

NUCLEAR REGULATORY COMMISSION

[NRC-2020-0262]

Proposed Evidence-Building and Evaluation Policy Statement

AGENCY: Nuclear Regulatory Commission.

ACTION: ~~Request for comment~~Policy statement; issuance.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is ~~requesting public comment on this proposed~~issuing an Evidence-Building and Evaluation Policy Statement that ~~presents~~describes the general standards that ~~will govern~~guide the NRC's ~~planning, conduct, and use~~"evidence-building" activities, consistent with the Foundations for Evidence-Based Policymaking Act of program evaluations2018. The policy statement is intended to provide agency personnel and stakeholders with a clear understanding of the expectations related to the NRC's ~~evaluation standards~~that standards for evidence-building activities, which includes analyses, research, assessments, and evaluations performed by the agency for programmatic, operational, regulatory, and policy decision making. These standards include rigor, relevance and utility, transparency, collaboration, independence and objectivity, and ethics.

DATES: This policy statement is effective on [INSERT date of publication in the Federal Register].

ADDRESSES: Please refer to Docket ID NRC-2020-0262 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:

~~**DATES:** Submit comments by **[INSERT DATE 30 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER]**. Comments received after this date will be considered if it is practical to do so, but the Commission is able to ensure consideration only for comments received before this date.~~

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

- **Federal Rulemaking Web Site:** Go to <https://www.regulations.gov> and search for Docket ID NRC-2020-0262. Address questions about NRC dockets to Dawn Forder; telephone: 301-415-3407; e-mail: Dawn.Forder@nrc.gov. For technical questions contact the individual listed in the FOR FURTHER INFORMATION CONTACT section of this document.

- ~~**E-mail comments to:** Rulemaking.Comments@nrc.gov. If you do not receive an automatic e-mail reply confirming receipt, then contact us at 301-415-1677.~~

~~**Mail comments to:** Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, ATTN: Rulemakings and Adjudications Staff. additional direction on obtaining information and submitting comments, see "Obtaining Information and Submitting Comments" in the SUPPLEMENTARY INFORMATION section of this document.~~

~~**FOR FURTHER INFORMATION CONTACT:** Matthew Meyer, Office of the Executive Director for Operations, U.S. Nuclear Regulatory Commission, Washington DC 20555-0001, telephone: 301-415-6198, e-mail: Matthew.Meyer@nrc.gov.~~

~~SUPPLEMENTARY INFORMATION:~~

~~I.—Obtaining Information and Submitting Comments~~

~~A.—Obtaining Information~~

~~Please refer to Docket ID NRC-2020-0262 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 Web Site:** Go to <https://www.regulations.gov> and search for Docket ID NRC-2020-0262.~~

- **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 “[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, at 301-415-4737, or by e-mail to pdr.resource@nrc.gov. The ~~proposed~~final Evidence-Building and Evaluation Policy Statement, in its entirety, is ~~available in ADAMS under Accession number ML20268A811~~in the attachment to this document.

- **Attention:** The Public Document Room (PDR), where you may examine and order copies of public documents is currently closed. You may submit your request to the PDR via e-mail 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: Matthew Meyer, Office of the Executive Director for Operations, U.S. Nuclear Regulatory Commission, Washington DC 20555-0001, telephone: 301-415-6198, e-mail: Matthew.Meyer@nrc.gov.

SUPPLEMENTARY INFORMATION:

B. Submitting Comments

~~Please include Docket ID NRC-2020-0262 in your comment submission.~~

~~The NRC cautions you not to include identifying or contact information that you do not want to be publicly disclosed in your comment submission. The NRC will post all comment submissions at <https://www.regulations.gov> as well as enter the comment submissions into ADAMS. The NRC does not routinely edit comment submissions to remove identifying or contact information.~~

~~If you are requesting or aggregating comments from other persons for submission to the NRC, you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that the NRC does not routinely edit comment submissions to remove such information before making the comment submissions available to the public or entering the comment into ADAMS.~~

