January 25, 2005

MEMORANDUM TO: Michael T. Lesar, Chief
Rules Review and Directives Branch
Division of Administrative Services
Office of Administration

FROM: Charles E. Ader, Director **/RA/**
Division of Risk Analysis and Applications
Office of Nuclear Regulatory Research

SUBJECT: NOTICE OF ISSUANCE, AVAILABILITY TO PROVIDE WRITTEN COMMENTS, AND NOTICE OF PUBLIC WORKSHOP FOR DRAFT NUREG 3-2005, "REGULATORY STRUCTURE FOR NEW PLANT LICENSING, PART 1: TECHNOLOGY-NEUTRAL FRAMEWORK"

Attached please find one signed original, four copies, and an electronic version on a 3.5-inch diskette of the subject *Federal Register Notice* for transmittal to the Office of the Federal Register for publication.

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Please note that this Notice requires the insertion of a date which written comments should be received. Insertion points are indicated in bold type on page 2 of the Notice.

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DATE	1/21/05	1/ 20/05	1 /14/05	1/18/05

January 14, 2005

AUTHORIZATION FOR DRAFT NUREG 3-2005

Draft NUREG 3-2005, "Regulatory Structure for New Plant Licensing, Part 1: Technology-Neutral Framework." Is to be printed, announced in the *Federal Register Notice* on the NRC external web site and distributed to power reactor licensees.

Charles E. Ader, Director
Division Risk Analysis and Applications
Office of Nuclear Regulatory Research

[7590-01-P]

NUCLEAR REGULATORY COMMISSION

Workshop on Regulatory Structure for New Plant Licensing, Part 1:

Technology-Neutral Framework

The U.S. Nuclear Regulatory Commission (NRC) has issued a working draft of a NUREG report "Regulatory Structure for New Plant Licensing, Part 1: Technology-Neutral Framework" (draft NUREG-3-2005) for public review and comment. The purpose of this working draft NUREG is to provide guidance to the NRC staff on an approach, scope, and acceptance criteria that could be used to develop a technology-neutral set of requirements for future plant licensing. At the present time, the material contained in the working draft NUREG is preliminary and does not represent a final staff position, but rather is an interim product issued for the purpose of engaging stakeholders early in the development of the document and to support a workshop to be held in March 2005. As such, certain sections of this document are incomplete and are planned to be completed following receipt of initial stakeholder feedback. It is the staff's intent to complete this document in late 2005 and issue it as a final draft for stakeholder review and comment.

The work represented in this document is, however, considered sufficiently developed to illustrate one possible way to establish a technology-neutral approach to future plant licensing and to identify the key technical and policy issues which must be addressed; accordingly, it can serve as a useful vehicle for engaging stakeholders and facilitating discussion.

The NRC staff has issued a working draft NUREG on "Regulatory Structure for New Plant Licensing, Part 1: Technology- Neutral Framework." The NRC staff requests comments within 90 days from the issuing date of this *Federal Register Notice*. Comments may be accompanied by relevant information or supporting data. Please mention draft NUREG-3-2005

in the subject line of your comments. You may submit comments by any one of the following methods.

Mail comments to: Rules and Directives Branch, Office of Administration, U.S. Nuclear Regulatory Commission, Washington DC 20555-0001.

Email comments to: NRCREP@nrc.gov. You may also submit comments via the NRC's rulemaking web site at http://ruleforum.llnl.gov. Address questions about our rulemaking website to Carol Gallagher (301) 415-5905; email CAG@nrc.gov.

Hand deliver comments to: Rules and Directives Branch, Office of Administration, U.S. Nuclear Regulatory Commission at (301) 415-5144.

Requests for information about the draft NUREG may be directed to Mr. A. Singh at (301) 415-0250, email AXS3@nrc.gov.

Comments will be most helpful if received by **April 22, 2005.** Comments received after this date will be considered if it is practical to do so, but the NRC is able to ensure consideration only for comments received on or before this date.

The NRC intends to conduct a workshop on March 14-16, 2005, to help facilitate the review and comment process. This workshop will be held in the auditorium at NRC headquarters, 11545 Rockville Pike, Rockville, Maryland.

