# MEMORANDUM TO: Marissa G. Bailey, Director

Division of Fuel Cycle Safety, Safeguards,

 and Environmental Review

Office of Nuclear Materials Safety
 and Safeguards

FROM: Margie Kotzalas, Chief

Programmatic Oversight and

 Regional Support Branch

Division of Fuel Cycle Safety, Safeguards,

 and Environmental Review

Office of Nuclear Materials Safety

 and Safeguards

SUBJECT: RESPONSE TO PUBLIC COMMENTS ON DRAFT NRC GENERIC LETTER 20XX-XX, “TREATMENT OF NATURAL PHENOMENA HAZARDS AT FUEL CYCLE FACILITIES”

A notice of opportunity for public comment on Draft Generic Letter 20XX-XX, “Treatment of Natural Phenomena Hazards at Fuel Cycle Facilities” was published in the *Federal Register on* August 8, 2014(79 FR 46472). Comments were received from Stephen McDuffie (Agencywide Document and Management System (ADAMS) Accession No. ML14281A266) and the Nuclear Energy Institute (ADAMS Accession No. ML14316A411). Enclosed are the staff responses to these comments.

For the NRC’s generic communications program, the staff solicited external stakeholder feedback on the cumulative effects of regulation (CER) in the *Federal Register* notice for this generic letter. The enclosure also provides responses to Nuclear Energy Institute comments regarding CER for this generic letter.

Enclosure:

Response to Public Comments

 on Generic Letter

CONTACT: Jonathan Marcano, NMSS/FCSE/PORSB

 (301) 287-9063

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| **DATE** | 12/01/2014 | 12/ 3 /2014 | 12/ 3 /2014 | 12/ /2014 |

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**RESPONSE TO PUBLIC COMMENTS ON**

**DRAFT NRC GENERIC LETTER 20XX-XX, “TREATMENT OF NATURAL PHENOMENA HAZARDS AT FUEL CYCLE FACILITIES”**

Comments on this draft generic letter are available electronically at the U.S. Nuclear Regulatory Commission’s (NRC's) electronic Reading Room at <http://www.nrc.gov/reading-rm/adams.html>. From this page, the public can gain entry into Agencywide Documents Access and Management System (ADAMS), which provides text and image files of NRC's public documents. Comments were received from the following individuals or groups:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Letter No.** | **ADAMS No.** | **Commenter Affiliation** | **Commenter Name** | **Abbreviation** |
| 1 | ML14281A266 | No Known Affiliation | Stephen McDuffie | SMcDuffie |
| 2 | ML14316A411 | Nuclear Energy Institute  | Janet R. Schlueter | NEI |

This document lists each public comment by Letter No. For each comment, the NRC has either repeated the comment as written by the commenter or summarized the comment for conciseness and clarity. Each comment is referred to in the form [XXX]-[YYY]-[ZZZ], where: [XXX] represents the Abbreviation from the above table, [YYY] represents the Letter No. from the above table, and [ZZZ] represents the sequential comment number from that commenter.

*SMcDuffie 1-1*

The fourth paragraph of the discussion section of the document refers to updated seismic hazard information from the U.S. Geological Survey (USGS). Presumably, this means either the 2008 or 2014 updates to the USGS National Seismic Hazard Map (NSHM). Given that this generic letter is directed at nuclear facilities, was consideration given to instead referring to the updated seismic source characterization provided in 2012 by the “Central and Eastern United States Seismic Source Characterization for Nuclear Facilities,” NUREG-2115 (CEUS-SSC)? The facilities targeted in this Generic Letter presumably have a number of Structures, Systems, and Components (SSCs) that would be categorized as Seismic Design Category (SDC) 2 or 3 per the categorization scheme of ANSI/ANS-2.26-2004 (R2010), “Categorization of Nuclear Facility Structures, Systems, and Components for Seismic Design.” Although ANS-2.26 Table A.2 recommends using the USGS 2500-year return period ground motion for SDC-2 SSCs, SDC-3 SSCs should use a site-specific uniform hazard response spectrum at the 4E-4 annual frequency of exceedance for the design basis ground motion. Applying the CEUS-SSC model would meet this standard for SDC-3 SSCs.

NRC Response

This comment is outside the scope of this generic letter. No change was made to the final generic letter as a result of this comment.

The purpose of the draft generic letter is to request addressees to submit information to demonstrate compliance with the regulatory requirements and applicable license conditions regarding the treatment of natural phenomena events in the facilities’ safety assessments. In accordance with NRC process, guidance for how licensees may respond to a generic communication (i.e., reference to NUREG-2115) is not included in the communication itself. NUREG-2115 is, however, available for licensees to use if they chose. The NRC will review the licensee’s responses to ensure that facilities are evaluating natural phenomena events consistent with applicable knowledge and methods to the characterization of site hazards.

