

License Amendment Requests and 10 CFR 2.390 Withholding

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License Amendments – Regulations

- 10 CFR 50.59(c)(1): a license amendment is required if:
 - 1) TS changes are required; and/or
 - 2) any of the eight criteria in 10 CFR 50.59(c)(2) are met
- 50.90: license amendment requires application to NRC, “fully describing the changes desired, and following, as far as applicable, the form prescribed for original applications” (50.36, NUREG-1537)
- 50.92(a): in determining whether to issue an amendment, NRC is “guided by the considerations which govern issuance of initial licenses ... to the extent applicable and appropriate”

License Amendment Requests (LARs) – Pre-Submission

- Early communication with NRC Project Manager
- Public meetings (e.g., “phase zero” meetings) or may confer informally with NRC staff

LARs – Submission

- Send to NRC Document Control Desk, or use NRC Electronic Information Exchange system (10 CFR 50.4(a))
- Must submit under oath or affirmation (10 CFR 50.30(b))
- Cover letter may include requested priority/timeframe/schedule (with basis), if appropriate

LARs – Acceptance Reviews

- Is there is sufficient technical information in scope and depth to allow NRC to begin detailed technical review?
- Does the LAR have any readily apparent information insufficiencies with respect to regulatory requirements or characterization of licensing basis?
- Acceptance review information requests are **separate** from request for additional information (RAI) process, and are intended to address completeness for docketing (and reduce RAIs)

LARs – Acceptance Reviews

- Does application describe:
 - What is being changed?
 - What is the relation to safety?
 - How is the licensing basis affected?
 - What makes the change acceptable?
- Are significant calculations or analyses missing?
- Does application include:
 - Oath or affirmation?
 - Marked-up TS change pages and description/justification for **ALL** TS/license changes?
 - Physical security, emergency planning, environmental, etc. information, if applicable?

LARs – Acceptance Reviews

- Generally complete within ~30 days from when LAR entered in ADAMS
- If LAR is not acceptable for review, NRC may discuss with licensee and send letter providing opportunity to supplement
- If LAR is acceptable for review, NRC will begin detailed technical review and send acceptance letter with estimated review schedule

LARs – RAIs

- NRC staff may request additional information (10 CFR 2.102)
- RAIs used when information needed to make a regulatory finding is:
 - Not included in initial submission;
 - Not contained in other docketed correspondence; and
 - Cannot be reasonably inferred from docketed or other public information.
- NRC staff may provide draft RAIs to ensure understanding
- RAI response deadline extensions require a letter to NRC

LARs – Issuance of Amendment

NRC staff must find that:

- There is reasonable assurance that the health and safety of the public will not be endangered by operation in the proposed manner;
- There is reasonable assurance that such activities will be conducted in compliance with NRC regulations; and
- The issuance of the amendment will not be inimical to the common defense and security or to the health and safety of the public.

LARs – Issuance of Amendment

- Do the licensee's bases for TS/license changes make sense?
- Has the licensee adequately considered implications for normal operation, as well as potential failure scenarios?
- Has the licensee provided enough detail that the NRC staff can independently reach safety conclusions (e.g., by using its own engineering judgement and/or confirmatory calculations)?

10 CFR 2.390, “Public inspections, exemptions, requests for withholding”

10 CFR 2.390 – Overview

- Licensees submitting a document to NRC may request that the document, or a portion of it, be withheld from public disclosure because it contains certain information (10 CFR 2.390(b))
- For example: “Trade secrets and commercial or financial information obtained from a person and privileged or confidential” (i.e., “proprietary information”) (2.390(a)(4)) can be withheld from disclosure

10 CFR 2.390 – Requirements for Withholding Requests

Requirements for withholding requests are in 2.390(b):

- Make request at the time document is submitted (2.390(b)(1))
- Mark documents (2.390(b)(1)(i)(A-B))
 - Language such as “proprietary information withheld from public disclosure under 10 CFR 2.390” at top of each page
 - Should generally also provide redacted version (without marking)
 - No requirement to mark transmittal documents if no sensitive information

10 CFR 2.390 – Requirements for Withholding Requests

Requirements for withholding requests (continued):

- Provide affidavit (2.390)(b)(1)(ii-iii)
 - Identifies document to be withheld, and the locations of sensitive information in the document
 - Identifies official position of person making affidavit
 - Includes harm statement
 - Declares basis for withholding (i.e., which part of 2.390(a))
 - For proprietary information to be withheld under 2.390(a)(4), executed by **owner** of information, and addresses with specificity **each** of the considerations listed in 2.390(b)(4)(i-v)

10 CFR 2.390 – Criteria for NRC Determination

In accordance with 10 CFR 2.390(b)(4)(i-v), when determining whether information is “proprietary information” that should be withheld from disclosure, the NRC will consider:

- Whether information has been held in confidence by owner
- Whether information is of a type customarily held in confidence by owner
- Whether information is transmitted to and received by NRC in confidence
- Whether information is available in public sources
- Whether disclosure of information is likely to cause substantial harm to owner’s competitive position

10 CFR 2.390 – Process

- Withholding request review is separate from a LAR acceptance review
- NRC will generally respond with letter accepting request, or explaining deficiencies
- Generally, licensee may request withdrawal of information if a withholding request is not granted

10 CFR 2.390 – A Few Other Points

- Security-related information: 10 CFR 2.390(d)
- Personal privacy information: 10 CFR 2.390(a)(6)
- Public meetings

Summary

- When in doubt... ask your PM

Thank you for your attention, any questions?

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