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November 12, 2014

Mr. Robert Taylor  
Deputy Director, Division of Safety Systems  
Office of Nuclear Reactor Regulation  
U.S. Nuclear Regulatory Commission  
Washington, DC 20555-0001

**Subject:** Stakeholder Input on "Review of Lessons Learned from the San Onofre Steam Generator Tube Degradation Event" (Mar. 20, 2014)

Dear Mr. Taylor:

On behalf of the nuclear energy industry, the Nuclear Energy Institute, Inc. (NEI)<sup>1</sup> appreciates the opportunity to provide input to the NRC staff's evaluation of lessons from the recent experiences related to the San Onofre Nuclear Generating Station (SONGS) steam generator event.<sup>2</sup> The Executive Director for Operations (EDO) has directed the staff to prepare a comprehensive SONGS lessons learned report addressing several topics. We offer the input in the attachment to this letter to document the industry positions on the 10 C.F.R. § 50.59 process, confirmatory action letter, and separation of function questions posed by the EDO.

Thank you in advance for your consideration of these comments. If you have any questions or require additional information, please contact me (202-739-8140; [ecg@nei.org](mailto:ecg@nei.org)) or Jonathan Rund (202-739-8144; [jmr@nei.org](mailto:jmr@nei.org)).

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<sup>1</sup> NEI is the organization responsible for establishing unified nuclear industry policy on matters affecting the nuclear energy industry, including the regulatory aspects of generic operational and technical issues. NEI's members include all utilities licensed to operate commercial nuclear power plants in the United States, nuclear plant designers, major architect/engineering firms, fuel fabrication facilities, materials licensees, and other organizations and individuals involved in the nuclear energy industry.

<sup>2</sup> See Memorandum from M. Satorius, Executive Director for Operations, Review of Lessons Learned from the San Onofre Steam Generator Tube Degradation Event (Mar. 20, 2014) (ML14028A028).

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Sincerely,

A handwritten signature in black ink, reading "Ellen C. Ginsberg". The signature is written in a cursive style with a large, stylized "E" and "G".

Ellen C. Ginsberg

Attachment

cc: Mr. Mark A. Satorius, Executive Director for Operations  
Mr. William Dean, Director, Office of Nuclear Reactor Regulation  
Mr. Glenn Tracy, Director, Office of New Reactors  
Mr. Marc Dapas, Regional Administrator, Region IV  
Margaret Doane, Esq., General Counsel

## **NUCLEAR ENERGY INSTITUTE COMMENTS ON NRC'S REVIEW OF LESSONS LEARNED FROM THE SAN ONOFRE STEAM GENERATOR TUBE DEGRADATION EVENT**

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### **I. Overview of Comments**

The Nuclear Energy Institute, Inc. (NEI)<sup>1</sup> appreciates the opportunity to provide input to the NRC staff's evaluation of lessons from the recent experiences related to the San Onofre Nuclear Generating Station (SONGS) steam generator event.<sup>2</sup> The Executive Director for Operations (EDO) has directed the staff to prepare a comprehensive report addressing the following topics:

- the 10 C.F.R. § 50.59 process;
- the confirmatory action letter (CAL) as a regulatory tool;
- steam generator technical review;
- organization/roles and responsibilities;
- communication and external interactions;
- Commission separation of function communication challenges;
- Inspection Manual Chapter (IMC) 0351; and
- vendor inspections.

In conducting this review, the EDO instructed the NRC staff to seek and incorporate input from all appropriate stakeholders. The staff has since reached out to stakeholders in a number of forums to address several of these topics.<sup>3</sup> The industry has been or will be providing the staff with input on many of these topics through these other opportunities. In addition, we offer the input in this attachment to clearly communicate the industry positions on the 10 C.F.R. § 50.59 process, CAL, and separation of function topics. For ease of reference, the EDO's questions on these topics are repeated in bold, followed by the industry responses.

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<sup>2</sup> See Memorandum from M. Satorius, Executive Director for Operations, Review of Lessons Learned from the San Onofre Steam Generator Tube Degradation Event (Mar. 20, 2014) (ML14028A028).

<sup>3</sup> See, e.g., Letter from P. Hiland, NRC, to E. Larson, San Onofre Nuclear Generating Station Lessons Learned (Aug. 13, 2014) (ML14206A841) (requesting industry input on the steam generator technical review issue).

