environmental assessment. The exemption from the requirement to have an STA in place is eligible for categorical exclusion under 10 CFR 51.22(c)(25)(vi)(H), which provides that exemptions from surety, insurance, or indemnification requirements are categorically excluded if the exemption would not result in any significant hazards consideration; change or increase in the amount of any offsite effluents; increase in individual or cumulative public or occupational radiation exposure; construction impacts; or increase in the potential for or consequence from radiological accidents. The NRC staff finds that the STA exemption involves surety, insurance and/or indemnity requirements and that granting Lost Creek this temporary exemption from the requirement of establishing a standby trust arrangement would not result in any significant hazards or increases in offsite effluents, radiation exposure, construction impacts, or potential radiological accidents. Therefore, an environmental assessment is not required.

IV. Conclusions

Accordingly, the NRC has determined that, pursuant to 10 CFR 40.14(a), the proposed temporary exemption is authorized by law, will not present an undue risk to the public health and safety, is consistent with the common defense and security, and is in the public interest. NRC hereby grants Lost Creek ISR, LLC an exemption from the requirement in 10 CFR part 40, Appendix A, Criterion 9 to set up a standby trust to receive funds in the event the NRC or the State regulatory agency exercises is right to collect the surety. This exemption will expire on February 10, 2015, for the Lost Creek ISR Project. At that time, Lost Creek will be required to ensure compliance with the STA requirements.

Dated at Rockville, Maryland, this 16th day of July 2015.

For the Nuclear Regulatory Commission.

Andrew Persinko,

Deputy Director, Division of Decommissioning, Uranium Recovery and Environmental Programs, Office of Nuclear Material Safety and Safeguards.

[FR Doc. 2015–18236 Filed 7–23–15; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2015–0172]

Clarification of Reporting Requirements

AGENCY: Nuclear Regulatory Commission.

ACTION: Draft regulatory issue summary; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is seeking public comment on a draft regulatory issue summary (RIS). This draft RIS clarifies reporting requirements related to analyses of emergency core cooling system performance and how these reporting requirements apply to applicants for and holders of nuclear power reactor operating licenses, construction permits, combined licenses, standard design approvals, and manufacturing licenses, and applicants for standard design certifications.

DATES: Submit comments by September 22, 2015. 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 (unless this document describes a different method for submitting comments on a specific subject):

- Federal Rulemaking Web site: Go to *http://www.regulations.gov* and search for Docket ID NRC–2015–0172. Address questions about NRC dockets to Carol Gallagher; telephone: 301–415–3463; email: *Carol.Gallagher@nrc.gov.* For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- Mail comments to: Cindy Bladey, Office of Administration, Mail Stop: OWFN–12–H08, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

For 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: Alexandra Popova, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, DC 20555–001; telephone: 301–415–2876, email: *Alexandra.Popova@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC–2015–0172 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 *http://www.regulations.gov* and search for Docket ID NRC–2015–0172.
- NRC's Agencywide Documents Access and Management System (ADAMS): You may obtain publicly-available documents online in the ADAMS Public Documents collection at *http://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.* The draft RIS is available in ADAMS under Accession No. ML15057A346.
- NRC's PDR: You may examine and purchase copies of public documents at the NRC's PDR, Room O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

B. Submitting Comments

Please include Docket ID NRC–2015–0172 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 *http://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, then 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.

II. Background

The NRC is issuing this draft RIS to clarify the reporting requirements under part 50.46 of Title 10 of the *Code of Federal Regulations* (10 CFR), ''Acceptance Criteria for Emergency

Core Cooling Systems for Light-Water Nuclear Power Reactors.'' Specifically, 10 CFR 50.46(a)(3) requires licensees to report to the NRC each change to or error discovered in an acceptable emergency core cooling system (ECCS) evaluation model, or in its application, and its estimated effect on the limiting ECCS analysis.

The NRC issues a RIS to communicate with stakeholders on a broad range of matters. This may include communicating and clarifying NRC technical or policy positions on regulatory matters that have not been communicated to or are not broadly understood by the nuclear industry.

Proposed Action

The NRC is requesting public comments on the draft RIS. The NRC staff will make a final determination regarding issuance of the RIS after it considers any public comments received in response to this request.

Dated at Rockville, Maryland, this 14th day of July 2015.

For the Nuclear Regulatory Commission.

Sheldon D. Stuchell,

Chief, Generic Communications Branch, Division of Policy and Rulemaking, Office of Nuclear Reactor Regulation.

[FR Doc. 2015–18113 Filed 7–23–15; 8:45 am]

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REAGAN-UDALL FOUNDATION FOR THE FOOD AND DRUG ADMINISTRATION

Request for Steering Committee Nominations

ACTION: Request for nominations to the Steering Committee for the Foundation's PredicTox project.