III. Background

The Foundations for Evidence-Based Policymaking Act of 2018 (“Evidence Act”) became law on January 14, 2019 (Public Law 115-435), to enhance evidence-building activities, make data more accessible, and strengthen privacy protections.¹ “[T]he Evidence Act creates a new paradigm by calling on agencies to significantly rethink how they currently plan and organize evidence-building, data management, and data access functions to ensure an integrated and direct connection to data and evidence needs.”²

The Evidence Act requires each agency to name an Evaluation Officer. At the NRC, the Director of the Office of Nuclear Regulatory Research holds this position and must “establish and implement an agency evaluation policy” to fulfill a primary function of this position.³ The agency evaluation policy “should guide the agency’s activities throughout the evaluation lifecycle.”⁴ ~~Evaluation activities include “developing and coordinating multi-year Learning Agendas, establishing Annual Evaluation Plans, planning and managing or conducting specific evaluations, summarizing evaluation findings for particular programs or policies, supporting other offices within an agency to interpret evaluation findings, and bringing evaluation-related evidence to bear in decision-making.”~~⁵ ~~In directing these activities, “the Evidence Act creates a new paradigm by calling on agencies to significantly rethink how they currently plan and organize evidence building, data management, and data access functions to ensure an integrated and direct connection to data and evidence needs.”~~⁶

¹ Pub. L. No. 115-435, 132 Stat 5529 (2019).

² Office of Management and Budget, M-19-23, “Phase 1 Implementation of the Foundations for Evidence-Based Policymaking Act of 2018: Learning Agendas, Personnel, and Planning Guidance,” 2 (July 10, 2019).

³ 5 U.S.C. § 313(d)(3).

⁴ Office of Management and Budget, M-20-12, “Phase 4 Implementation of the Foundations for Evidence-Based Policymaking Act of 2018: Program Evaluation Standards and Practices,” Appendix C (March 10, 2020) (M-20-12).

⁵ Id. at Appendix A.

⁶ ~~Office of Management and Budget, M-19-23, “Phase 1 Implementation of the Foundations for Evidence-Based Policymaking Act of 2018: Learning Agendas, Personnel, and Planning Guidance,” 2 (July 10, 2019).~~

The Office of Management and Budget (OMB) has provided guidance to agencies on establishing an agency evaluation policy based on “approaches that Federal agencies have found useful.”⁷ This guidance includes “[e]nsuring that the agency evaluation policy incorporates the evaluation standards” recommended by OMB.⁸ OMB developed these evaluation standards through an interagency council that “reviewed an extensive list of source documents to identify widely accepted standards for evaluation.”⁹ The interagency council identified the following evaluation standards: relevance and utility, rigor, independence and objectivity, transparency, and ethics.¹⁰

The Evidence Act focuses on the importance of sound evidence-building, which includes evaluation, to make informed evidence-based decisions. The evaluation standards developed by the interagency council, including an additional standard developed by the NRC (collaboration), are applicable to all of the NRC’s evidence-building activities.

Historically, the NRC has relied on high-quality evidence ~~for its environmental and safety evaluations of civilian applications to utilize nuclear technologies.~~¹⁴ ~~Frequently, the agency has obtained such evidence~~ from external entities or through its own capacity, ~~largely centered in the Office of Nuclear Regulatory Research.~~¹² ~~In undertaking these activities, the NRC has been guided by its own Principles of Good Regulation: independence, efficiency, clarity, reliability, and openness.~~¹³ In recent years the agency has begun evidence-building activities to support licensing new or novel nuclear technologies, including advanced, non-light water reactor designs; accident

⁷ M-20-12, Appendix C.

⁸ *Id.*

⁹ *Id.* at 2.

¹⁰ *Id.* at 3-5.