Please notify Mr. A. Singh at (301) 415-0250, email AXS3@nrc.gov, if you plan to attend the workshop so that you can be pre-registered. Pre-registration will help facilitate your entry into the NRC facility for the workshop. In addition, please arrive at NRC headquarters 45 minutes prior to the start of the workshop so that you have adequate time to be processed through security.

Please notify Mr. A. Singh at (301) 415-0250, email AXS3@nrc.gov, if you would like to make a formal presentation at the workshop. Once all the presenters have been identified, you

will be notified with the time allocated for your presentation.

BACKGROUND

The Commission, in its Policy Statement on Regulation of Advanced Nuclear Power Plants, stated its intention to “improve the licensing environments for advanced nuclear power reactors to minimize complexity and uncertainty in the regulatory process.” The staff noted in its Advanced Reactor Research Plan to the Commission, (SECY-03-0059, ML023310534) that a risk-informed regulatory structure applied to license and regulate new reactors, regardless of their technology, could enhance consistency and efficiency of NRC’s regulatory process across reactors with radically different concepts. As such, this new process, if implemented, could be available for use later in the decade.

The NRC’s past light-water reactor (LWR) experience, especially the recent efforts to risk-inform the regulations, has provided insight into the potential value of following a top-down approach for the development of a regulatory structure for a new generation of reactors. Such an approach could also facilitate the implementation of performance-based regulation, as well as ensure a greater degree of coherence among the resulting regulations for new reactors than found among current regulations.

The development of a technology-neutral regulatory structure will help ensure that a systematic approach is used during the development of the regulations that will govern the design, construction, and operation of new reactors. This structure will ensure uniformity, consistency, and defensibility in the development of the regulations, particularly when addressing the unique design and operational aspects of new reactors.

DISCUSSION

A working draft of NUREG-3-2005, “Regulatory Structure for New Plant Licensing, Part

1: Technology-Neutral Framework," has been issued for stakeholder review and comment. The objective of the regulatory structure for new plant licensing is to provide a technology-neutral approach to enhance the effectiveness and efficiency of new plant licensing in the longer term (beyond the advanced designs currently in the pre-application stage). This regulatory structure has four major parts:

(1) a technology-neutral framework

(2) a set of technology-neutral requirements

(3) a technology-specific framework

(4) technology-specific regulatory guides

Currently, only work related to Part 1 of the regulatory structure for new plant licensing, the technology-neutral framework, has proceeded. Work has not been initiated on the other three parts. The staff has done enough work to demonstrate the feasibility of developing a technology-neutral framework. The framework is a hierarchal structure that combines deterministic and probabilistic criteria for developing technology-neutral requirements to ensure the protection of the public health and safety. The framework contains criteria for developing—

- safety philosophy
- protective strategies
- risk, design, construction and operational objectives
- treatment of uncertainties
- process for defining scope of requirements
- performance-based concepts

For each of these items, the staff has developed preliminary "working" criteria that demonstrate the feasibility of a technology-neutral framework in sufficient detail to start soliciting stakeholder input. There are, however, difficult technical and policy issues associated with of these items that are being addressed by the staff that need to be resolved before the framework can be

completed and implemented. These issues will be discussed in detail at the workshop (see below).

WORKSHOP AGENDA

A final agenda will be provided at the workshop. The preliminary agenda is as follows:

Monday, March 14, 2005

- 8:30 am to 10:00 am — Introduction and NRC presentation (Overview of Regulatory Structure for New Plant Licensing, and Policy and Technical Issues)
- 10:00 am to 5:30 pm — Open discussion with stakeholders on policy and technical issues (Safety Philosophy, Protective Strategies, Risk Objectives, Design, Construction, Operational Objectives, Treatment of Uncertainties and Defense-in-Depth, Performance-Based Concepts)

Tuesday, March 15, 2005

- 8:30 am to 11:00 am — Open discussion with stakeholders on implementation and other issues (includes example of applying the framework)
- 12:15 pm to 5:30 pm — Breakout Sessions (Small, parallel group discussions on various policy and technical issues, to be identified)

Wednesday, March 16, 2005*

- 8:30 am to 12:30 pm — Specific comments on the working draft NUREG and formal stakeholder presentations

*Workshop may be extended into the afternoon if additional time is needed to accommodate stakeholder presentations.