*SMcDuffie 1-2*

Requested action 1.a asks the addressees to submit their definitions of unlikely, highly unlikely, and credible for natural phenomena hazard events. Why does not the NRC provide uniform definitions of these terms, i.e., annual expected frequencies such as 1E-2 for credible, 1E-3 for unlikely, and 1E-4 for highly unlikely? This should be the role of the regulator. Varying definitions from each licensee does not seem sensible.

NRC Response

The NRC disagrees with the comment. No change was made to the final generic letter as a result of this comment.

As explained in the Statements of Consideration for the 10 CFR Part 70 final rule (56211 FR Vol. 65, No. 181, September 18, 2000) the regulations in Part 70 apply to different types of fuel cycle facilities, some of which are more complex and have more accident sequences than other. Since the application of the terms unlikely, highly unlikely, and credible are specific to the individual context in which they are applied; definition of these terms in rule language is impracticable.

*NEI 2-1*

Overall, the basis for the generic letter remains unclear given the small number of facilities affected by it and the following facts: 1) the facility-specific ISA, which consider NPH, were reviewed and accepted by NRC and the ISA Summaries are on the docket; 2) NRC has unfettered access to all facility information at any time to supplement its understanding of the ISA; and 3) NRC conducted relevant inspections in accordance with TI 2600/15 at operating facilities, which could be repeated as a less resource intensive alternative for collecting the requested information.

NRC Response

The NRC disagrees with the comment. No changes were made to the final generic letter as a result of this comment.

After completion of inspections under Temporary Instruction (TI) 2600/015, “Evaluation of Licensee Strategies for the Prevention and/or Mitigation of Emergencies at Fuel Facilities,” the NRC inspectors found, in a number of facilities, insufficient supporting documentation to justify the licensees’ ISA assumptions used for natural phenomena hazards. Insufficient documentation to allow NRC inspectors to verify compliance with the performance requirements is the basis for the generic letter. Issuance of a generic letter is appropriate for the purpose of collecting information from licensees on issues of generic applicability.

*NEI 2-2*

The draft generic letter states that, at a number of facilities, there was insufficient documentation to justify assumptions and the lack of supporting documentation raises questions about the validity of such assumptions. However, the NRC issued URIs to further assess whether the evaluated licensees are in compliance with license conditions, and the requirements of 10 CFR 70.61 and 10 CFR 70.62(c). Since, as the draft generic letter states, the facilities are adequate to protect public health and safety and individual license conditions are involved, the NRC should continue the resolution of the URIs, as necessary, through the normal process with individual licensees. If there are issues that become relevant to the fuel cycle industry at large, a generic communication such as a Regulatory Issue Summary or Information Notice could be issued to alert licensees to these issues and encourage licensee review of facility-specific ISAs for applicability.

NRC Response

The NRC disagrees with the comment. No changes were made to the final generic letter as a result of this comment.

After completion of TI 2600-015, NRC inspectors opened unresolved items (URIs) to further assess whether the licensees are in compliance with license conditions, and the requirements of 10 CFR 70.61 and 10 CFR 70.62(c). The URIs represent an issue with generic applicability across the nuclear fuel facility industry. The NRC is requesting this information because a review of operating fuel cycle facilities and NRC inspections were unable to validate that the facilities were in compliance with their licensing basis for NPH. The inspections found that many operating fuel cycle facilities lacked facility design information; that there were significant variations in the level of detail and rigor in the facility ISAs; that the assumptions used in developing the safety analysis were not clearly described; and that some supporting analyses were limited or missing.

In accordance with NRC Management Directive 8.18,”Generic Communications Program,” a generic letter provides a path for the staff to request information from licensees consistently across the industry. Although at this time the staff does not believe that the URIs represent an issue of immediate safety concern, failure of properly evaluating the impacts of natural phenomena events may lead to accident sequences that exceed the performance requirements in 10 CR 70.61. Responses to the generic letter may reveal unanalyzed conditions that may lead to accident sequences that exceed the performance requirements of 10 CFR 70.61 for which prevention or mitigation measures are needed.