## II. 10 C.F.R. § 50.59 Process

**During the inspection and technical review following the SONGS Unit 3 steam generator tube leak event, a number of issues were raised concerning the requirements and guidance of Title 10 of the Code of Federal Regulations (10 CFR) 50.59, "Changes, Tests, and Experiments."**

### **Items to Consider:**

#### **(1) Does the 10 CFR 50.59 rule continue to be adequate for major or complex component replacements?**

The 10 C.F.R. § 50.59 process continues to be adequate for major and complex component replacements. The NRC contemplated the Section 50.59 process would be used for major or complex component replacements,<sup>4</sup> and there is no indication the rule is inadequate to be used in such cases. The rule's long history demonstrates the value and effectiveness of the Section 50.59 process. Since the 1960s, Section 50.59 has provided a workable means of evaluating changes at nuclear power plants. As the NRC has recognized, the fundamental purpose of the rule "is to permit licensees to make changes to the facility, *provided the changes maintain acceptable levels of safety.*"<sup>5</sup> Licensees need this flexibility to maintain safe and efficient plant operations without having to request prior NRC review and approval for changes having minimal or no impact on plant safety.

The NRC amended Section 50.59 in 1999 after a comprehensive rulemaking process that included a thorough reevaluation by the agency and significant industry and stakeholder input. At the time, many U.S. reactors had recently completed or were planning to undertake steam generator replacement projects, in addition to tens of thousands of more routine changes. The changes to Section 50.59 were designed to encompass the full range of potential changes or activities while ensuring regulatory stability for this extensively used regulation. As amended, the rule continues to be a critical tool for the nuclear industry in evaluating activities affecting plant design and operation without creating an excessive burden for the regulatory system. The issues at SONGS (which primarily involved design control issues under 10 C.F.R. Part 50, Appendix B, Criterion III) do not suggest that the Section 50.59 process has not served its intended purpose or that licensee implementation of the rule has been ineffective.

As the Office of the Inspector General (OIG) recently pointed out, reactor licensees perform approximately 49,000 Section 50.59 screenings or evaluations each year, or nearly 500 per reactor.<sup>6</sup> Experience has shown that licensee implementation of Section 50.59 has been

<sup>4</sup> See, e.g., Final Rule, Changes, Tests, and Experiments, 64 Fed. Reg. 53,582, 53,584 (Oct. 4, 1999).

<sup>5</sup> See *id.* at 53,583 (emphasis added).

<sup>6</sup> OIG, NRC Oversight of Licensee's Use of 10 CFR 50.59 Process To Replace SONGS' Steam Generators: Event Inquiry at v (2014).

effective in controlling activities affecting plant design and operation, including many major or complex component changes. For instance, OIG's report notes that some 53 nuclear power plants have undertaken steam generator replacement using the Section 50.59 process.<sup>7</sup> In fact, the former Director of the Office of Nuclear Reactor Regulation (NRR) expressed the view that the NRC has not had "a lot of problems with the generic use of 50.59 by licensees or a problem with NRC oversight of the 50.59 process."<sup>8</sup> The former NRR Director further noted that "NRC has not had an issue with the approximately 53 nuclear power plants that have changed their steam generators under the 10 CFR 50.59 process."<sup>9</sup> Significantly, OIG's report does not recommend any change to Section 50.59, or identify changes to the rule that could have prevented the issues that arose at SONGS.

It is also important to note that Section 50.59 is an evaluative tool. The rule establishes a threshold for regulatory review—not a final determination of safety—of proposed activities. It is only one part of the NRC's complementary regulatory processes that ensure actions are not taken without proper analysis, review, and approval. A licensee's evaluation under Section 50.59 must be documented and available for review by the NRC as required by Section 50.59(d)(1). For major or complex component replacements, the licensee typically will keep the NRC well informed of the planned activities. As part of this interaction or otherwise, the NRC staff may review the licensee's Section 50.59 evaluation and request additional information to address any perceived deficiencies or weakness in the evaluation. The staff may even disagree with the licensee's determination and insist on prior NRC review of the planned activity. Therefore, the NRC's regulatory processes ensure that Section 50.59 continues to serve as an efficient mechanism to screen major and complex component replacements to determine if NRC approval is required.