SUMMARY: The Reagan-Udall Foundation (RUF) for the Food and Drug Administration (FDA), which was created by Title VI of the Food and Drug Amendments of 2007, is requesting nominations for its PredicTox Steering Committee. The Steering Committee will provide oversight and guidance for the PredicTox project, and will report to the Reagan-Udall Foundation for the FDA's Board of Directors.

DATES: All nominations must be submitted to the Reagan-Udall Foundation for the FDA by August 28, 2015. The PredicTox Steering Committee members will be selected by the Reagan-Udall Foundation for the FDA's Board of Directors; those selected will be notified by September 30 regarding the Board's decision. See the **SUPPLEMENTARY INFORMATION** section for Steering Committee responsibilities, selection criteria and nomination instructions.

ADDRESSES: The Reagan-Udall Foundation for the FDA is located at 1025 Connecticut Ave. NW., Suite 1000, Washington, DC 20036.

FOR FURTHER INFORMATION CONTACT: Questions should be sent to The Reagan-Udall Foundation for the FDA, 202–828–1205, *PredicTox@ReaganUdall.org.*

SUPPLEMENTARY INFORMATION:

I. Background

The Reagan-Udall Foundation for the FDA (the Foundation) is an independent 501(c)(3) not-for-profit organization created by Congress to advance the mission of FDA to modernize medical, veterinary, food, food ingredient, and cosmetic product development; accelerate innovation; and enhance product safety. The Foundation acts as a neutral third party to establish novel, scientific collaborations. With the ultimate goal of improving public health, the Foundation provides a unique opportunity for different sectors (FDA, patient groups, academia, other government entities, and industry) to work together in a transparent way to create exciting new research projects to advance regulatory science.

PredicTox is a public-private partnership led by the Foundation, which brings together multiple stakeholder groups to leverage collective knowledge, technical expertise, data, funding, and other resources to explore systems pharmacology approaches to better understand and predict adverse events (AEs). Developing new tools and approaches for mechanism-based drug safety assessment and prediction is a priority for the FDA, as highlighted in the Agency's 2011 *Strategic Plan for Advancing Regulatory Science.* This project aims to harness scientific and technological knowledge, data and computational capacity across various sectors and disciplines to develop and apply systems-based approaches and multi-scales models to drug safety assessment in a coordinated manner.

While systems-based approaches can be applied to the development of predictive models for any class of drug or AE, the PredicTox pilot seeks to first provide a proof of concept pilot by focusing on large and small molecule tyrosine kinase inhibitors (TKIs) and cardiac AEs, specifically left ventricular dysfunction. TKIs are a rapidly growing treatment for oncology and select other therapeutic areas, making them an area of intense importance for patients, the FDA, and pharmaceutical manufacturers. Learnings from the PredicTox pilot will then be applied to other drug classes and/or other toxicities.

The primary objective of PredicTox is to advance systems-based science and tools necessary to support mechanism-based drug safety assessment and prediction. To accomplish this objective, the PredicTox pilot project will be conducted in an iterative, phased manner over the course of several years. The first phase will center on building and populating a knowledge management platform for molecular data, preclinical in vivo pharmacologic and toxicologic data as well as clinical data from both public and private sources.

The PredicTox platform will enable integration, mining, and analysis of highly heterogeneous data not typically combined. Future phases of the project will focus on data mining and development of analytic and visualization tools along with development of multi-scale predictive models capable of linking events at the molecular level with events at the clinical level (AEs) for improved safety assessment. For additional project information, see the Reagan-Udall Foundation Web site.

II. PredicTox Steering Committee Roles and Responsibilities

The PredicTox Steering Committee will provide guidance on the operation of PredicTox, in conjunction with the RUF Board, project staff, and others. The Steering Committee will provide overall programmatic oversight to ensure a focus on the long-term vision of the project, while the Scientific Advisory Committee will provide highly specialized technical expertise.

The PredicTox Steering Committee will be charged with several responsibilities, including:

- Reviewing and approving the PredicTox Charter
- Monitoring adherence to the PredicTox mission and operational principles in the Charter
- Developing metrics and evaluating the project at various milestones
- Reviewing and approving the PredicTox Research Agenda
- Reviewing proposals and contracts submitted to the project

The PredicTox Steering Committee Chair must be able to complete additional responsibilities, including:

- Defining the Steering Committee's meeting agendas and facilitating those meetings
- Recommending for termination, as necessary, any PredicTox Steering Committee members demonstrating dereliction of duties as specified in the PredicTox Charter