*NEI 2-3*

The generic letter should not be addressed to applicants and licensees subject to 70.64, “Requirements for new facilities or new processes at existing facilities.” Specifically, such entities had to demonstrate that the design provides for adequate protection against natural phenomena hazards with consideration of the most severe documented historical events for the site. Such designs were recently reviewed and approved by NRC. Most, if not all, of the requested information is included in the license application and/or ISA Summary and all information is available on site. Further, the draft generic letter anticipates that the NRC may already have the information based on the note on page 7, i.e., licensees or facilities subject to 70.64(a)(2) may reference sections of their license application and/or ISA summaries as a response to applicable requested actions. Since this is a small number of facilities and it appears the NRC may already have most, if not all, of the requested information and has access to it, it would appear more efficient for the NRC to address the facilities on an individual basis to obtain any additional information needed.

NRC Response

The NRC disagrees with the comment. No changes were made to the final generic letter as a result of this comment.

As stated in responses to NEI 2-1 and NEI 2-2, the results of the TI 2600/015 identified issues of generic applicability to the fuel cycle industry and thus a response is required from all addressees. As outlined in the generic letter, licensees subjected to 10 CFR 70.64(a)(2) may reference sections of their license application and/or ISA summaries as a response to applicable requested actions. In addition, if an addressee cannot meet the requested response date, the addressee can provide a description of the alternative course of action that it proposes to take, including the basis of the acceptability of the proposed alternative course of action and estimated completion dates.

*NEI 2-4*

During the September 2014 public meeting, industry understood NRC to state that draft generic letter item (2)a., “evaluation basis for natural phenomenon events” is the licensee’s site specific design basis determination (magnitude and likelihood) for the applicable natural events. If this is the case, it would appear that this information would be needed prior to performing item (1)b.iii, “assessment of consequences….that result in intermediate or high consequence events.” NRC should clarify its expectations on this issue in the draft guidance and final generic letter.

NRC Response

The NRC disagrees with the comment. No changes were made to the final generic letter as a result of this comment.

Requested action item (1)b.i., “Likelihood and severity of the natural phenomena events, such as earthquakes, tornadoes, floods, hurricanes, and other wind storms,” is the original design basis events for the facility SSC. The design basis for the facility may come from building codes at the time of construction or from hazard evaluations performed to evaluate the impacts of natural phenomena events. If a change to the assumptions used in the facility safety analysis is identified as a result of requested action item (1) that results in new accidents sequences that exceed the performance requirements of 10 CFR 70.61, then the licensee should identify the evaluation basis hazard that will be used in the new assessment. For example, in the case of non-existent design calculations for seismic loading, a licensee can opt for performing a seismic evaluation of the facility to demonstrate compliance with the 10 CFR 70, Subpart H requirements. Requested action item (2) a., “The evaluation basis for natural phenomena hazard events” is the information that describes the basis for the selection of a hazard that will be used in the new assessment.

*NEI 2-5*

NRC should clarify whether a response to Question (1)c. is required only if there is a change in methodology, likelihood and severity of NPH with that used in the original design/evaluation of the facility (this assumes responses to (1)a. and (1)b. provide the bases for existing NPH used by the licensee). Also, this question appears to be similar to question (2) with the exception that any required actions have been completed.

NRC Response

The NRC disagrees with this comment. No changes were made to the final generic letter as a result of this comment.

Requested action item (1)c. requests licensees to submit a summary of an evaluation between the original design/evaluation basis of the facility and how changes in the methodology, data or modeling techniques may impact the ISA assumptions with regards to natural phenomena hazards. For example, for seismic events, the licensee may provide a summary of how the hazard applicable to the site has changed (i.e. increase, decrease) with regards to the original design basis (e.g., building code used for original design). This evaluation informs whether the current condition of the facility can cope with the hazards or if there are additional mitigation strategies needed to reduce the overall risk of potential impacts from natural phenomena events.

If as a result of the evaluations from requested action item (1)c. a licensee identifies a change in the assumptions used in the ISA that affects the basis to show compliance with regulatory requirements, requested action items (2)a-e. request additional information to support the basis for the “new” assessment to restore compliance.

*NEI 2-6*

NRC should clarify whether a response to Question (2) is required only if additional actions are needed to validate assumptions used by the licensee in their NPH assessments. If true, it is anticipated that few, if any, fuel cycle facilities would be required to provide a response to Question (2).

NRC Response

The NRC agrees with this comment. No changes were made to the final generic letter as a result of this comment.

Refer to response to NEI 2-5. As stated in the draft generic letter, response to the set of requested action items (2)a-e. is only needed if an addressee identifies a change in the assumptions used in the ISA that affects the basis for compliance with regulatory requirements.

*NEI 2-7*

NRC should clarify how the generic letter will be closed. During the September 2014 public meeting, NRC staff stated that it would issue a letter to document closure of the generic letter response review process. As such, industry assumes that NRC would issue a letter to each facility when NRC completes its review of that facility, rather than NRC issuing a single letter to summarize the aggregated review of all facilities. Therefore, we request NRC clarification on the process to be used.