As a proposed change becomes more complex, the Section 50.59 process typically requires a more elaborate justification from the licensee. As described in the industry guidance document NEI 96-07, "the basis for the engineering judgment and the logic used in the determination [that a change is appropriate under Section 50.59] should be documented . . . to a degree commensurate with the safety significance and complexity of the activity."<sup>10</sup> Thus, under the current Section 50.59 process and longstanding industry practice, licensees provide written evaluations of changes that reasonably reflect the significance of the proposed change and its effect on plant design and operation.

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<sup>7</sup> *Id.* at v.

<sup>8</sup> *Id.* at 27.

<sup>9</sup> *Id.* at 27-28.

<sup>10</sup> NEI 96-07, Rev. 1, Guidelines for 10 CFR 50.59 Implementation at 74 (Nov. 2000). NEI 96-07 is endorsed by NRC Regulatory Guide 1.187, Guidance for Implementation of 10 CFR 50.59, Changes, Tests, and Experiments (Nov. 2000).

Accordingly, the industry believes that Section 50.59 continues to be adequate for major and complex component replacements. Nevertheless, the industry also supports additional training for NRC staff as noted below and additional training for industry personnel on the lessons learned from SONGS, including implementation of Section 50.59. Such training will help to ensure both the NRC and the industry consistently apply Section 50.59.

**(2) Does the agency need to provide additional 10 CFR 50.59 guidance and information to:**

**a. licensees for large or complex component replacements**

The industry's guidance, NEI 96-07, "Guidelines for 10 CFR 50.59 Implementation, Revision 1," as endorsed in Regulatory Guide 1.187, "Guidance for Implementation of 10 CFR 50.59, Changes, Tests, and Experiments," has been reviewed and approved by the NRC as providing acceptable methods to comply with the standards in 10 C.F.R. § 50.59. This guidance is comprehensive enough to be appropriately used for large or complex component replacements. The guidance addresses all of the key steps a licensee must follow to apply the Section 50.59 process after determining a proposed activity is safe and effective through appropriate engineering and technical evaluations. Specifically, it addresses: (1) applicability and screening to determine if a Section 50.59 evaluation is required; (2) evaluations applying the eight criteria of Section 50.59(c)(2) to determine if a license amendment must be obtained; and (3) documentation and reporting to ensure the NRC may appropriately oversee activities implemented under Section 50.59. The guidance also provides numerous examples illustrating the proper application of the Section 50.59 process. As noted above, the guidance also describes how licensee evaluations must be commensurate with the safety significance and complexity of the proposed change. This guidance was developed with significant input from licensees and with active coordination with the NRC staff. Licensees provide training to their technical staffs based upon this guidance and require responsible staff to be formally qualified on this process before performing Section 50.59 reviews.

**b. inspectors for their review of 10 CFR 50.59 evaluations of large or complex component replacements**

Additional training for NRC inspectors on the use of the endorsed guidance in order to ensure proper implementation of the 10 C.F.R. § 50.59 process is likely to be beneficial. As noted in the OIG report, at least one NRC inspector believed that Section 50.59 training could be improved. Additional training would further the agency's continuous improvement efforts.

**c. project managers for their review of 10 CFR 50.59 evaluations**

Industry is unaware of any formal training for NRC project managers on the use of the endorsed guidance for proper implementation of the 10 C.F.R. § 50.59 process. To the extent additional training would help NRC project managers better perform their responsibilities with respect to oversight of Section 50.59 activities, industry supports NRC providing that training.

**(3) Does the agency need to clarify the commonly used phrase “like-for-like replacement” with respect to 10 CFR 50.59?**

The phrase “like-for-like” is used to describe a particular type of component replacement. It is not used as a justification for licensees to conclude that prior NRC review and approval of the replacement are unnecessary. Regardless of whether the component is a “like-for-like” replacement, the change would not require a license amendment if it did not require a change to a technical specification or if it did not meet any of the criteria in Section 50.59(c)(2). Thus, efforts to define this phrase would not affect implementation of the 10 C.F.R. § 50.59 process.

