

UNITED STATES OF AMERICA  
NUCLEAR REGULATORY COMMISSION  
OFFICE OF NUCLEAR REACTOR REGULATION

William M. Dean, Director

In the Matter of	)	Docket Nos. 50-275 and 50-323
	)	
Pacific Gas and Electric Company	)	License Nos. DPR-80 and DPR-82
	)	
Diablo Canyon Power Plant	)	
Units 1 and 2	)	

**PROPOSED DIRECTOR'S DECISION UNDER 10 CFR 2.206**

**I. Introduction**

By letter dated July 14, 2016 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML16196A294), as supplemented by e-mail and the transcript from a teleconference held on August 2, 2016 (ADAMS Accession Nos. ML16215A109 and ML16232A570, respectively), Mr. David Lochbaum (the petitioner) of the Union of Concerned Scientists filed a petition under Title 10 of the *Code of Federal Regulations* (10 CFR), Section 2.206, "Requests for Action Under this Subpart." The petitioner requested that the U.S. Nuclear Regulatory Commission (NRC or the Commission) take enforcement action against Pacific Gas and Electric Company (PG&E, the licensee) related to the Diablo Canyon Power Plant, Units 1 and 2 (DCPP).

Mr. Lochbaum's letter, dated July 14, 2016, requested that the NRC "issue a Demand for Information pursuant to 10 CFR 2.204 to PG&E requiring the company to provide the NRC with a written explanation as to why its June 17, 2015, license amendment request [ADAMS Package Accession No. ML15176A539] failed to include all the accurate information needed by the NRC staff to complete its review and the measures it will implement so as to comply with

10 CFR 50.9 [“Completeness and Accuracy of Information”] in future submittals to the NRC.” As a basis for the request, the petitioner states, that “the NRC’s RAI [request for additional information] constitutes *prima facie* evidence that PG&E violated 10 CFR 50.9 by failing to provide complete information with its license amendment request dated June 17, 2015.” Also, the petitioner states, that “[t]he apparent violation of 10 CFR 50.9 required the NRC staff to expend additional resources to issue numerous requests for additional information and later to re-review the license amendment request along with the supplemental information. Had this licensee satisfied 10 CFR 50.9 with a complete and accurate license amendment request, these NRC staff resources would not have been squandered in such a non-productive way.”

On August 2, 2016, the petitioner spoke with the NRC’s Petition Review Board through a public and recorded telephone conference and provided additional information concerning his request. By letter dated November 9, 2016 (ADAMS Accession No. ML16285A220), the NRC notified the petitioner that it acknowledged receiving his petition and accepted the petition for review under the 10 CFR 2.206 process because the concerns meet the criteria provided in Management Directive (MD) 8.11, “Review Process for 10 CFR 2.206 Petitions” (ADAMS Accession No. ML041770328).

## **II. Discussion**

### **License Amendment Review Process:**

During the review of a licensing application by the NRC staff, the NRC has several regulatory tools available to ensure that the agency receives all the materials necessary to support a review and render a decision.

In accordance with 10 CFR 2.101, “Filing of Application,” it is the policy of the Office of Nuclear Reactor Regulation (NRR) to review an application to amend a license for

completeness and acceptability for docketing. The acceptance review process is detailed in NRR Office Instruction LIC-109, Revision 2, "Acceptance Review Procedures" (ADAMS Accession No. ML16144A521). This office instruction describes in detail the three possible results of an acceptance review: (1) unacceptable with no opportunity to supplement, (2) unacceptable with opportunity to supplement, and (3) acceptable for review. In the first scenario (unacceptable with no opportunity to supplement), if the NRC staff finds deficiencies so significant that they impede completion of the review, the staff will return the requested licensing action (RLA) to the licensee or applicant as unacceptable for review. In the second scenario (unacceptable with opportunity to supplement), if the NRC staff finds the RLA incomplete, the NRC staff may request supplemental information from the licensee or applicant to address any insufficiencies in the RLA in a reasonable timeframe. The NRC will accept an application for review if the NRC staff concludes that the application and supplemental information (if necessary), reasonably appear to contain sufficient technical information, both in scope and depth, for the NRC staff to complete the detailed technical review and render, in an appropriate timeframe for the associated action, an independent assessment of the proposed action with regard to applicable regulatory requirements and the protection of public health and safety.

