July 13, 2016

MEMORANDUM FOR: Diane T. Jackson, Chief
Advanced Reactor and Policy Branch
Division of Engineering, Infrastructure, and Advanced Reactors
Office of New Reactors

FROM: Joseph F. Williams, Senior Project Manager **/RA/**
Advanced Reactor and Policy Branch
Division of Engineering, Infrastructure, and Advanced Reactors
Office of New Reactors

SUBJECT: SUMMARY OF A PUBLIC STAKEHOLDER MEETING DISCUSSING USE OF TIER 2* IN FUTURE DESIGN CERTIFICATIONS

On June 9, 2016, staff from the U.S. Nuclear Regulatory Commission (NRC) conducted a Category 3 public meeting with stakeholders to discuss use of the Tier 2* designation in future design certifications. Meeting attendees are shown in Enclosure 1. Copies of presentation materials used by the NRC staff can be found in the Agencywide Documents Access and Management System (ADAMS) under Accession Number ML16154A287.

The NRC staff's presentation noted that the "Post-Combined License Part 52 Implementation Self-assessment Working Group Report"[1] identified the need to address issues associated with Tier 2*, stating that the guidance for designation and documentation of Tier 2* information could be enhanced. A multi-discipline working group was formed within the NRC Office of New Reactors (NRO) in late 2013 to address this issue.

BACKGROUND

The design control document (DCD) supporting a design certification rule divides information into 3 categories, Tier 1, Tier 2, and Tier 2*. Tier 1 information is defined as "the portion of the design-related information contained in the generic DCD that is approved and certified by" a design certification rule. A licensee or applicant referencing a certified design who wishes to deviate from Tier 1 must obtain NRC approval of an exemption from the certification rule before changes can be implemented.

Tier 2 is defined as "…the portion of the design-related information contained in the generic DCD that is approved but not certified by… " the certification rule. Licensees or applicants referencing a certified design can make changes to Tier 2, without prior NRC approval, if criteria given in Section VIII of the certification rules are fulfilled. These criteria are often referred to as

[1] The report was issued on July 22, 2013. See ADAMS Accession No. ML13196A403.

"50.59-like" criteria, or as the "50.59-like" process, due to the similarity to change control criteria given in 10 CFR 50.59 applicable to all currently operating facilities.

Tier 2 includes a subcategory of information designated as Tier 2*. The "50.59-like" process does not apply to Tier 2* changes. Instead, departures from Tier 2* require NRC approval prior to their implementation, as described in Section VIII of the certified design rules.

MEETING SUMMARY

At the meeting, the NRC staff outlined plans to develop a Commission paper discussing alternatives for use of Tier 2* in future design certifications. The staff's presentation included a discussion of the original intent of Tier 2* as described to the Commission. The category is supposed to have a significance commensurate with Tier 1 information, and would presumably be considered Tier 1 if the Tier 2* designation did not exist. When the Tier 2* designation was created in the early to mid-1990s, it was thought the designation would be beneficial to reduce the amount of information in Tier 1 and would provide additional flexibility to applicants and licensees who wish to make changes. The meeting presentation described correspondence from the NRC staff to the Commission and rulemaking documents which describe this intent. For example, the 2007 revision to 10 CFR Part 52[2] stated that:

> Tier 2* information has the same safety significance as Tier 1 information and would have received the Tier 1 designation, except that NRC decided to provide more flexibility for this type of information.

The NRC staff described how the original intent for the category has not always been reflected in practice. For example, some information originally designated as Tier 2* has subsequently been determined to be sufficiently controlled when re-designated as Tier 2 via license amendments. Licensing action experience to date also suggests that exemptions for Tier 1 information are not significantly more difficult to obtain than amendments to Tier 2* information, which suggests that the additional flexibility envisioned when the category was created may not be significant. However, the staff noted that NRC has yet to face challenges in addressing safety effects of reduced standardization per the requirements of 10 CFR 52.63, "Finality of standard design certifications," so there may be a set of topics where changes might be more challenging to address if designated as Tier 1 versus Tier 2*. In addition, experience to date has largely focused on civil and structural engineering issues, so additional insights might be gained as construction shifts to installation and testing of mechanical and electrical equipment, along with instrumentation and controls.