NRC Response

The NRC agrees with this comment. No changes were made to the final generic letter as a result of this comment.

As part of the generic letter closure process, the NRC will provide a closure letter to each individual licensee documenting the review of the generic letter responses. In accordance with NRC Management Directive 8.18, “Generic Communications Program,” once the licensee responses to the generic letter have been submitted to the NRC, the staff will perform its review of the responses and issue requests for additional information as appropriate. In addition, the staff may perform site inspections or other follow-up actions as applicable to complement the review/closure process. Once the staff confirms that a licensee has responded adequately to the generic letter, the staff will provide a letter to each individual licensee stating that the NRC’s review is complete and that the generic letter is closed for that facility.

*NEI 2-8*

Also during the September 2014 public meeting, NRC stated that an Interim Staff Guidance (ISG) is being developed to facilitate licensee responses to and compliance with the generic letter. The timing of such guidance is unclear, and was not reflected in the September version of NRC’s regulatory initiatives integrated schedule. Admittedly, there are pros and cons to issuing a final ISG before or after issuance of a final generic letter. For example, the final generic letter could be issued first, thereby informing the final ISG or vice versa. That being said, we suggest that a draft ISG be issued for comment with a due date in advance of the final generic letter being issued for the following reasons: 1) review of the draft ISG could reveal to NRC different interpretations of what is expected in the industry responses to the generic letter that would need to be resolved prior to issuing the final generic letter; 2) stakeholder comments on the draft ISG could further inform the contents and scope, and improve the clarity, of the final generic letter; and 3) licensees would gain the insights provided by the draft ISG and, in practical terms, be afforded additional time to prepare their responses. With this approach, the final ISG could be issued simultaneously with issuance of the final generic letter.

NRC Response

The NRC agrees with the comment. However, no changes were made to the generic letter as a result of this comment.

The NRC will develop general staff guidance on the topic of treatment of NPH (e.g., seismic hazards) and will notice it in the *Federal Register*. The staff guidance will be generic to address the topic and will not be linked with the closure of the generic letter. To ensure that external stakeholders have the opportunity to see the staff’s guidance, it will be issued for public comment with a due date in advance of the final generic letter. In addition, as part of the agency’s effort to consider CER, the schedule for the issuance of the staff guidance will be included in the NRC’s regulatory initiatives integrated schedule. The NRC staff will track the status for development of the generic letter and ISG using the fuel cycle facilities “Integrated Schedule for Cumulative Effects of Regulation,” available on the NRC public website at <http://www.nrc.gov/materials/fuel-cycle-fac/regs-guides-comm.html#cumeffects>.

*NEI 2-Attachment 1 (Cumulative Effects of Regulation)*

In addition to comments provided to the draft generic letter, the Nuclear Energy Institute (NEI) provided responses to the questions with regards to this generic letter as it relates to CER. No changes were made to the GL as a result of NEI’s responses to the CER-questions.

**a. In light of any current or projected cumulative effects, does this generic letter**

**request provide sufficient time for licensees to respond with the information requested, including any need to develop this information through supporting engineering calculation or analyses?**

NEI Response

At this time, the draft generic letter appears to provide sufficient time for licensees to respond with the information requested or make a determination on whether to request an extension of time to respond. This position is based on the fact that the draft generic letter was issued in August 2014 for public comment by November 6, 2014, a public meeting was held in September 2014 and the final generic letter is not expected until winter 2015. Had it been issued in final without this draft and discussion phase, the time allowed for response and any analyses would likely have been inadequate.

NRC Response

No change resulted to the generic letter as a result of this response.

The NRC is committed to minimizing CER impacts by providing adequate time and opportunities (i.e., public comment via the *Federal Register* and/or public meetings) for stakeholders to provide feedback on NRC regulatory issues.

**b. If a current or projected cumulative effect poses a significant challenge, what should be done to address it? For example, if more time is required to develop and provide information, what period of time is sufficient? Are there equally effective alternatives to providing the requested information to the NRC that reduce the cumulative effect?**

NEI Response

The necessary time and appropriate mechanism used by NRC or industry to address the cumulative impact from a specific regulatory initiative will vary depending on its safety or security significance, and corresponding level of effort, resources and time to address it as well as other priorities. In this case, NRC has in its possession or has access on-site at the licensed facility to a large portion if not all of the information requested in the draft generic letter. Therefore, requiring the licensee to replicate and consolidate it (e.g., definitions of “highly unlikely”) and, in the absence of an identified safety issue, submit it in a different format simply for a different regulatory purpose appears to be a poor use of limited industry and NRC resources.