¹⁴ ~~Nuclear Regulatory Commission, NUREG 1350, 2019-2020 Information Digest, at 4-5 (August, 2019).~~

¹² ~~*Id.* at 10.~~

¹³ ~~*Id.* at 3.~~

tolerant nuclear fuel; and digital instrumentation and controls.¹⁴ Additionally, the NRC has increasingly sought to rely on evidence-based metrics to improve internal agency performance including budgeting and financial management.¹⁵ To develop the following evidence-building and evaluation policy statement, the NRC sought to enhance its existing evidence-building activities through the activities directed in the Evidence Act. The NRC envisions that this approach will strengthen the agency's oversight of existing uses of nuclear technology, enhance the agency's readiness to license and regulate new and novel nuclear technologies, and further the NRC's ongoing efforts to improve its internal processes.

II. Public Comments ~~III. Proposed Evaluation Policy Statement~~

The NRC published the Proposed Evaluation Policy Statement in the Federal Register for a 30-day comment period on December 8, 2020 (85 FR 79042). The NRC received a total of nine public comments.

These comments were generally supportive of the policy statement and the NRC's commitment to ensuring that its regulatory decisions are supported with evidence and sound technical bases. However, commenters also generally requested that the NRC clarify the applicability of the policy statement to evidence-building activities other than "evaluation" as that term is defined in the Evidence Act (5 U.S.C. § 311(3)), such as licensing, inspections, rulemaking, generic communications, and other regulatory activities including backfitting analyses, environmental reviews performed under the National Environmental Policy Act). The NRC agrees that additional clarity is warranted.

¹⁴ ~~*Id.* at 4.~~ Nuclear Regulatory Commission, NUREG-1350, 2019-2020 Information Digest, at 4 (August 2019).

¹⁵ ~~*Id.* at 7.~~

and has made revisions to the policy statement to make clear that the general standards articulated in the policy statement apply to all agency “evidence-building” activities. This includes not only “evaluations” conducted to review the effectiveness and efficiency of NRC programs, policies, and organizations, but other types of evidence-building such as regulatory analyses, compliance analyses, and performance assessments. A complete table of the comments received on the draft policy statement and NRC staff responses to those comments is available at ADAMS Accession No. **ML21XXXXXX**.

III. Procedural Requirements

Congressional Review Act

This policy statement is not a rule as defined in the Congressional Review Act (5 U.S.C. 801-808).

Paperwork Reduction Act

This Policy Statement does not contain new or amended information collection requirements and, therefore, is not subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.).

The text of the Evidence-Building and Evaluation Policy statement is attached.

IV. Specific Request for Comments

~~The NRC is interested in obtaining feedback from stakeholders on the proposed Evaluation Policy Statement. The focus of this request is to gather information that will permit the NRC staff to develop the final Evaluation Policy Statement. The NRC is particularly interested in comments that address the extent to which the proposed Evaluation Policy Statement will facilitate the agency’s review of new and novel~~

~~technologies and the agency's efforts to improve internal performance.~~

Dated: Month Day, 2021.

For the Nuclear Regulatory Commission.

Annette L. Vietti-Cook,
Secretary of the Commission.

Attachment

Evidence-Building and Evaluation Policy Statement

The purpose of this Evidence-Building and Evaluation Policy Statement is to ~~present~~describe the general standards that ~~will~~ govern the NRC's planning and conduct of evidence-building. Evidence-building includes activities such as analysis, assessment, research, and program evaluations (evaluations). ~~This policy statement is required by the~~evaluation (evaluation).¹⁶ The Foundations for Evidence-Based Policymaking Act of 2018 ~~and is a commitment to~~requires an agency evaluation policy to guide the agency's evaluation activities throughout the evaluation lifecycle. The NRC is committed to using evidence and scientific methods when ~~conducting evaluations to make informed~~making evidence-based decisions.

¹⁶ The Evidence Act defines "evaluation" as "an assessment using systematic data collection and analysis of one or more programs, policies, and organizations intended to assess their effectiveness and efficiency" (5 U.S.C. § 311(3)). "Evaluation can look beyond the program, policy, or organizational level to include assessment of projects or interventions within a program" (OMB M-20-12).