The petitioner uses the example of the license amendment request (LAR) submitted by PG&E on June 17, 2015, to revise the licensing bases to adopt the alternative source term. During the acceptance review of the DCPD alternate source term LAR, the NRC staff used the Office Instruction LIC-109 process to obtain supplemental information necessary to allow the NRC staff to begin its detailed technical review. In a letter dated August 13, 2015, the NRC informed the licensee of the results of the NRC staff's acceptance review and identified supplemental information needed in order to make the application complete (ADAMS Accession No. ML15219A016). The licensee responded in a letter dated August 31, 2015, with the

requested supplemental information (ADAMS Accession No. ML15243A363). The NRC staff reviewed the supplemental information and by e-mail dated September 8, 2015, NRC staff “determined that PG&E’s responses provided adequate information to begin the technical review” (ADAMS Accession No. ML15252A006).

As stated, in part, in Office Instruction LIC-109, “[w]hile the goal of the acceptance review process is to facilitate submittal of acceptable RLAs, resulting in fewer RAIs, the acceptance of an RLA in no way implies that RAIs may not be raised during the detailed review process, that these RAIs may not identify serious insufficiencies in the application (possibly resulting in the denial of the RLA), or that the application will be or must be approved. Rather, the acceptance review is a tool used by the NRC staff to identify unacceptable RLAs early in the review process so they can be returned to the licensee, or applicant.”

After the NRC has accepted a licensing application, the NRC staff starts its detailed technical review following the guidance in Office Instruction LIC-101, Revision 5, “License Amendment Review Procedures” (ADAMS Accession No. ML16061A451). Section 2.102, “Administrative Review of Application,” of 10 CFR states that during review of an application, an applicant may be required to supply additional information. The NRC staff can send RAIs to the licensee to obtain all relevant information needed to make a regulatory decision on an LAR that is fully informed, technically correct, and legally defensible. RAIs are necessary when the information is required to make a safety determination but the information is not included in the initial submittal, is not contained in any other docketed correspondence, or cannot reasonably be inferred from the information available to the staff. In accordance with 10 CFR 2.108, “Denial of Application for Failure to Supply Information,” the NRC may deny an application if a licensee or applicant fails to respond to an RAI within 30 days from the date of request, or within such other specified time.

In the case of the DCPD LAR noted in the petition, the NRC used the RAI process to request various technical information. The petitioner specifically references the NRC's RAIs regarding meteorological (Met) data and atmospheric dispersion model input and output files in e-mails dated October 1, 2015, and February 17, 2016 (ADAMS Accession Nos. ML15278A049 and ML16048A232, respectively). The licensee then provided supplemental information in a timely manner in its letters dated November 2, 2015, and April 21, 2016 (ADAMS Accession Nos. ML15321A235 and ML16120A026, respectively). The initial set of RAIs dated October 1, 2015, focused on acquiring Met data and their characteristics, input and output files for ARCON96 atmospheric dispersion modeling runs used to estimate dispersion at onsite receptor locations, including Met data formatted for input to that model, input files for the proprietary EN-113 dispersion model (used to estimate dispersion at offsite receptor locations), and a description of the input file structure and plant drawings used to determine certain model input parameters for both models. The NRC staff used this information to confirm the results of the licensee's ARCON96 and EN-113 dispersion modeling analyses, which provided direct input to the calculation of onsite and offsite doses. The second set of RAIs focused on addressing whether the appropriate Met data were input to the modeling runs and if the data were representative of long-term conditions at the DCPD site.

