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]

BILLING CODE 7590–01–P

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

• Other responsibilities as required upon implementation of PredicTox

A full list of Steering Committee responsibilities, as well as responsibilities of the Chair, may be found on the Reagan-Udall Foundation Web site.

III. PredicTox Steering Committee Positions and Selection Criteria

RUF is seeking nominations for 7 voting members of the PredicTox Steering Committee, comprised of the following 5 categories:

• Patient Advocate: 1 member
• Pharmaceutical sector: 2 members
• Technology sector: 1 member
• Academia/Research Institute: 2 members
• At Large: 1 member

The Steering Committee will also have 2 members from the FDA (appointed by the FDA) and 1 member from the National Institutes of Health (appointed by the National Institutes of Health). These 3 individuals will be non-voting members.

Nominees for the voting positions will be evaluated by the RUF Board based on the following required criteria for each of the 7 positions:

• Ability to complete Steering Committee responsibilities, listed above
• Currently employed by/volunteering for stakeholder field (*e.g.,* pharmaceutical, academia, patient advocate, etc.) with several years of relevant experience
• Leading expert in their relevant field (based on position, publications, or other experience)
• Working knowledge of at least one of the following areas: Risk assessment; drug safety profiling; pharmacology or systems pharmacology; toxicology or systems toxicology; biostatistics; cardiology; oncology; bioinformatics; ontology; multi-scale modeling; knowledge management platforms; software development; or data sharing
• Prior experience serving on a related or similar governance body
• Understanding of the landscape and the impact on the stakeholder group they are representing with their seat

IV. Terms of Service

• The PredicTox Steering Committee meets in-person at least twice per year, with teleconferences in between meetings as deemed necessary by the Chair
• Members will serve two or three year, staggered terms, as determined by the RUF Board
• Members do not receive compensation from RUF
• Members can be reimbursed by RUF for actual and reasonable expenses incurred in support of PredicTox in accordance with applicable law and their specific institutional policies
• Members are subject to the PredicTox Conflict of Interest policies (additional information can be accessed on the Reagan-Udall Foundation Web site)

V. Nomination Instructions

• The nomination form can be accessed on the Reagan-Udall Foundation Web site
• Individuals may be nominated for 1 or more of the 5 stakeholder categories
• Individuals may nominate themselves or others
• The nomination deadline is August 28, 2015.

Dated: July 20, 2015.

Jane Reese-Coulbourne,

Executive Director, Reagan-Udall Foundation for the FDA.

[FR Doc. 2015–18123 Filed 7–23–15; 8:45 am]

BILLING CODE 4164–04–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–75491; File No. SR–CBOE–2015–064]

Self-Regulatory Organizations; Chicago Board Options Exchange, Incorporated; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change Relating to the Options Regulatory Fee

July 20, 2015.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934,[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on July 10, 2015, Chicago Board Options Exchange, Incorporated filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

Chicago Board Options Exchange, Incorporated (the ''Exchange'' or ''CBOE'') proposes to amend the Options Regulatory Fee. The text of the proposed rule change is available on the Exchange's Web site (*http://www.cboe.com/AboutCBOE/CBOELegalRegulatoryHome.aspx*), at the Exchange's Office of the Secretary, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to decrease the Options Regulatory Fee (''ORF'') from $.0086 to $.0064 per contract in order to help ensure that revenue collected from the ORF, in combination with other regulatory fees and fines, does not exceed the Exchange's total regulatory costs. The proposed fee change would be operative on August 1, 2015.

The ORF is assessed by the Exchange to each Trading Permit Holder for all options transactions executed or cleared by the Trading Permit Holder that are cleared by The Options Clearing Corporation (''OCC'') in the customer range (*i.e.,* transactions that clear in a customer account at OCC) regardless of the exchange on which the transaction occurs.[3] In other words, the Exchange imposes the ORF on all customer-range transactions executed by a Trading Permit Holder, even if the transactions do not take place on the Exchange. The ORF also is charged for transactions that are not executed by a Trading Permit Holder but are ultimately cleared by a Trading Permit Holder. In the case where a Trading Permit Holder executes a transaction and a different Trading Permit Holder clears the transaction, the ORF is assessed to the Trading Permit Holder who executed the transaction. In the case where a non-Trading Permit Holder executes a transaction and a Trading Permit Holder clears the transaction, the ORF is assessed to the Trading Permit Holder who clears the

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] The ORF also applies to customer-range transactions executed during Extended Trading Hours.