Documents issued prior to 2000 that are cited in the presentation may be found under ADAMS Accession No. ML003761550.

Representatives of the Nuclear Energy Institute (NEI) noted at the meeting that, to date, about half of all amendments for the AP1000 combined license holders involve changes to Tier 2*. NEI expressed an opinion that many of these amendments would not have been needed if the information had been designated as Tier 2, as an evaluation of the changes per the requirements of the "50.59-like" criteria of Section VIII of the AP1000 design certification rule would not have led to a requirement for NRC review and approval before the change was implemented.

[2] *72 FR 49517*, August 28, 2007.

NRC staff stated that review of license amendment review experience can contribute to understanding of the efficacy of the Tier 2* category and test the claim that the "50.59-like" change criteria are sufficient to ensure NRC engagement on all safety significant changes. However, staff noted that arguments regarding the effectiveness of the change control criteria do not address the expected significance of Tier 2* information, which was originally intended to be similar to the significance of Tier 1. For Tier 2* information that would otherwise be considered Tier 1, the effectiveness of the change criteria is not the only factor which should be considered, as, by definition, changes to Tier 1 information must be approved by NRC. The intent of Tier 2* is to provide an alternative and more flexible path for NRC approval of changes to significant information than if that information were designated as Tier 1. It is likely that the change control criteria could adequately address many changes to Tier 1 information, as well, but categorizing that information as Tier 1 addresses the need to provide information sufficient to characterize the certified design.

NRC staff also noted that insight might be gained from examination of license amendment topics that would not trip the change criteria as they currently exist, but a reasonable basis can be provided that NRC review is needed regardless. Staff noted that there are some topics presently addressed in Tier 2*, such as human factors, where the change control criteria do not clearly apply because of the difficulty in quantifying the effect of changes on probability or consequences of accidents. Identification of such gaps can help inform efforts to improve guidance and perhaps the regulations.

NEI representatives expressed a view that the "50.59-like" process is working well for all engineering disciplines, though improvements can be discussed. NEI representatives stated that the focus should be on what information goes into Tier 1 and Tier 2. It was noted that in May 2015, NEI submitted its views on how to describe Tier 1 content to NRC in NEI 15-02, "Industry Guideline for the Development of Tier 1 and ITAAC [Inspections, Tests, Analyses, and Acceptance Criteria] Under 10 CFR Part 52."[3]

NRC staff outlined the alternatives available to address Tier 2* in the future. The NRC has already determined that the status quo is undesirable, as discussed in a report prepared to identify lessons learned from the first 10 CFR Part 52 combined license reviews.[4] The remaining alternatives are to end usage of Tier 2* altogether, or to reduce the scope of usage to a manner consistent with its original intent. Stakeholder feedback was solicited regarding the advantages and disadvantages of these alternatives.

NRC staff discussed feedback on a December 19, 2014 letter[5] where NEI had described the basis for its view that Tier 2* should not be used in the future. The letter included a table where NEI described its assessment that the "50.59-like" process provides adequate control for all Tier 2* information in the AP1000 design certification. NRC staff provided some generic feedback on this table. However, staff noted that it was not appropriate to provide a view regarding any particular AP1000 Tier 2* topic can be re-designated as Tier 2, as any such statements would be prejudicial to possible future licensing action requests by combined license applicants or licensees, or adjustments to the AP1000 certified design rule that might be sought by a reactor designer. The table NEI provided was also conceptual in nature, and did not

[3] ADAMS Accession No. ML15147A672.
[4] "Post-combined License Part 52 Implementation Self-Assessment Working Group Report," July 22, 2013, ADAMS Accession No. ML13196A403.

provide the level of detail necessary for an authoritative evaluation. Staff also noted that conclusions that might be drawn for the AP1000 might not apply to other reactor designs.