**III. Confirmatory Action Letter as a Regulatory Tool**

**During the inspection and technical review following the SONGS Unit 3 steam generator tube leak event, the staff issued a Confirmatory Action Letter (CAL). The contents of this CAL became the topic of legal proceedings before the Atomic Safety Licensing Board. The Board’s decision on whether the SONGS CAL constituted a de facto license amendment was later vacated by the Commission.**

**Items to Consider:**

**(1) Did the staff’s actions in response to the event at SONGS call into question the appropriateness of the use of CALs as a regulatory tool?**

The NRC staff’s actions in response to the event at SONGS do not call into question the appropriateness of the use of CALs as a regulatory tool. Rather, use of the hearing process to resolve whether the staff appropriately issued a CAL calls into question whether CALs can continue to be used as an effective regulatory tool.

CALs are a well-established and useful part of the NRC’s inspection and enforcement program. As the Commission’s Enforcement Policy explains, the NRC uses administrative actions, including CALs, to supplement its enforcement program.<sup>11</sup> The Enforcement Policy makes clear that “[t]he NRC expects licensees and other persons subject to the Commission’s jurisdiction to adhere to any obligations and commitments resulting from administrative actions and will consider issuing additional Orders, as needed, to ensure compliance.”<sup>12</sup>

The Enforcement Policy specifies that a CAL is a letter “confirming a licensee’s or contractor’s agreement to take certain actions to remove significant concerns regarding health and safety, safeguards, or the environment.”<sup>13</sup> NRC’s Enforcement Manual Section 3.4 further provides

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<sup>11</sup> NRC, Office of Enforcement, NRC Enforcement Policy at 24 (July 9, 2013) (ML13228A199) (NRC Enforcement Policy).

<sup>12</sup> *Id.*

<sup>13</sup> *Id.* at 75.

that CALs are issued to licensees to emphasize and confirm a licensee's agreement to take certain actions in response to a specific safety issue or concern.<sup>14</sup> Unlike an order, CALs do not themselves create legally-binding commitments other than reporting requirements.<sup>15</sup> As such, CALs are generally used to confirm how a licensee will adhere to existing requirements.<sup>16</sup> For example, CALs may be issued to confirm compliance with equipment maintenance or root cause analysis requirements.<sup>17</sup> CALs also may be used to confirm improvements to training, procedures, or security measures.<sup>18</sup> Additionally, CALs may be issued to confirm a voluntary, temporary suspension of licensed activities or, as in SONGS, confirm a licensee's agreement to obtain prior NRC approval before resuming licensed activities.<sup>19</sup> As such, a CAL is a valuable regulatory tool that allows the NRC staff to address issues in a timely and efficient manner while continuing to evaluate whether any further action is necessary and appropriate.

Because CALs are issued pursuant to the NRC's normal inspection and enforcement process, and merely confirm an agreement to comply with existing requirements, CALs are separate and distinct from license amendments. Commission case law makes clear that the NRC staff's approval of a licensee's actions will only be considered a *de facto* license amendment if the approval grants the licensee "greater operating authority" beyond the authority already granted under the existing license and NRC regulations.<sup>20</sup>

Consistent with the NRC Enforcement Manual, a CAL does not grant a licensee greater operating authority. Within the scope of the existing license and NRC regulations, the commitments confirmed in a CAL involve actions that are already authorized—and often required—by NRC regulations and the existing license.<sup>21</sup> Thus, any CAL that merely documents a licensee commitment to adhere to existing regulatory requirements is not granting action for which a license amendment would be required.

Similarly, a CAL issued to confirm a licensee's agreement to obtain prior NRC approval before resuming licensed activities does not involve granting a licensee greater operating authority.<sup>22</sup>

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<sup>14</sup> NRC, Office of Enforcement, Nuclear Regulatory Commission Enforcement Manual, Rev. 9 at 197 (Aug. 27, 2014) (ML102630150) (NRC Enforcement Manual).

<sup>15</sup> *Id.* at 199.

<sup>16</sup> *Id.* at 197 (explaining that "CALs may be used to confirm that a licensee will adhere to existing provisions").

<sup>17</sup> *Id.* at 198.

<sup>18</sup> *Id.*

<sup>19</sup> *Id.*

<sup>20</sup> *Cleveland Elec. Illuminating Co.* (Perry Nuclear Power Plant), CLI-96-13, 44 NRC 315, 326 (1996) (citations omitted).

<sup>21</sup> NRC Enforcement Manual at 198; *see also* 10 C.F.R. Part 50, Appendix B, Criterion XVI (Corrective Action).