The NRC is ~~a learning and an~~ evidence-based organization, with a culture of continuous learning and improvement. The NRC's ~~evaluations are used to make informed decisions, are based on~~evidence-building activities use objective, technical analyses and assessments ~~of available information and to make~~ documented evidence-based decisions with ~~an~~ explicitly stated rationale. Furthermore, the NRC commits to implementing ~~evaluation~~the standards of rigor; relevance and utility; transparency; collaboration; independence and objectivity; and ethics in the conduct of its ~~evaluations, evidence-building activities.~~ This policy statement ~~presents the NRC's evaluation~~describes these general standards.

The Commission, as a collegial body, formulates policies, develops regulations governing nuclear reactor and nuclear material safety, issues orders to licensees, and adjudicates legal matters. The collegial decision-making process results in actions reflecting the collective judgment of a group rather than an individual, aided by professional and administrative staff and advisory committees, such as the Advisory Committee on Reactor Safeguards. Strict requirements govern the admission and consideration of "evidence" when the Commission acts in its adjudicatory capacity. This policy ~~is intended to apply~~applies to the NRC's non-adjudicatory functions.¹⁷

The NRC's Principles of Good Regulation, which include independence, efficiency, clarity, reliability, and openness, have guided the agency's regulatory activities and decisions using evidence and scientific methods. The principles focus on meeting the agency's important safety and security mission while appropriately considering the interests of stakeholders, including licensees; State, local, and Tribal governments; nongovernmental organizations; and the public. The agency's openness

¹⁷ This policy does not apply to the admission and consideration of evidence when the Commission acts in its adjudicatory capacity. The NRC's rules of practice and procedure in 10 CFR Part 2 govern that process.

principle explicitly recognizes that the public must be informed about and have an opportunity to participate in the regulatory process.

Evidence-building ~~and evaluation are~~ used to inform agency activities and actions, such as licensing, oversight, budgeting, program improvement, accountability, management, rulemaking, guidance development, and policy development. The emphasis on evidence is meant to support innovation, improvement, and learning. ~~The NRC uses many types~~ Examples of ~~evidence, including evaluations. Other evidence types include, but are not limited to, descriptive studies, performance measurements, financial and cost data, and program administrative data.~~ The ~~how the~~ NRC carries out evidence-building ~~and evaluation activities to~~ include (1) ~~identify, evaluate~~ identifying, evaluating, and ~~resolve~~ resolving safety issues; (2) ~~ensure~~ ensuring that an independent technical basis exists to review licensee submittals; (3) ~~evaluate~~ evaluating operating experience and results of risk assessments for safety implications; ~~and~~ (4) ~~support~~ supporting the development and use of risk-informed regulatory approaches; (5) conducting research with scientific integrity; and (6) ensuring that licensing and oversight findings are supported by evidence.

~~Evaluation~~ Evidence-Building Standards

The NRC ~~staff will use~~ uses the following ~~evaluation~~ standards when conducting ~~evaluations~~ evidence-building activities.

1. Rigor - The NRC is committed to using rigorous ~~evaluation~~ evidence-building methods by qualified ~~evaluators~~ staff with relevant education, skills, and experience to ensure ~~evaluations~~ findings are appropriate and feasible within statutory, budgetary, and other constraints.

Rigorous ~~evaluations require~~evidence-building requires inferences about cause and effect to be well founded (internal validity); clarity about the populations, settings, or circumstances to which results can be generalized (external validity); and the use of measures that accurately capture the intended information (measurement reliability and validity). The NRC's ~~evaluation~~evidence-building activities are conducted by qualified staff with relevant education, skills, and experience for the methods undertaken. The NRC's ~~evaluation~~evidence-building activities use appropriate designs and methods that adhere to widely accepted scientific principles to answer key questions while balancing goals, scale, timeline, feasibility, and available resources. Additionally, the NRC's Information Quality Program¹⁸ ensures that all information relied on by the NRC is subject to rigorous quality standards.

2. Relevance and Utility - The NRC ~~will ensure~~ensures that ~~evaluations~~evidence-building activities are relevant and provide useful findings to inform agency activities ~~and~~, actions , and stakeholders.