The NRC staff discussed issues identified in review of the NEI table. While the table provides a view regarding the effectiveness of the "50.59-like" change process, it does not provide a view on how the various topics conform to the original intent of the Tier 2* designation. The staff noted how problems with several topics addressed by NEI illustrate some of the challenges that can arise when licensees perform a "50.59-like" evaluation. For example, NEI's discussion of containment pressure changes did not address the impact of changes in that parameter on loss of coolant accident peak fuel cladding temperature. In the discussion of potential modifications to steel composite (SC) panels used in the AP1000 shield building, the table did not discuss requirements in 10 CFR 50.150 to address effects on aircraft impact assessment. Discussion of potential changes in reactor coolant pump design addressed the likelihood of pump malfunction, but did not address how the consequences of a malfunction might be different, as required by the "50.59-like" process. The staff noted that the issues described did not necessarily prove NEI's claims were ill-founded. Rather, the issues illustrate that it can be difficult to complete a thorough evaluation, but they do not demonstrate that such evaluations are inherently impractical.

NRC staff said that issues such as these, along with issues identified in the course of AP1000 construction, contribute to individual staff skepticism about the effectiveness of change control processes as implemented in the field. An industry representative at the meeting expressed surprise that NRC staff are concerned about the 10 CFR Part 52 "50.59-like" process, stating that there is good enforcement experience with licensee implementation of those regulations and the similar requirements in 10 CFR Part 50. NRC replied that the skepticism described does not reflect an official NRC position, but does reflect perceptions of individual staff members.

Stakeholder feedback was sought on a preliminary list of advantages and disadvantages if Tier 2* usage is ended. NRC staff stated that it appears that, consistent with NEI's claims, the change control processes are adequate in many cases, so eliminating the category would reduce licensee and NRC efforts for processing license amendments with little or no safety significance. The benefits of the process are also not clear, as experience to date suggests that processing a Tier 2* license amendment is not significantly easier than processing a Tier 1 exemption, so the original flexibility justification for Tier 2* is arguably weak. Elimination of the category would also reduce complexity of certification applications and associated rules.

NEI representatives indicated agreement with these advantages, expressing a view that elimination of the category would "simplify Part 52 in a major way." An opinion was also offered that it would be harder to develop guidance on what Tier 2* should be than it would be to identify and apply what NEI refers to as "first principles" for Tier 1 information, as described in their NEI 15-02 submittal.

NRC staff also described potential disadvantages of elimination of Tier 2*. It was noted that it is likely that some Tier 2* information would likely be designated as Tier 1, which is consistent with the original intent of the Tier 2* classification. However, it was noted that a subset of Tier 2* information reverts to Tier 2 status when a new facility first reaches full power. Means will have to be identified to address any such information that is placed in Tier 1.

NRC staff anticipates that moving fuel design information into Tier 1 could affect licensees' ability to obtain fuel from alternative vendors. Tier 1 changes are subject to requirements that

changes be evaluated for the safety impact of differences from the standard design. Given that fuel designs are based upon a considerable amount of proprietary information and methodologies, the staff believes that while alternative fuel vendors may be able to demonstrate their design meets other regulatory requirements, they may not be able to provide information sufficient to address differences from the proprietary standard design. NEI representatives expressed a view that it is not obvious that fuel design should be Tier 1. Other industry representatives stated that fuel is already heavily regulated, so a Tier 1 designation for fuel should not be necessary. NRC staff said that it is not expected that facilities licensed under 10 CFR Part 52 would have fuel regulatory regimes more restrictive than existing 10 CFR Part 50 facilities.

Ending use of Tier 2* may also eliminate a potentially useful regulatory tool for complex engineering topics, such as steam dryer design. Further, while NRC and industry have extensive experience with large light water reactor designs, there is much less experience with prospective small modular and non-light water reactor designs. NEI representatives expressed a view that Tier 2* is not needed, regardless of the design. However, that conclusion is speculative, given the lack of experience.