POLICY AND TECHNICAL ISSUES

The staff is soliciting comments on the issues associated with development and implementation of the framework document. These issues include, but are not limited to, the following topics:

1. Safety Philosophy (Level of Safety)

An issue for Commission consideration with respect to developing a new regulatory structure is defining the goal in the technology-neutral requirements for achieving enhanced safety. The Advanced Reactor Policy states that the Commission "expects that advanced reactor designs will comply with the Commission's Safety Goal Policy" and that "advanced reactors will provide enhanced margins of safety." The framework proposes a safety philosophy that will define a level of safety that will meet the expectation of enhanced safety. In the framework, the staff proposes a safety philosophy directly tied to the Commission's 1986 Safety Goal Policy (51 FR 28044); that is, the staff proposes that the technology-neutral requirements be written to achieve the level of safety defined by the Safety Goal Policy Quantitative Health Objectives.

- Is it appropriate to use the Commission's Safety Goal Policy Quantitative Health Objectives (QHO) as the level of safety the technology-neutral regulations should be written to achieve? If not, what should be used?

2. Protective Strategies

Protective strategies are identified that define the safety fundamentals for safe nuclear power plant design, construction, and operation. They are the fundamental building blocks for developing technology-neutral requirements and regulations. Acceptable performance in these protective strategies provides reasonable assurance that the overall mission of adequate

protection of public health and safety is met. Moreover, the protective strategies go further, implicitly requiring a defense-in-depth approach that will ensure uncertainties in performance do not compromise achieving overall plant safety objectives.

- Is the process described for the development of a technology-neutral regulatory structure reasonable? Is it complete? Is the relationship between the different pieces of the framework understandable? If not, where is it not understandable?
- What is meant by each protective strategy? For example, Barrier Integrity protective strategy: what constitutes or defines barrier?
- Is the use of protective strategies a reasonable approach for defining high level safety functions? If not, what other approaches should be considered?
- Is the approach of using a deductive analysis of each protective strategy to identify technology-neutral requirements and performance-based measures reasonable?
- Are the protective strategies described in Chapter 3 reasonable? Are they complete? If not, what strategy is missing?
- Are the basic principles of a performance-based approach as presented in Chapter 3 sufficiently clear and reasonable? If not, where are they not clear or not reasonable?

3. Quantitative Risk Objectives and Criteria; and, Design, Construction and Operational Objectives and Criteria

The risk objectives and the design, construction, and operational objectives complement the protective strategies. The risk and design objectives lay out a parallel safety approach for meeting safety and risk goals for all facilities. This approach keeps worker risk and land contamination to acceptable levels, and sets specific design expectations that amount to defense-in-depth requirements at the design level.

- Is meeting a frequency/consequence (F-C) curve an appropriate way to achieve

enhanced safety for new reactors? If so, how should the F-C curve be interpreted? How could this interpretation be done on a practical basis? Should another approach be used? If so, what should it be?

- The TLRC (top level regulatory criteria) is another curve that represents exposure at the site boundary under various conditions. What are the advantages and disadvantages of these two curves?
- With respect to implementing the F-C curve, where and how should the consequence be evaluated? Evaluated at a particular site and its boundary? Averaged over all weather or for a conservatively defined weather?)
- Should the frequency-consequence curve shown in Figure 4-1 be expressed in terms of dose or curies released?
- Should the frequency-consequence curve be used as the acceptance criteria for all event sequences analyzed? If so, how should the cumulative effects of all event sequences be considered? Or, should the F-C curve frequency represent a cumulative frequency of all event sequences leading to a defined consequence?
- Can specific regions under the F-C curve be related to safety margins so as to facilitate implementation of safety decision-making?
- Are the ICRP (International Commission on Radiation Protection) guidelines the appropriate metrics to use for specifying radiological limits for new reactors? Should other guides be used? If so, what are they?
- Are the proposed technology-neutral risk metrics appropriate? If not, what should be used?
- Is the proposed use of 10 CFR Part 20 and GDC 19 of 10 CFR 50 Appendix A for worker protection appropriate? If not, what would be better?
- Is the proposed approach for protection of the environment adequate and appropriate?

Are there better alternatives?

