

Draft License Amendment Template for Tornado Missile Related Changes to Licensing Bases

(Office of Nuclear Reactor Regulation Office Instruction LIC-109 and LIC-101 based criteria) (version – 5/10/16)

For license amendments, the staff would perform acceptance reviews in accordance with the Office of Nuclear Reactor Regulation (NRR) Office Instruction LIC-109, "Acceptance Review Procedures,"¹ and review of the amendment, including requests for additional information (RAIs) and generation of a safety evaluation (SE), in accordance with NRR Office Instruction LIC-101, "License Amendment Review Procedures."²

The following guidance, from these documents, provides a roadmap for the specific attributes of a tornado missile protection related amendment:

Acceptance Review Criteria: (LIC-109 / amendment specific guidance)

- **Completeness of Scope:** Determine if there are significant analyses or evaluations missing from the license amendment (e.g., an application is missing a loss-of-coolant accident analysis when it appears that the proposed change would impact that analysis). Often, the appropriate analyses are designated in industry Codes and Standards, NRC Regulatory Guides, Regulatory Issue Summaries, etc. An amendment lacking an analysis necessary for the NRC staff's review should be considered unacceptable.
 - Amendment would fully describe the purpose for the changes, provide appropriate background information to the current configuration (current licensing basis), state whether deterministic or risk informed factors are to be considered in amendment, identify all structures, systems, and components (SSCs) that are not in compliance, describe the methodology elements used to evaluate those SSCs, and describe the measurement criteria used to determine if non-protected SSCs can remain non-protected.
 - The amendment will be applicable to the plant site, and not a single unit on a multi-unit site.
 - The amendment will describe the site-specific current licensing basis, and appropriate regulatory basis for the design basis of the plant(s), including applicable regulations, regulatory guidance, and standard review plan relevance.
- **Sufficiency of Information (SI):** Determine if there are significant, obvious, problems with the information and analyses provided. Technical staff may use various measures for this criterion, such as the volume and magnitude of questions that could be generated based simply on the initial reading of the application. The information provided should support a comparison of the license amendment to the

¹ Agencywide Documents Access and Management System (ADAMS) Accession No. ML091810088.

² ADAMS Accession No. ML113200053.

licensee's existing processes or programs, if applicable, with justification for the change. If significant, obvious problems are identified, the amendment should be considered unacceptable.

The Amendment would contain the following:

License Amendment Request Element	Cross-reference with Tornado Missile Risk Evaluator Action Items
SI1 - Description of tornado magnitude and frequency for the site-specific area. Where generic information is used, a full justification for the applicability to the site would be provided.	1e, 1f, 1k, 1l, 3c, 4a, 4b
SI2 - Description of quantity and characteristics of the missiles expected at the site, including expected behavior and relevance for causing damage to SSCs.	1f, 1l, 3c
SI3 - Justification for number of missiles used in analysis. Where generic information is used, a full justification for site-specific applicability to the number of missiles considered will be provided.	3c, 3d, 3e, 4c, 4d
SI4 - Full description of non-protected SSCs, including those SSCs determined to screen out, as well as those SSCs determined to be applicable targets. Use of drawings, pictures, and other visual attributes, while not required, are recommended.	1g, 1h, 1j, 3d
SI5 - A list of SSCs that are assumed to fail due to the tornado conditions (i.e., high winds, differential pressure, loss of offsite power) even if they are not struck by a missile to confirm that this list does not make inappropriate assumptions that would decrease the change in risk estimate.	
SI6 - A description of the processes, including the walk down process used to identify missiles, and to develop and validate the list of affected SSCs.	3a, 3b, 3f,
SI7 - Discussion of potential for indirect failure consequences of SSCs responsible for losses of safety functions, such as consideration for: flooding damage to safety-related SSCs from large tank failures, toppling impact on near-by otherwise protected transformers or electrical delivery equipment, and losses of non-safety related buildings that generate additional missiles and/or expose additional SSCs.	1c
SI8 - Description of safety function relevance to non-protected SSCs, including rationale for warranting consideration for screened out and screened SSCs against maintenance of the applicable safety function.	
SI9 - Description of defense-in-depth and compensatory measures to be considered beyond design/licensing basis, if used to justify probabilistic risk analysis (PRA) based changes to core damage frequency.	4d