Elimination of Tier 2* may also increase risk of disagreements regarding fulfillment of ITAAC as a facility is completed. NRC approval of changes to Tier 2* information should increase confidence that any ITAAC associated with that information will be completed satisfactorily. If that information is designated as Tier 2 instead, staff have speculated that there may be changes made using the “50.59-like” process which NRC does not agree with that are revealed relatively late in construction when NRC is confirming ITAAC completion. However, NRC staff also noted that there is already the possibility of ITAAC disagreements arising out of Tier 2 changes that have not been reviewed by NRC. While elimination of Tier 2* may increase the scope of information that may be problematic, it does not create a new problem altogether. NEI representatives indicated that they do not believe this issue is an impediment to eliminating Tier 2*.

NRC staff also stated that eliminating Tier 2* could create regulatory guidance challenges, as guidance documents would need to address designs with Tier 2* and without. NEI representatives expressed an opinion that elimination of Tier 2* would substantially simplify application of the 10 CFR Part 52 licensing processes.

Overall, NEI representatives expressed agreement with the described advantages of ending use of Tier 2*, and also expressed skepticism that the disadvantages are actually true.

The NRC staff then described potential advantages and disadvantages of reducing use of Tier 2* to a scope consistent with the original intent. Some advantages for reduced use of Tier 2* are similar to elimination of the category, though likely not to the same extent, such as reduced licensee and NRC effort to process license amendments with low safety significance.

Other advantages of reduced Tier 2* usage can address some of the disadvantages of completely eliminating the category. When the category was first envisioned, considerable effort was expended by NRC staff and industry to characterize the category and identify topics which would benefit by the designation. Permitting continued use in a manner consistent with its original intent arguably preserves a useful tool for future design certification reviews. Continued use might be particularly beneficial for designs which differ substantially from existing light water reactor designs. Continued usage also addresses concerns regarding disagreements regarding fulfillment of ITAAC to some extent.

Disadvantages of reduced use of Tier 2* include the potential for scope creep, or the expansion over time of usage of the category in a manner less and less consistent with the original intent. NRC staff noted that there may be some difference in views of vendors versus licensees and applicants. Vendors have an interest in completing the certification review as soon as possible, which can lead to compromises with NRC staff to use Tier 2* as a means to help resolve problematic issues. On the other hand, licensees and applicants have an interest in having maximum flexibility to make changes without prior NRC approval, which suggests an interest in minimal use of Tier 2*. NEI representatives responded that licensees, applicants, and vendors share a common position that Tier 2* can be eliminated.

A disadvantage of reduced use of Tier 2* is the need to develop objective guidance for identification of Tier 2* content. For example, the characteristics of information eligible to be placed in the category would need to be determined. Such an effort would require interaction between NRC and external stakeholders to identify robust and manageable criteria.

An industry representative expressed an opinion that part of the problems associated with Tier 2* arise from the fact that such information is typically identified relatively late in the design certification review, and so tend to receive less scrutiny than other DCD content. The individual stated that there is less opportunity to craft language and set the proper scope of Tier 2* information, as opposed to Tier 1 or Technical Specification content which is substantially described at the very beginning of the review and refined by the applicant as the NRC staff's review proceeds. NRC staff agreed that Tier 2* is identified relatively late, but noted that it is challenging to finalize both Tier 1 and Tier 2* before Tier 2 information is confirmed to be adequate.

NRC staff agreed that improved guidance for Tier 1 content would be beneficial, regardless of whether Tier 2* is eliminated or retained. However, the staff also noted that such an effort introduces issues outside the scope of Tier 2*. Description of Tier 1, Tier 2, and Tier 2* content affects the form and content of both a certification application and a certification rule. An effort to align on the Tier 1 first principles, the description of Tier 1 content, along with any adjustments to the "50.59-like" process and guidance affects issues other than Tier 2*, such as ITAAC.