- Are the objectives and issues identified in the discussion of construction objectives appropriate? Are they sufficiently complete? What additional considerations will be important for new reactor designs?
- Are the operational objectives appropriate? What issues are likely to be important for new reactors that are not discussed? Are any of the identified issues unnecessary for new reactors?

The Commission approved the use of probabilistic criteria for identification of events that must be considered in the design, for safety classification of Structures, Systems and Components (SSCs) and to replace the single failure criterion. The approach proposed in the framework involves identifying event sequence categories by frequency to define abnormal operational occurrences (AOOs), design basis accidents (DBAs), and beyond-design-basis events, classifying SSCs as either risk-significant or non-risk-significant based on the SSCs' quantified risk importance and criteria consistent with the work done in support of the 10 CFR 50.69 rulemaking, and replacing the single failure criterion with event sequences from the design-specific probabilistic risk assessment (PRA).

- Is the proposed approach for the selection of AOOs and DBAs reasonable? Should another approach be used? If so, what should it be? Are the acceptance criteria reasonable?
- Can a technology-neutral definition of accident prevention be developed? If so, what should it be? If not, what technology-specific definitions should be used?
- Should a risk-informed safety classification process build upon the risk metrics and process contained in 10 CFR 50.69? If not, what metrics and process should be used?
- What risk metrics and criteria are appropriate for non-LWR concepts (e.g., high temperature gas reactors) to address accident prevention, safety classification?

- How should acceptance criteria be set in consideration of uncertainties? Should they be set at a defined level of confidence; or should evaluation of uncertainty in both the challenge and the capability be required?

The Commission approved the use of scenario-specific source terms provided that the staff understands the fission product behavior and plant conditions and performance. In the framework, the staff used a flexible, performance-based approach to establish scenario-specific licensing source terms. The key features of this approach are that (1) Scenarios are to be selected from a design-specific PRA; (2) Source term calculations are based on verified analytical tools; (3) Source terms for compliance should be 95% confidence level values based on best-estimate calculations; and (4) Source terms for licensing decisions should reflect scenario-specific timing, form, and magnitude of the release.

- The approach used for selecting DBAs may result in smaller source terms than used for LWR safety analyses. Is this approach reasonable for siting? Or should siting be based on a large source term?

The Commission asked the staff to provide further details on the options for, and associated impacts of, requiring that modular reactor designs account for the integrated risk posed by multiple reactors.

- Should the consideration of integrated risk be applied to all reactors on a site, not just modular reactors?
- If integrated risk is to be considered on a per site basis, how should it be accounted for?
    - limit the number of reactors on a site?
    - site specific criteria?
    - nationwide criteria?
    - other?

Note: see ACRS letter of April 22, 2004 for additional considerations

The Commission approved the staff proposal that no change to emergency preparedness requirements is needed in the near term. The Commission also approved, for the longer term, the staff developing guidelines for assessing possible modifications to emergency preparedness requirements as part of the work to develop a description of defense-in-depth.

- What should be the role of emergency preparedness in defense-in-depth as it relates to possible simplification of the emergency planning requirements, (e.g., reduction in the size of the emergency planning zones (EPZs), for reactors that are designed with greater safety margins than the current light water reactors)?
- In considering possible changes to the existing emergency preparedness regulations or guidance, should factors other than reactor size and location, level of safety (i.e., likelihood of release), magnitude and chemical form of release, and timing of release be addressed? Are these factors reasonable? If not, why are they not reasonable? In addition, should the changes address the following:
    1. consideration of the full range of accidents
    2. use of the defense-in-depth philosophy
    3. prototype operating experience
    4. acceptance by Federal, State, and local agencies
    5. acceptance by the public

4. Treatment of Uncertainties and Defense-in-Depth

The Commission approved the staff recommendation for developing a definition of defense-in-depth that would be incorporated into a policy statement. In licensing future reactors, the treatment of uncertainties will play a key role in ensuring safety limits are met and

the design is robust with respect to unanticipated factors. In general, uncertainties associated with new plants will tend to be larger than uncertainties associated with existing plants due to new technologies being used, the lack of operating experience or, in the case of some proposed LWRs, new design features (e.g., increased use of passive systems). Any licensing approach for new plants must account for the treatment of these uncertainties. The aim is to develop an approach for future reactors which can be reconciled with past practices used for operating reactors, but which improves on past practices by being more consistent and by making use of quantitative information where possible. The approach recommended for dealing with uncertainties when ensuring the safety of new plants is the concept of multiple successive layers of barriers and lines of defense against undesirable consequences. This approach is usually referred to as defense-in-depth. The concept of defense-in-depth is fundamental to the treatment of uncertainties.

