equipment needed to mitigate beyond-transition break size (TBS) loss-of-coolant accidents should be subject to an additional limitation to preclude a significant decrease in the level of safety provided by the new design. The staff's response to the ACRS recommendations regarding new reactors follows.

The draft final rule states in paragraph (c)(2) that an applicant for a construction permit, design approval, design certification, manufacturing license, or combined license or a holder of a design approval seeking to implement the requirements of § 50.46a shall demonstrate why the proposed reactor design is similar to the designs of reactors licensed before the effective date of the rule. That demonstration must include a recommendation for an appropriate TBS and a justification that the recommended TBS is consistent with the technical basis for the rule. Acceptance criteria in paragraph (c)(3)(vi) require that the TBS includes sufficient margin to provide assurance that, when considering the limited availability of data and the uncertainty in the estimation of loss of coolant accident frequency, the estimated frequency of breaks larger than the TBS for all initiators does not exceed 10^{-5} per year. Also, paragraph (f)(3)(iv) of the rule requires the new reactor applicants under 10 CFR Part 52 to supplement the allowable increases in core damage frequency and large early release frequency with an evaluation demonstrating that implementing the proposed plant changes will also not result in a significant decrease in the level of safety otherwise provided by the new reactor design.

Further, in the responses to public comments related to the application of § 50.46a to new reactor designs, the staff explains that if, in response to the staff's policy paper, SECY-10-0121, "Modifying the Risk-Informed Regulatory Guidance for New Reactors," dated September 14, 2010, the Commission directs the staff to promulgate guidance that describes new metrics to be used for new reactors, the staff will also make appropriate conforming changes § 50.46a by rulemaking.

The staff agrees with the final ACRS recommendation that if new reactor applicants under Part 52 are permitted to implement the requirements of § 50.46a, they must justify the allowable time for operating in configurations without a demonstrated capability to mitigate beyond-TBS pipe breaks to preclude a significant decrease in the level of safety provided by the new design. The staff has added a provision to paragraph (d)(5) of the rule to implement this ACRS recommendation.

With these additions, the staff believes that the requirements in the draft final rule and the clarifying provisions in its supporting documentation are sufficient to continue to recommend that the Commission apply the rule to new reactor designs. Should the Commission direct the staff, in response to SECY-10-0121, to adopt an approach other than the option (Option 2) recommended by the staff, the staff will respond appropriately.