NRC staff suggested that the Tier 2* scope found in the first design certification DCDs might be informative. NEI representatives noted that those certifications pre-dated changes to 10 CFR 50.59, so the context of those original decisions may not align with current expectations.

NEI representatives expressed considerable dismay at the NRC's slow rate of progress in addressing Tier 2*, particularly given that the staff is currently reviewing a design certification application, with another certification application expected within the next several months.

The NRC staff then outlined supporting activities, stating that regardless of whether Tier 2* is eliminated or reduced, actions are needed to reflect experience gained in design certification and combined license reviews, and to support the planned course of action.

NRC staff stated that improved descriptions for Tier 1 and Tier 2 content are needed. It is expected that some information that would otherwise be Tier 2* will be classified as Tier 1 in the future, especially if Tier 2* is not used. Applying a Tier 1 classification to such information would be consistent with the original intent for Tier 2*. Other DCD content would be designated as Tier 2. Feedback from NEI representatives regarding the importance of Tier 1 first principles is

consistent with the NRC staff's view on the need for improved DCD content descriptions. NRC staff noted that NEI's December 19, 2014 letter stated that improved criteria and guidance for delineating Tier 1 and Tier 2 information were under development. NEI representatives confirmed that this statement referred to what became NEI 15-02, and stated that that document was written assuming Tier 2* would not be used. NRC staff appreciated this clarification, as such a statement was not made in NEI 15-02 or the cover letter which forwarded the document.

NRC staff also indicated a need for review of the "50.59-like" process to ensure that topics which might otherwise be designated as Tier 2* will be adequately controlled if designated as Tier 2. NRC staff noted that existing guidance was developed for a regulatory scheme that includes Tier 2*, so confirming adequacy of guidance is appropriate if the scope of information addressed by the process is increased. Clarity of criteria and guidance associated with methodology changes has frequently arisen in staff discussions, particularly in the context of completing final designs, such as for digital instrumentation and control systems. NEI also cited the addition of the methodology criterion to the "50.59-like" process as part of the basis for not requiring Tier 2* in its December 19, 2014 letter.

NRC staff noted that inspection program adjustments might be appropriate to ensure implementation of robust change controls by licensees. For example, the frequency and scope of change control inspections might be adjusted to ensure timely identification and resolution of problems.

NRC staff also discussed benefits of training to improve NRC staff understanding of the "50.59-like" change control process and its implementation. The complexity of the process and associated guidance are not well-understood by some staff, so training can improve confidence that the combination of the change control process, licensee quality assurance efforts, and NRC inspection and enforcement are capable of identifying and resolving issues in a timely manner to ensure safety.

NRC staff also noted that it appears that the regulatory basis of Tier 2* is not well-understood. NRC personnel are understandably much more familiar with how Tier 2* has been used in recent certification reviews than they are with positions described in Commission correspondence from the early and mid-1990s. Providing information to the staff regarding the intent of Tier 2* can be beneficial, especially if the option for use of the classification is retained in the future.

Meeting attendees discussed what steps might be taken to continue progress. NEI representatives expressed an interest in understanding what Tier 2* items NRC staff is most concerned about. As noted above, NRC staff stated that it is problematic to discuss particular designs, and that what is true for one design may not be true of others.

NEI representatives also indicated interest in engaging with NRC on Tier 1 first principles. While NRC staff at the meeting indicated agreement of the benefit of addressing this topic to resolution of Tier 2*, it was noted that there is a broader set of topics and stakeholders that need to be considered. Identification of Tier 1 first principles and associated content guidelines addresses the full scope of a design certification application and rule; Tier 2* is a subset of that scope.

NEI representatives expressed a view that there is ample basis for eliminating use of Tier 2*, and that NRC management should balance perceived Tier 2* benefits with associated costs.

NEI representatives also indicated they plan to engage with NRO managers regarding integration of Tier 1 first principles with Tier 2* activities.