- Are the types of uncertainty adequately described? If not, what should be changed or added?
- A major reason for including a deterministic (structuralist) component in the defense-in-depth model (i.e., the protective strategies) is to address the unknown contributors (initiating events, failure mechanisms, physical performance, etc.) to accidents. The deterministic component of the model requires that each protective strategy is implemented, however, the extent or degree to which each strategy is implemented is tempered by the associated risk (which is the probabilistic or rationalist component of the model).
    - What approaches to determining the degree of defense-in-depth provided by each protective strategy would be appropriate?
    - How relevant is the rationalist approach, given the uncertainty associated with the unknown contributors?

- Are expert judgment approaches appropriate? What caveats and controls would be needed?
- Are there ways to structure the uncertainty associated with “unknown” aspects of the risk that can be helpful? Could these be used to provide a qualitative description of the uncertainty that would provide a basis for assessment?
- What other possibilities are there?

• Are there additional defense-in-depth principles that should be adhered to? If so, what are they?

• Is the proposed defense-in-depth criteria for containment appropriate? If not, what should be used?

• Is the defense-in-depth model advocated in the report appropriate? Does it achieve the proper balance between structuralist and rationalist aspects? If not, how should it be changed?

• Is the implementation of the defense-in-depth model described in the report appropriate? If not, how it should be changed?

• Are incompleteness uncertainties reasonably accounted for? If not, how should they be dealt with?

• Are the proposed factors for considering changes to existing emergency preparedness regulations or guidance appropriate?

The Commission asked the staff to develop containment functional performance requirements and criteria working closely with industry experts (e.g., designers, Electric Power Research Institute, etc.) and other stakeholders regarding options in this area, taking into account such features as core, fuel, and cooling systems design. The Commission also stated that the staff should pursue the development of functional performance standards and then submit options and recommendations to the Commission on this important policy decision.

- Does the proposed functional performance requirement and criterion for containment take into account such features as the fuel, core and cooling system design?
- Are the proposed performance requirement and criterion performance-based?
- Is the proposed performance requirement and criterion risk -informed?
- Does the proposed performance requirement and criterion adequately account for uncertainties including completeness uncertainties?
- Would the proposed performance requirement and criterion result in excessive regulatory burden including containment design, construction and operating costs?
- Does the proposed performance requirement and criterion provide for public confidence?
- How should the options, including the proposed option, be revised in consideration of the above questions?

5. Process for Defining Scope of Requirements (and General Implementation Issues)

A deductive process is developed to identify and define the scope and content of detailed technical and administrative requirements that are necessary to ensure the safety objectives and criteria are met.

- Should the technology neutral requirements be developed as an independent alternative to licensing under 10 CFR 50?
- Is there a near-term (3-5 year) need for the framework?
- The derivation of detailed technical requirements is still being developed. Is the process described (and illustrated with the barrier integrity example) for the identification of the scope and content of the detailed technical requirements from the protective strategies reasonable? How could it be improved?
- The approach to obtaining the needed administrative requirements is also still being

developed. Is the process described so far reasonable? Are the discussions on analysis methods and qualification, and on research and development appropriate?

- Should the technology-neutral requirements build upon and utilize 10 CFR 50 requirements as much as possible (i.e., whenever 10 CFR 50 requirements are technology neutral they should be incorporated)?
- Are the desired characteristics of a technology-neutral regulatory structure listed in Sections 1.4 and 6.3 of the framework reasonable? Is the list complete? If not, what characteristic(s) is missing?
- Are the described checks for completeness of the framework adequate? What other checks could be performed?
- Is it reasonable and practical to maintain a living PRA that would be used to periodically reclassify reactor accidents as operating experience accrues?
- From a regulatory perspective, in terms of enforceability, is it practical to include the technology-specific details in a regulatory guide, although included as part of the license, or directly in a regulation?
- Would performance-based requirements developed according to Appendix A sufficiently address enforceability (given that prescriptive requirements are easier to enforce)?
- At what stage should the technology-specific regulatory guides be developed and to what level of detail? Currently, it is envisioned, prior to pre-application or pre-certification, to develop the technology-specific regulatory guides for each technology type, not for each applicant. The technology-specific regulatory guide would specify how to interpret such statements in the technology-neutral regulation as fuel damage, accident prevention.
- It is envisioned that these new technology-neutral regulations would be a voluntary