NRC Response

No change resulted to the generic letter as a result of this response. Please refer to the NRC’s responses to NEI 2-1 and NEI 2-2.

**c. Do other (NRC or other regulatory agency) regulatory actions (e.g., Orders, rules, generic letter, bulletins, 50.54(f) requests) influence licensee responses to this draft generic letter? If so what are they and do you have a suggested approach to reduce the cumulative effects in light of these other regulatory actions?**

NEI Response

Yes. NRC staff stated its intent to issue guidance to help licensees inform their responses to a generic letter on natural phenomena hazards during the winter of 2015. As noted in item 7 of our cover letter on this matter, a draft Interim Staff Guidance (ISG) should be issued for comment with a due date in advance of the final generic letter being issued for the following reasons: 1) review of the draft ISG could reveal to NRC different interpretations of what is expected in the industry responses to the generic letter that would need to be resolved prior to issuing the final generic letter; 2) stakeholder comments on the draft ISG could further inform the contents and scope, and improve the clarity, of the final generic letter; and 3) licensees would gain the insights provided by the ISG and, in practical terms, be afforded additional time to prepare their responses. With this approach, the final ISG could be issued simultaneously with issuance of the final generic letter.

NRC Response

No change was made to the generic letter as a result of this comment. Please refer to the NRC’s response to NEI 2-8 regarding the staff’s plans to issue an ISG.

**d. Are there other projects that licensees are undertaking, plan to undertake, or should be undertaking that provide greater safety benefit, that might be displaced or delayed as a result of the expenditure of effort and resources to respond to this generic letter?**

NEI Response

Yes. As we have stated on several occasions, industry has delayed or protracted its efforts to implement certain facility-initiated program or operational improvements due to the heavy workload associated with the many ongoing NRC-initiated regulatory initiatives (See the integrated schedule for fuel cycle industry initiatives on NRC’s website). Consistent with our letter dated April 3, 2013, the following are a few examples of such facility-initiated improvements that are delayed or protracted yet would yield greater safety benefit if pursued than most if not all of the current regulatory initiatives underway.

* Increase the periodicity of station-specific worker training
* Improve the timeliness of field labeling of certain Items Relied On For Safety
* Improve the pace of systematic elimination of administrative controls - where engineered controls could be used
* Improve on meeting the goal of conducting a systematic re-review of the ISA at a specified periodicity
* Improve the periodicity of the conduct of self-assessments and efforts to implement best practices
* Increase the amount of time that managers and senior experts spend on the facility floor
* Improve the time to develop new processes to recover special nuclear material
* Improve the time to develop new or improved low-level waste minimization efforts

NRC Response

No changes were made to the generic letter as a result of this comment.

As discussed in the NRC’s response to comment NEI 2-8 above, the status of the generic letter and related ISG are tracked on the fuel cycle CER Integrated Schedule (Integrated Schedule) along with other regulatory activities. Although the facility-initiated projects (e.g., those listed in the comment) are not tracked on the Integrated Schedule, the NRC is open to feedback from stakeholders during quarterly CER meetings on the need to adjust milestones on the Integrated Schedule due to facility-initiated projects.

Note: Regulatory activities with safety or security significance and items with Commission directed due dates may have milestones which are not open for adjustment.

**e. Are there unintended consequences associated with responding to this generic letter at this time?**

NEI Response

Due to the sheer number of regulatory initiatives with due dates by year’s end and other concurrent initiatives, the time to conduct a critical review and provide insightful comments on this draft generic letter and has been relatively limited and less than one would prefer.

NRC Response

No changes were made to the generic letter as a result of this comment.

The NRC staff recognizes the Agency has multiple fuel cycle regulatory activities that are under development concurrently with the generic letter, many of which are tracked on the fuel cycle Cumulative Effects of Regulation Integrated Schedule. As part of NRC’s continuing CER efforts, the NRC adjust when possible its regulatory milestones to provide stakeholders adequate time to provide comments.

**f. Please comment on the NRC’s supporting justification for this generic letter.**

NEI Response

Given the relatively low risk of consequences of concern to the public or environment as a result of a natural phenomenon event at a fuel cycle facility, the resources expended to conduct any necessary analyses, assimilate and submit the information and potentially respond to Requests for Additional Information or related inspection findings is difficult to justify from a cost-benefit perspective.

NRC Response

No changes were made to the GL as a result of this comment.

The information requested in the generic letter will be used to further assess whether licensees are in compliance with license conditions and regulatory requirements. Please refer to the NRC response to comment NEI 2-1 for additional detail.