License Amendment Request Element	Cross-reference with Tornado Missile Risk Evaluator Action Items
SI10 - Redline/strike out version of proposed updated final safety analysis report (FSAR) and/or technical specification (if applicable) incorporating changes to the site-specific licensing basis. Identification of unprotected SSCs to be probabilistically excluded, and listing and unprotected but screened out SSCs, with justification for screening, should be clearly described in the proposed FSAR change.	
SI11 - Licensees that submit risk information would address each of the principles of risk-informed regulation discussed in Regulatory Guide (RG) 1.174, "An Approach for Using Probabilistic Risk Assessment in Risk-Informed Decisions on Plant-Specific Changes to the Licensing Basis," ³ and identify how their chosen approaches and methods, data, and criteria for considering risk are appropriate for the decision to be made. The amendment will contain the following information regarding the risk evaluations:	
SI11.1 - A description of changes made to the PRA model to support the application.	
SI11.2 - For each SSC that is modeled as failing from tornado missiles, details of the basic events added to the model, including failure probability. All parameters used to estimate the failure probabilities of SSCs, such as SSCs' exposed areas, generic missile strike probabilities, or correlations with other tornado missile basic events would be provided and justified.	1a,
SI11.3 - If generic missile strike probabilities are used, a discussion would be provided to justify the applicability of those values considering site-specific information, such as the missile distribution, relative location of missiles and unprotected SSCs, potential structures that could shield those components from missiles, and other factors related to geometry and configuration of the site that could impact the generic values.	1b, 1d, 1n, 1i, 1j, 1k, 1l
SI11.4 - Base core damage frequency (CDF) and large early release frequency (LERF) for the chosen event trees; that is, CDF and LERF calculated with the tornado IEF and with the tornado missile basic event probability for the unprotected SSCs set to zero.	
SI11.5 - A description of how the change in CDF and LERF were estimated.	2a
SI11.6 - Demonstration that delta CDF and LERF (in conjunction with CDF and LERF for the as-built, as-operated plant) meet RG 1.174 guideline values.	

³ ADAMS Accession No. ML100910006.

License Amendment Request Element	Cross-reference with Tornado Missile Risk Evaluator Action Items
SI11.7 - The sensitivity to the delta CDF and delta LERF to changes in the following parameters or assumptions: number of missiles, different generic missile impact parameters, and degree of correlation among tornado missile basic events.	
SI11.8 - A discussion of defense-in-depth consistent with elements outlined in RG 1.174.	
SI11.9 - A discussion of safety margins to justify that safety margins, while reduced, are still acceptable.	
SI11.10 - A discussion of how the risk from tornado missiles will be monitored, tracked, and/or controlled. For example, if missile-free zones are credited in the analyses, the licensee should provide a description of the programmatic controls used to ensure that they remain in place.	
SI11.11 - A discussion on the acceptable scope, level of detail, and technical adequacy of the PRA used to support the application. Provide PRA peer-review findings for supporting requirements that affect the application.	

- Regulatory Basis (RB):** Determine whether the applicable regulations and criteria are properly applied. The licensee or applicant should identify the regulatory criteria used to determine that the license amendment is acceptable. The NRC staff may utilize guidance documents such as the Standard Review Plan (SRP) or any specific review standards for specific amendments (e.g., extended power uprates). When the licensee proposes an alternative to an approved approach described in a guidance document, the NRC staff should verify the completeness of the scope and logic of the alternate methodology. From the information contained in the application, the NRC staff should be able to identify the applicable criteria by which to evaluate the proposed action.

License Amendment Request Element	Cross-reference with Tornado Missile Risk Evaluator Action Items
RB1 - Amendment will describe the applicable regulatory basis for the design basis and current licensing basis, including:	
RB1.1 – General Design Criterion 2, “ <i>Design bases for protection against natural phenomena</i> ,” ⁴ draft design guidance, or specific design criteria as defined in the unit/site’s FSAR	
RB1.2 – Regulatory Guide 1.117 (Rev. 1), “Tornado Design Classification,” ⁵ RG 1.76 (Rev. 1), “Design-Basis Tornado and	

⁴ Title 10 of the *Code of Federal Regulations*, Part 50, Appendix A, “General Design Criteria for Nuclear Power Plants”

⁵ ADAMS Accession No. ML003739346.