<sup>22</sup> NRC Enforcement Manual at 198.



To the contrary, such a CAL documents a licensee's temporary agreement to less—not greater—operating authority. As the Commission observed in the *Perry* proceeding:

That the Staff may wish to verify in advance that a proposed revision [to a licensee's reactor vessel specimen withdrawal schedule] conforms to the required technical standard does not make Staff approval a license amendment. By merely ensuring that required technical standards are met, the Staff's approval does not alter the terms of the license, and does not grant the Licensee greater operating authority. Such a review indeed *enforces* license requirements. As an enforcement policy matter, the Staff may wish to police some licensee-initiated changes *before* they go into effect. To insist—as the Intervenor do—that the NRC Staff may never require prior approval for any change or activity without effecting some sort of major licensing action, would frustrate the agency's ability to monitor licensees and enforce regulations.<sup>23</sup>

In sum, the Commission has held that a CAL documenting a licensee commitment to obtain NRC approval before engaging in activities that are already authorized by an existing license does not grant a licensee greater operating authority, and therefore, is not a license amendment.

NRC's use of the hearing process to address whether a CAL was properly used in a specific case both discourages licensees from agreeing to enter into a CAL and adversely affects the NRC's regulatory process. If the NRC continues to use the hearing process to determine whether the NRC staff properly issued a CAL, as it did in SONGS, the likely effect will be to discourage licensees from agreeing to the use of this regulatory tool in the future, undermining the agency's discretion to select the enforcement action that best fits the circumstances at hand.<sup>24</sup> In that regard, the NRC staff often uses CALs to more quickly reach agreement with the licensee on the action necessary to resolve the significant safety concerns at issue. Even uncontested license amendment proceedings often last a year or more. Treating a CAL as a license amendment would not serve the NRC's interest in expeditiously resolving safety issues and, equally importantly, would add no concomitant benefit offsetting the delay.

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<sup>23</sup> *Perry*, CLI-96-13, 44 NRC at 328-29; see also *In re Three Mile Island Alert, Inc.*, 771 F.2d 720, 730 (3rd Cir. 1985) ("Section 189(a) is not implicated when the Commission enters an order lifting a suspension so that a licensee may operate under existing authority during the course of an enforcement proceeding."); *San Luis Obispo Mothers for Peace v. NRC*, 751 F.2d 1287, 1312 (D.C. Cir. 1984) ("[T]he lifting of a license suspension does not fall within any of the enumerated categories of Commission action for which a hearing must be held.").

<sup>24</sup> See *Alaska Dep't of Transp. & Pub. Facilities* (Confirmatory Order Modifying License), CLI-04-26, 60 NRC 399, 409-10, *reconsideration denied*, CLI-04-38, 60 NRC 652 (2004).

Further, treating a CAL as a license amendment would likely lead to a more adversarial relationship between the NRC staff and licensees during the inspection and enforcement process.<sup>25</sup> If there is a potential for CALs to be treated as license amendments, licensees would be less likely to reach agreement with the staff because of their interest in avoiding a lengthy and expensive license amendment proceedings.

If CALs are treated as license amendments, the NRC staff could resort to issuance of confirmatory orders (which only offers limited hearing rights).<sup>26</sup> However, orders generally are considered to reflect the agency's view that more serious issues must be addressed. Orders also are more difficult to change than CALs. The result could be a diversion of NRC staff resources from ensuring safety to implementing the more complicated administrative process associated with issuance of orders.<sup>27</sup>

In summary, treatment of a CAL as a license amendment would discourage both licensees and the NRC staff from using this tool, to the detriment of potentially quicker and more effective resolution of safety concerns.

**(2) Are changes needed to strengthen CAL guidance or implementation (*e.g.*, when CALs are appropriate or not appropriate)?**

To the extent additional guidance is needed to strengthen CAL implementation, such guidance should ensure that the NRC properly addresses the inappropriateness of hearing requests challenging the NRC staff's use of CALs. The Commission should make clear that absent an amendment request from a licensee or a confirmatory order, the 10 C.F.R. § 2.206 process provides members of the public with the exclusive means to challenge issues covered in a CAL.