alternative to Part 50. Should it be voluntary or mandatory? What would be the motivation for an applicant to use this alternative? Should a licensee be allowed to seek an exemption to Part 50 and propose an alternative approach based on the technology-neutral regulations?

- Is a technology-neutral framework desirable for licensing future reactors? What are the advantages of using a technology-neutral framework? What are the difficulties of using such a framework?

6. Appendices

Several appendices have been identified to provide further detailed information in understanding the criteria and guidelines in the Framework document.

- Will the identified set of appendices be helpful? Should any be dropped or redirected?
- Would additional appendices be helpful? If yes, what should be the topic and to what level should it be written?

To date, the following appendices have been identified:

- **A. Guidance for the Formulation of Performance-Based Requirements.** Provides an explanation of how the topics that must be addressed to provide defense-in-depth protection via the protective strategies can be implemented through performance-based requirements. Identifies the steps in this process including the need for safety margin.
  - Are there additional performance-based considerations that should be included in Appendix A?
- **B. Current Quantitative Guidelines for LWRs**. The Framework discusses the possibility of using surrogates to demonstrate that the risk objectives of the frequency-consequence curve have been met. Appendix B illustrates how core damage frequency and large early release frequency are used for current LWRs as surrogates for the risk

objectives expressed by the latent cancer QHO and early fatality QHO, respectively.

- Are there additional examples of the use of surrogates to achieve higher level risk objectives that would be useful here?

- **C. Safety Characteristics of New Reactors**. Brief summary descriptions of a number of possible new reactor concepts. Includes a discussion of safety features (and vulnerabilities, if identified) structured to make clear the linkage to the Framework.
  - Are there additional characteristics/features/attributes of the various innovative designs that should receive special attention in Appendix C?
- **D. Probabilistic Risk Assessment Quality Needs for New Reactors.** There are now standards for PRA of LWRs. This appendix will define PRA in a technology-neutral manner (e.g., core damage frequency as a definition for Level 1 is technology-specific), identify extensions and changes that may be needed for some new reactors, and will describe how PRA is related to the development of regulatory requirements for new reactors (e.g., development of a living PRA and what a living PRA entails)
  - What should be the scope and depth of this appendix? At a higher level and look to professional organization to develop standard?
- **E. Assessment of Part 50 for New Reactors.** A review of Part 50 requirements against a specific new reactor design. Identifies where current requirements are directly applicable, which requirements are not applicable, which requirements need to be adapted to the new design concept, and what design features and uncertainties call for new requirements.
- **F. Completeness Check.** A review of other work being performed in this area to identify any significant holes. Review and compare against the NEI-02-02 framework and the technical document being prepared by IAEA on technology-neutral regulations.

- Are there other sources that should be reviewed?

7. Glossary

A glossary is being developed that will a standard set of definitions and usage of terms in an effort to a have common understanding to help facilitate discussions and communication regarding the regulatory structure for new plant licensing

- Have the appropriate terms been identified? If not, what terms should be deleted or added?
- Are the definitions reasonable given the context? If not, why is the definition not reasonable?
- Should these definitions be standardized? That is, can these definitions be used elsewhere? If not, which definitions can not be standardized and why not?

For information about the working draft NUREG and the workshop may be directed to Mr. A. Singh at (301) 415-0250; email axs3@NRC.GOV.

Although a time limit is given for comments on this draft document, comments and suggestions in connection with items for inclusion in guides currently being developed or improvements in all published guides are encouraged at any time.

(5 U.S.C. 552(a))

Dated at Rockville, Maryland, this _____ day of _____ 2005.

FOR THE NUCLEAR REGULATORY COMMISSION

_____
Charles E. Ader, Director
Division of Risk Analysis and Applications
Office of Nuclear Regulatory Research