NEI representatives thanked the staff for an “honest assessment” of Tier 2* history, expressing an opinion that Tier 2* has given the (10 CFR Part 52) licensing process a “black eye.” The view was offered that the case for retaining Tier 2* was not compelling, and potential problems identified by the staff are already adequately addressed.

NRC staff said that stakeholders can continue to provide feedback after the meeting, indicating that any email or other written communications will be made publicly available in ADAMS.

Enclosure: Meeting Attendees

NEI representatives also indicated they plan to engage with NRO managers regarding integration of Tier 1 first principles with Tier 2* activities.

NEI representatives thanked the staff for an “honest assessment” of Tier 2* history, expressing an opinion that Tier 2* has given the (10 CFR Part 52) licensing process a “black eye.” The view was offered that the case for retaining Tier 2* was not compelling, and potential problems identified by the staff are already adequately addressed.

NRC staff said that stakeholders can continue to provide feedback after the meeting, indicating that any email or other written communications will be made publicly available in ADAMS.

Enclosure: Meeting Attendees

ADAMS Accession No. ML16180A452 ***via email** **NRO-002**

OFFICE	PM:NRO/DEIA/APRB	LA:NRO/DEIA/APRB	PM:NRO/DEIA/APRB	DD:NRO/DEIA
NAME	NDevaser	ARedden	JWilliams	DJackson
DATE	06/30/16	07/05/16	07/12/16	07/13/16

OFFICAL RECORD COPY

SUBJECT: SUMMARY OF A PUBLIC STAKEHOLDER MEETING DISCUSSING USE OF TIER 2* IN FUTURE DESIGN CERTIFICATIONS

DISTRIBUTION:
E-Mail:
MMayfield
FAkstulewicz
DJackson
JMonninger
SFlanders
RCaldwell
MCheok
LBetancourt
JHoellman
JHoncharik
JHuang
POBryan
EStutzcage
VThomas
CVanWert
RVettori
AWilson
JZhao
CWelch

Attendees
June 9, 2016
Public Stakeholder Meeting Discussing Use of Tier 2* In Future Design Certifications

Name	**Affiliation**
Nathan Hottle	Areva
Millie Ronnlund	Balch & Bingham, LLP
Steven Klein	Bechtel
Jana Bergman	CurtisWright
Michael Brandon	DTE Energy
David Scott	Electric Power Research Institute
Rob Burg	Engineering Planning and Management, Inc.
Karl Herchenroeder	Exchange Monitor Publications and Forums
Patricia Campbell	GEH
Daegun (Tony) Ahn	KHNP
Woochong Chon	KHNP
Seokhwan Hur	KHNP
Heok Jeong	KHNP
Jungho Kim	KHNP
Taehan Kim	KHNP
Jiyong (Andy) Oh	KHNP
Steven Frantz	Morgan Lewis
Kati Austgen	NEI
Russ Bell	NEI
Anne Cottingham	NEI
Luis Betancourt	NRC
Joseph Colaccino	NRC
Arlon Costa	NRC
Nishka Devaser	NRC
Jordan Hoellman	NRC
Ata Istar	NRC
Debbie Jackson	NRC
Michael Mayfield	NRC
Edward Stutzcage	NRC
Vaughn Thomas	NRC
Robert Vettori	NRC
Donna Williams	NRC
Joseph Williams	NRC
Anthony Wilson	NRC
Gary Becker	NuScale
Tony Lentz	NuScale
Zackary Radd	NuScale
Don Williams	Oak Ridge National Laboratory
James Mallon	PSEG
David Robillard	PSEG
Arnie Cribb	SCE&G
David Jones	SNC
Jason Redd	SNC

Attendees
June 9, 2016
Public Stakeholder Meeting Discussing Use of Tier 2* In Future Design Certifications

Zach Harper	Westinghouse
Ray Kuyler	Westinghouse
Brian McIntyre	Westinghouse
Rob Sisk	Westinghouse
Camille Zozula	Westinghouse