The NRC staff can also leverage appropriate communication means, such as public meetings and teleconferences, in order to enhance clarity and understanding both during the development of draft RAIs and after sending RAIs to the licensees. Use of such communication tools with the licensees facilitates the staff's understanding of licensee submittals, can reduce the number of RAIs needed, and enhances the licensees' understanding of RAIs and their ability to respond effectively. In some cases, a regulatory audit is useful and appropriate to allow NRC staff to gain better understanding of the analysis being reviewed, to verify

information, and to identify information that will require docketing to support the basis of the licensing decision. Performing a regulatory audit often allows the staff to more efficiently conduct its review or gain insights on the licensees' programs or processes. However, in order for the NRC to use the information obtained during the audit to make a regulatory or technical decision, the information must be formally submitted by the licensee or applicant on the docket. Additional information on NRR's regulatory audit process can be found in Office Instruction LIC-111, "Regulatory Audits" (ADAMS Accession No. ML082900195).

Due to the complex nature of the dispersion modeling analyses in the DCCP LAR (including the licensee's use of the proprietary EN-113 model), the NRC staff determined a regulatory audit was necessary and prudent to examine and evaluate specific technical information, including the calculations performed in support of the analyses, as described in the NRC's regulatory audit plan dated July 12, 2016 (ADAMS Accession No. ML16193A332). The audit report can be found in ADAMS under Accession No. ML16279A343. Following the audit on August 3-4, 2016, NRC staff submitted RAIs dated September 7, 2016 (ADAMS Accession No. ML16251A091), to obtain information discussed in the audit, on the docket, in order for NRC staff to complete the review of the DCCP alternate source term LAR. In response to the RAIs, the licensee provided supplemental information in letters dated October 6, 2016, and December 27, 2016 (ADAMS Accession Nos. ML16287A754 and ML17006A051, respectively).

The NRR Leadership Team provided additional guidance to further clarify the NRR licensing process, including LIC-101, LIC-109, and LIC-111, in a memorandum dated April 18, 2016 (ADAMS Accession No. ML16202A029). The memorandum, referred to as the "Expectations Memo," outlines a common set of expectations regarding the acceptance review (e.g., estimated hours/schedule, RAIs, complex reviews, group submittals, etc.), that ensure NRC has a continued focus on safety while effectively leveraging established processes to

maintain the workflow in the office. The NRC incorporated these expectations into the latest revisions of Office Instructions LIC-101 and LIC-109. In the Expectations Memo, the technical staff is directed to develop a draft safety evaluation (SE) as it performs the technical review. As the technical staff determine additional information is necessary or required for further clarification in the draft SE, which corresponds to a "hole," the technical staff will develop an RAI to obtain the information. The supervisor is expected to confirm that the holes in the draft SE align with the RAIs being asked. Prior to sending a second (and any subsequent) round of RAIs in the same technical area, the associated supervisor and technical and licensing division senior management must approve the path forward, whether that is to submit another round of RAIs or to pursue alternative methods, such as a public meeting or an audit, for determining the necessary information that the licensee needs to submit on the docket. These additional steps enhance the NRC's safety focus by ensuring that the agency obtains the necessary information to complete the licensing review while providing greater clarity and discipline into the RAI development process.

The use of RAIs, audits, and public meetings are tools to obtain the necessary information to make an appropriate, informed regulatory finding. Specifically, during the review of the DCPD alternate source term LAR, the NRC responded with the appropriate tools for requesting supplemental and additional information, consistent with well-established licensing processes, in order to facilitate an efficient and effective regulatory review of the LAR.