Tornado Missiles for Nuclear Power Plants,” ⁶ and/or NUREG-75/086 or NUREG-0800, “Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants: LWR [light-water reactor] Edition,” references for site specific licensing basis	
RB1.3 - NUREG/CR-4461, “Tornado Climatology of the Contiguous United States,” ⁷ or other siting basis used to determine tornado frequency.	
RB1.4 - EPRI NP-2005, “Tornado Missile Simulation and Design Methodology (TORMIS),” or other probabilistic model reference(s) used to perform probabilistic exclusion modeling	
RB1.5 - RG 1.174, Rev.2, specific reference and description of risk insights used in analysis for change in core damage and large early release frequencies.	
RB1.6 - RG 1.200, Rev. 2, “An Approach for Determining the Technical Adequacy of Probabilistic Risk Assessment Results for Risk-Informed Activities,” ⁸ for determining the technical adequacy of the PRA used to support the application.	
RB 2 – Amendment should follow similar guidance for application information to the five (5) points provided in RIS 2008-14, “Use of TORMIS Computer Code for Assessment of Tornado Missile Protection.” ⁹	

- **Use of Approved Guidance (AG):** Determine whether any approved codes or topical reports cited in the application are used in accordance with the limitations and conditions imposed by the NRC staff. A licensee’s use of unapproved codes or topical reports (or the use of codes and topical reports outside the limitations imposed by the NRC staff) may be acceptable if the licensee or applicant has provided a full analysis to justify that the proposed use satisfies NRC regulations and is appropriately conservative. However, simply referencing an unapproved topical report or code is unacceptable. Additionally, deviations from guidance should not be considered acceptable unless fully justified.

Amendment should reference generally accepted engineering codes used in fragility analysis or SSC or protective structure determination for robustness to effects of tornadoes.

⁶ ADAMS Accession No. ML070360253.

⁷ ADAMS Accession No. ML070810400.

⁸ ADAMS Accession No. ML090410014.

⁹ ADAMS Accession No. ML080230578.

- **Use of Precedent (UP):** Determine whether cited precedents are justified and used appropriately and whether any deviations from the precedent appear to be justified. A previous precedent of approval itself is not a justification for a proposed change, but can facilitate a resource savings by allowing the technical staff to make appropriate use of information from previously-approved reviews. The technical staff should be aware that, in addition to inappropriate use of a cited precedent, there may also be an applicable precedent that was not cited. Although the licensee or applicant is not required to cite a precedent, the technical staff should remain cognizant of other applicable licensing information and operational experience. Evaluation against this criterion is not meant to initiate exhaustive search of all operational experience, but instead promote awareness of any readily-available information or knowledge pertinent to the license amendment.
 - Amendment should cite precedent, where applicable, for prior safety evaluation approved amendments most similar to methodology used by licensee (following first approved amendments, licensees should cite first approved amendment)
 - If deviations to the methodology used in the precedent amendment are incorporated by the licensee, a section specifically defining the deviations and justification for alternative methodology should be provided.
- **Consolidated Line Item Improvement Process (CLIIP):** In the case of RLAs utilizing the CLIIP process, determine whether the application deviates in any way (allowing for necessary deviations such as plan-specific names for similar systems) from the model CLIIP. If so, there may still be sufficient information to perform the review; however, the application should be removed from the CLIIP process and metric. This is a shared criteria against which both the project manager and the technical staff should evaluate the application.

License Amendment Review - (LIC-101)

Pre-Application Meeting:

Although not required, it is suggested that a pre-submittal application meeting be held between the staff and licensee to discuss expected amendment deliverables, schedule, and special considerations such as deviations from precedent(s), handling of screened out SSCs, extent of site walk downs, discussion of lessons learned, and scheduling of deliverables.

For the first amendment, if the licensee agrees, the staff would accommodate a Category 1 (or 2) public meeting to allow other licensees the benefit of understanding the amendment process, staff expectations, etc. This should help promote efficiencies in future amendment applications.

Acceptance Review:

Per LIC-109, a 20 business day acceptance review target has been established. Within that window, the staff will review the amendment and determine whether to accept, not accept with opportunity to supplement, or not accept the amendment. For non-acceptances, the staff will provide specific comments as to items found unacceptable. For the opportunity to supplement, the licensee has 13 calendar days to provide and acceptable supplement.