Section 2.206(a) of the Commission's regulations provides any person with the opportunity to request the institution of a proceeding to "modify, suspend, or revoke a license, or for any other action as may be proper." Notably, the U.S. Court of Appeals for the D.C. Circuit and the Commission have identified Section 2.206 as a viable alternative to an adjudicatory

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<sup>25</sup> *Pub. Serv. Co. of Ind.* (Marble Hill Nuclear Generating Station, Units 1 & 2), CLI-80-10, 11 NRC 438, 441-42 (1980) ("We believe that public health and safety is best served by concentrating inspection and enforcement resources on actual field inspections and related scientific and engineering work, as opposed to the conduct of legal proceedings. This consideration calls for a policy that encourages licensees to consent to, rather than contest, enforcement actions. Such a policy would be thwarted if licensees which consented to enforcement actions were routinely subjected to formal proceedings possibly leading to more severe or different enforcement actions.").

<sup>26</sup> *See Alaska Dep't of Transp.*, CLI-04-26, 60 NRC at 411 (holding that a petitioner may not use the hearing process to seek additional measures beyond those set out in a confirmatory order).

<sup>27</sup> *See* NRC Enforcement Manual at 199 (suggesting that if a licensee did not agree to the commitments in a confirmatory action letter, the NRC staff would likely issue an order).

proceeding.<sup>28</sup> Thus, if a member of the public desires enforcement of more stringent or different restrictions than the NRC staff has already documented in a CAL, Section 2.206 provides for such an opportunity.

**(3) Is additional formal communication needed to licensees from the NRC regarding future use of CALs?**

Additional formal communication should be broadly disseminated to all stakeholders regarding the status of CALs. As noted above, the Commission should issue guidance clarifying its treatment of hearing requests on CALs and directing requestors to instead use the 10 C.F.R. § 2.206 process.

**IV. Commission Separation of Function Communication Challenges (Issue 6)**

**During the review of the SONGS steam generator event, the Commission assumed an adjudicatory role. The staff's communication to the Commission on SONGS was required to meet *ex parte* communication restrictions.**

**Items to Consider:**

**(1) Were there instances in which the separation of functions created communication challenges between the staff and Commission?**

NEI has no knowledge of any instances where separation of functions created communication challenges between the NRC staff and Commission.

**(2) Is additional guidance to staff needed to help ensure common understanding of what information can and cannot be discussed with the Commission during adjudicatory processes?**

The Commission could have avoided any *ex parte* concerns by not establishing a proceeding when none previously existed and one was not legally required.

The Atomic Energy Act contains no legal mechanism for the public to enforce NRC regulations. Instead, if a petitioner has concerns about a CAL, the 10 C.F.R. § 2.206 process is the appropriate means for raising these issues before the agency.

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<sup>28</sup> See *Bellotti v. NRC*, 725 F.2d 1380, 1382 (D.C. Cir. 1983) ("A petition is not a futile gesture, for the Commission may not deny it arbitrarily."); *Alaska Dep't of Transp.*, CLI-04-26, 60 NRC at 407 n.35 (indicating that if an individual believes that NRC has not gone far enough to remedy a safety concern, then they are free to file a Section 2.206 petition); *Marble Hill*, CLI-80-10, 11 NRC at 442 ("[T]he NRC already provides a separate procedure, under 10 C.F.R. 2.206, for any interested person to seek enforcement actions beyond those adopted.").

The commencement of a proceeding was inappropriate, inconsistent with the NRC's long-established regulatory processes, and incompatible with effective and efficient regulation. NRC case law establishes that the agency does not "convene an adjudicatory proceeding in order to determine whether an adjudicatory proceeding is warranted."<sup>29</sup>

In addition to the unnecessary *ex parte* limitations, requiring licensees to devote hearing resources to address inappropriate claims made by interested parties distorts the NRC's established processes and regulatory framework, creates an unnecessary burden, and increases regulatory uncertainty. As such, the Commission should summarily deny any hearing request not tied to any specific, pending licensing action or any published notice of opportunity for hearing. Consistent with Commission precedent, such challenges must be brought under Section 2.206.

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<sup>29</sup> *N. Ind. Pub. Serv. Co.* (Bailly Generating Station, Nuclear-1), CLI-78-7, 7 NRC 429, 432 (1978), *aff'd sub nom. Porter County Chapter of Izaak Walton League v. NRC*, 606 F.2d 1363 (D.C. Cir. 1979).