**History of 10 CFR 50.9:**

The NRC promulgated 10 CFR 50.9 in 1987 in an attempt to codify Commission case law from the Virginia Electric Power Company (VEPCO) case, CLI-76-22 (1976). In that case, the licensee failed to disclose in its LAR certain seismic information regarding the location of North

Anna Power Station. At the time, such information was evaluated under the “material false statement” standard. The Commission concluded in the VEPCO case that there is no scienter requirement for material false statement (i.e., the licensee need not know that the statement is false at the time), that an omission can constitute material false statement, and that materiality is determined by whether information could influence NRC staff in making a regulatory decision (52 FR 49363). The NRC continued administering the enforcement program under the VEPCO holding until its codification in the 1987 rulemaking.

The concept of a “material false statement” was broken into two separate regulations. The NRC’s regulations at 10 CFR 50.9 cover information that is materially incomplete or inaccurate and 10 CFR 50.5(a)(2) addresses deliberately providing information to the NRC or a licensee, etc., that the person submitting the information knows to be materially incomplete or inaccurate. The Statements of Consideration for the 10 CFR 50.9 rule demonstrate that the NRC staff explicitly contemplated the implications of the rule on RAIs in the licensing process. Specifically, the NRC staff stated that “the Commission intends to apply a rule of reason in assessing completeness of a communication. For example, in the context of reviewing an initial application or a renewal application for a license, it is not uncommon for an NRC reviewer to seek additional information to clarify his or her understanding of the information already provided. This type of inquiry by the NRC does not necessarily mean that incomplete information which would violate this rule has been submitted” (52 FR 49366).

#### **History of Enforcement in Licensing Matters:**

Consistent with the basis described in the Statements of Consideration of 10 CFR 50.9, the NRC has seldom issued violations for information submitted in the licensing process. In 1994, the NRC’s Executive Director for Operations established a review team to assess the

NRC enforcement program. The team's final report, NUREG-1525, "Assessment of the NRC Enforcement Program," dated April 1995 (ADAMS Accession No. ML092240713), discusses deterrence as an enforcement objective and specifically contemplates that enforcement occurs "after the fact."<sup>1</sup> Specifically, the team was responding to the idea that the deterrent effect of enforcement, such as civil penalties, was no longer needed due to the "other motivations for compliance, such as dual regulation by other agencies, reputation in the local community and among industry peers, the economic rewards of being a 'good performer,' professional dedication to quality, and the overriding motivation of safety."<sup>2</sup> The report goes on to say that "[a]ll enforcement is, by nature, *after the fact*; while licensing, inspection, and other NRC functions can help to anticipate and prevent violations and other safety problems from occurring, enforcement action is only taken when the noncompliance has already occurred (i.e., after the other motivations for compliance have, at least in this instance, been insufficient)."<sup>3</sup> In the case of licensing actions, the "other motivation" for compliance is the NRC's acceptance of the application and/or granting of the requested licensing action. In other words, the staff's primary, and arguably, most effective recourse for poor quality licensing submittals is to decline to accept the application and/or grant the requested licensing action.

Section 182 of the Atomic Energy Act, from which NRC derives the authority to promulgate 10 CFR 50.9 states that "[t]he Commission may at any time after the filing of the original application, and before the expiration of the license, require further written statements in order to enable the Commission to determine whether the application should be granted or denied..." This suggests that a reasonable recourse for inadequate responses to RAIs is denial

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<sup>1</sup> NUREG 1525 at II.A-4.

<sup>2</sup> *Id.*

<sup>3</sup> *Id.*

of the requested licensing action rather than an enforcement sanction. Furthermore, as stated above, the Statements of Consideration for 10 CFR 50.9 (52 FR 49366) make it clear that NRC staff RAIs are not necessarily indicative of a violation of 10 CFR 50.9 as suggested by the petitioner.