For the first amendment, a public meeting would be scheduled (with licensee agreement) to discuss the acceptance process, in general, and specific amendment.

Amendment Review:

Overall Timeliness:

Typically, the staff completes a licensing amendment review with safety evaluation within 12 months. For this type of amendment, the last similar (deterministic TORMIS amendment) took 9 months. The staff believes that the first amendment could be completed in less than 12 months. For subsequent amendments, and dependent on the level of continuity among amendments to the first amendment, incorporation of lessons learned, etc. that amendments would progressively be completed in less time than the first amendment. The staff's expectation is that licensees will be cognizant of previous RAIs and technical concerns so that submittal "N+1" addresses the issues raised during submittal "N."

The staff, to the extent possible, will share lessons learned among technical reviewers such that consistency and repeatability for the review process is maintained. With incorporated meeting elements below, licensees should be able to promptly understand and follow first and subsequent amendment lessons learned to gain efficiencies.

As example, the following represents a LIC-101 and LIC-109 based ***roughly estimated*** schedule that provides review element milestones (such as LIC-109 20-day review and LIC-101 30-day licensee RAI response expectations:

Time zero	September 1, 2016
Acceptance Review – (accepted)	September 29, 2016 (starts 12-month clock)
Review and draft RAIs	November 4, 2016
Conference Call/public Meeting #1	November 18, 2016
Submittal of Final RAIs (#1)	November 24, 2016
Response to RAIs (#1)	December 23, 2016
Draft SE, RAIs (#2)	February 24, 2017
Conference Call/public Meeting #2	March 14, 2017
Audit	April 3, 2017
Final RAIs (#2)	April 14, 2017
Response to RAIs (#2)	May 12, 2017
Draft Final SE (internal)	June 9, 2017
Safety Evaluation to licensee	July 7, 2017 (Approximately 10 months)

Requests for Additional Information (RAIs):

If RAIs are necessary (typically, one round occurs), then the staff would draft RAIs, provide them in draft form to the licensee, hold a conference call to discuss the draft RAIs and modify as necessary for clarity as final RAIs, then submit to the licensee. Once the final RAIs are received, the licensee is expected to respond within 30 days. Note that if second round RAIs and site audit is not necessary (as would likely apply to subsequent LARs), then this example schedule reduces by approximately 5 months.

For the first and subsequent initial amendments, the staff plans to incorporate the following as part of the RAI process:

- Use of template RAIs, where each RAI is maintained in a data base and re-used verbatim to the extent possible for subsequent licensees. This helps maintain consistency in the scope of RAIs and acceptance of standard responses by multiple licensees.
- Periodic documentation of acceptable responses to template RAIs, such that licensees can understand example responses and craft site-specific or generic responses, as appropriate.
- Public meetings (probably Category 1) for RAI conference calls (if acceptable to licensee), and periodically (probably Category 2) to discuss collective template RAIs and acceptable responses (likely following SE for first amendment).

Audits:

If multiple rounds of RAIs (2 or more) are necessary, or specific issues result from staff understanding of SSC walk down or screening processes, then an audit may be requested by the staff. Dependent on the extent or specific issue, the audit may be at the site and/or with the licensee responding to an NRC office. Typically, if the audit does not resolve remaining issues with the amendment, the staff will begin to consider denial; however, with the first amendment it may be of long term benefit to consider additional review efforts.

With the first amendment, the staff will engage with the licensee before entertaining denial of the amendment. Consideration will include additional expenditure of resources by both the staff and licensee, and understanding to the licensee, if review continues, that review costs above normal may result. The staff will also consider the long term benefit for additional work to implement a first amendment and the potential for later return on investment to establish a repeatable and cost effective product. The staff may consider the use of contractor expertise, if deemed important to establish a repeatable product. Prior to using contractors, the staff will engage with the licensee so that additional expenditure for the review are understood and agreeable.

Withdrawn/denial:

If the staff cannot complete a safety evaluation, typically within one year from acceptance of the amendment, then the licensee will have the opportunity to withdraw the amendment, or the staff will initiate denial of the amendment.

For the first amendment, the staff may recommend continuance of the review beyond a year (up to no more than 2 years), with the licensee's understanding of additional expense.