The NRC performs ~~evaluation~~evidence-building activities to examine questions of importance and serve the information needs of stakeholders. The ~~NRC's evaluations~~presentNRC presents findings that are clear, concise, actionable, and available within a timeline that is appropriate to the questions under consideration. The NRC's ~~evaluation~~evidence-building priorities consider legislative requirements; the NRC's strategic ~~safety and security~~ goals, objectives, and strategies; and the interests and views of stakeholders.

¹⁸ Management Directive 3.17, "Information Quality Program," ensures that peer review is conducted on all influential scientific information and highly influential scientific assessment that the agency intends to disseminate.

3. Transparency – The NRC is committed to conducting ~~evaluation~~evidence-building activities in an open and transparent manner, which keeps stakeholders informed ~~of the agency's evaluation activities~~.

~~NRC~~The NRC's evidence-building activities ~~will be~~are conducted openly and the public must be informed about and have an opportunity to participate in the NRC's regulatory process. As a regulator, the NRC ~~will listen~~listens to, ~~respect~~respects, and ~~analyze~~analyzes different views from its stakeholders. The NRC ~~will also ensure~~ensures open channels of communication are maintained between ~~the NRC~~internal and external stakeholders, including Congress, other government agencies, licensees, nongovernmental organizations, individual members of the public, and international and domestic nuclear communities. The NRC takes reasonable ~~efforts~~measures to make all information, including information about the NRC's ~~evaluation~~evidence-building activities (including their purpose, objectives, design, findings, and ~~evaluation~~ methods), broadly available and accessible. The NRC releases public ~~evaluation~~evidence-building findings in a timely manner and archives the ~~evaluation~~ data for secondary use by stakeholders, as appropriate.

4. Collaboration – The NRC is committed to working collaboratively when conducting ~~evaluation~~evidence-building activities and draws on the expertise of subject matter experts to ensure diversity in perspectives.

The NRC fosters a collaborative work environment that encourages diverse views, alternative approaches, critical thinking, creative problem solving, unbiased ~~evaluations~~findings, and honest feedback. The NRC emphasizes trust, respect, and open communication to promote a positive work environment that maximizes the potential of all individuals, which improves evidence building and evaluation activities. A collaborative environment leverages expertise from subject matter experts and enables

peer reviews to ensure rigorous ~~evaluations~~evidence-building. The NRC~~also~~ conducts research and collaborates with organizations that develop consensus standards to improve data and methods used in risk analysis. The NRC collaborates with national laboratories, Agreement States, other Federal agencies, universities, and international organizations.

5. Independence and Objectivity – As an independent Federal agency, the NRC is committed to conducting ~~evaluation~~evidence-building activities that are independent and based on objective assessments and analysis of all relevant information.

The NRC was established as an independent agency to regulate civilian uses of radioactive material. The NRC's ~~evaluations will be~~ evidence-building activities are independent and objective to maintain credibility ~~and integrity~~. The implementation of ~~evaluation~~evidence-building activities, including the selection and ~~function~~assignment of the ~~evaluators~~staff, should be appropriately insulated from factors that may affect ~~their~~ objectivity, impartiality, and professional judgment. ~~Evaluations are~~ Evidence-building is inclusive and ~~seek~~the NRC seeks diverse ~~participation~~input from stakeholders in setting ~~evaluation~~ priorities, identifying ~~evaluation~~ questions, and assessing the implications of findings. The NRC strives for objectivity in the planning and conduct of ~~evaluation~~evidence-building activities.

6. Ethics – The NRC is committed to conducting ~~evaluation~~evidence-building activities that adhere to Government-wide ethics standards to protect the public and maintain public trust.

The NRC's ~~evaluation~~evidence-building activities comply with relevant legal requirements and are conducted in a manner that is free from conflicts of interest, undue influence, ~~and the appearance of bias~~, and ~~that~~ safeguards the dignity, rights, safety, and privacy of participants. The NRC complies with Governmentwide ethics standards

contained in Federal statutes and regulations, which are intended to ensure that every citizen can have confidence in the integrity of the Federal Government.