The NRC Enforcement Policy (ADAMS Accession No. ML16271A446), provides the NRC staff the authority to take an enforcement action for submittals of incomplete or inaccurate information. Whether a particular issue constitutes a violation of 10 CFR 50.9 is evaluated by the facts and circumstances in a particular case. While the NRC staff seldom issues violations for information submitted in the initial phase of the licensing process, it can and has taken enforcement actions (including escalated enforcement) for cases where licensees provide inadequate information that the NRC used or considered in reaching a decision. Examples include providing incomplete or inaccurate information related to a revision to technical specifications, license transfer application, and exceptionally egregious examples of providing inaccurate information in response to RAIs.<sup>4</sup>

**Policy Issues:**

Whether or not the NRC issues violations for information that is incomplete or inaccurate in the context of licensing submittals is a matter of policy. While the NRC has an interest in receiving quality products for review, the agency also has an interest in maintaining efficiency in the regulatory process. If the NRC frequently cites violations of 10 CFR 50.9 for license applications and responses to RAIs, then it is likely that licensees will naturally tend to provide as little information as possible. This could thwart the candid and fulsome exchange of

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<sup>4</sup> EA-2004-189, EA-2012-030, EA-2013-058 and EA-2013-201 (ADAMS Accession Nos. ML043090082, ML12213A182, ML13239A398, and ML14094A052, respectively).

information and decrease the efficiency of the licensing. The routine use of enforcement in this area may tend to create a “chilling effect” on licensees when providing information, which is contrary to the principles of good regulation.

As previously discussed, the primary means for dealing with unacceptable licensing submittals is denying the requested regulatory action. To the extent that the NRC staff believes the licensee’s conduct is exceptionally egregious, enforcement is an available option, but, as noted earlier, in the Statements of Consideration, an NRC reviewer requesting additional information in the context of licensing is not necessarily indicative of a violation. The NRC Enforcement Manual contains guidance to the staff on evaluating these issues (ADAMS Accession No. ML102630150). Specifically, the manual states that “generally, no enforcement action is taken for inaccurate or incomplete information submitted in the licensing process...”<sup>5</sup> However, “the NRC has the authority to do so on a case by case basis if a particular submission warrants such action.”<sup>6</sup> As explained above, the NRC staff does not believe enforcement action is warranted for the DCPD alternate source term LAR.

**RAIs and the NRC Budget:**

The petitioner states in its e-mail dated August 2, 2016, that “Our concern is heightened by the downsizing being undertaken via Project AIM. If the NRC staff continues to inefficiently apply FTEs [full-time equivalents] to reviews and re-reviews and re-re-reviews of licensee submittals until they finally obtain complete and accurate information, those will be FTEs unavailable for more productive safety work.”

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<sup>5</sup> Enforcement Manual at page 324.

<sup>6</sup> *Id.*

To be clear, Project AIM is an NRC initiative used for long-term workload forecasting for the agency, along with a framework and series of on-going recommendations to enhance the NRC's ability to plan and execute its mission in a more effective, efficient, and agile manner. Successful implementation of these strategies, along with the inculcation of the underlying tenets of Project Aim into agency culture, is expected to play a key role in helping the agency to accomplish the agency's safety and security mission more effectively and efficiently while operating with fewer resources. More on Project AIM can be found on NRC's external Web site at <https://www.nrc.gov/about-nrc/plans-performance/project-aim-2020.html>.

### **III. Conclusion**

Based on the NRC staff's use of appropriate regulatory tools in reviewing the DCPD alternate source term LAR, consistent with established licensing processes, and review of the Enforcement Policy regarding the use of 10 CFR 50.9 in the license amendment review process, the NRC staff concluded that the requested demand for information, per 10 CFR 2.204, is not warranted for the DCPD alternate source term LAR. Therefore, the NRC denies the petitioner's requested enforcement action against the licensee.

As provided in 10 CFR 2.206(c), a copy of this director's decision will be filed with the Secretary of the Commission for the Commission to review. As provided for by this regulation, the decision will constitute the final action of the Commission 25 days after the date of the decision unless the Commission, on its own motion, institutes a review of the decision within that time.

Dated at Rockville, Maryland, this            day of            , 2017.

For the Nuclear Regulatory Commission.

William M. Dean, Director,  
Office of Nuclear Reactor Regulation.