

C.2.7 Design Center Review Approach

OVERVIEW

The NRC promotes the standardization of applications to enhance the safety of nuclear power plants, and to facilitate a predictable and consistent method for application review. The Commission's 1987 Nuclear Power Plant Standardization Policy Statement, (52 Fed. Reg. 34884) laid the foundation for the later rulemaking related to ESP, DC, and COLs under 10 CFR Part 52. In 2006, the agency's design-centered review approach (DCRA) strategy was formalized via Regulatory Issue Summary (RIS) 2006-06 (ADAMS Accession No. ML053540251), "New Reactor Standardization Needed to Support the Design-Centered Licensing Review Approach." The DCRA was endorsed by the Commission's Staff Requirements Memorandum (SRM) SECY-06-0187, "Semiannual Update of the Status of New Reactor Licensing Activities and Future Planning for New Reactors," dated November 16, 2006. The DCRA subsequently continued to evolve via greater process definition and in response to changing projections of subsequent COL applications (COLAs).

Under the DCRA, staff perform one technical review for each issue outside the scope of the DC, and intend to make one consistent and justifiable decision to support COLA reviews. This approach is applicable to COLAs that reference a DC as discussed in C.2.6 of this regulatory guide. RIS-2006-006 requested that for a given referenced DC, either under review or after certification, a design center working group (DCWG) would voluntarily form and designate a lead COLA to serve as the reference COL (R-COL) application and use annotation of the FSAR, Part 2 of the COLA, and other portions of the application, to clearly identify: a) sections that incorporate by reference the generic DCD; b) sections that are standard for all COL applicants that reference the same DCD; and c) sections that are site-specific and thus only apply to the specific location. Other subsequent applications in the design center are designated as subsequent COL (S-COL) applications and reference the "standard content" established in the R-COL.

At a June 2, 2015, public meeting on revisions to RG 1.206, NEI made a presentation entitled "Integrated FSAR for a COL Application," (ADAMS accession No. ML15152A297) which proposed more integrated referencing of previously reviewed content from R-COLAs, earlier S-COLAs as well as post-license actions in an integrated FSAR that could be used for future COLAs. Post-licensing actions would include departures and LARs associated with construction challenges and ITAAC resolution and closure such as those associated with the Vogtle and Summer COLs.

This regulatory topic provides guidance relevant to the DCRA as it has evolved as well as the concept of an integrated FSAR. It focuses on current approaches to referencing previous NRC reviews that can be used or enhanced by future COL applicants. It includes several relevant examples from COLAs and COLs. A brief discussion of the evolution of the DCRA is provided in Appendix A of this regulatory topic.

GUIDANCE

The development of the NRC staff's DCRA involved substantial input from vendors, applicants, as well as the ACRS and the Commission. The initial plan to focus on a single R-COL selected

by a DCWG, while other S-COLs delayed submittal was considered logical and beneficial¹ at the time. The tradeoffs associated with this approach became apparent later as projections for new COLAs changed and some COLAs were suspended or withdrawn, compromising construction schedules of some S-COLAs. In addition to describing the DCRA, RIS-2006-006 indicated that due to the projected applications, NRC planned to prioritize COLAs based on the level of standardization. Though the DCRA has proven to be a robust model, RIS 2006-06's planned prioritization based on level of standardization is less relevant now, given the level of evolution, and current projections for new COLAs and DC renewal applications.

The "integrated FSAR" concept presented by NEI in June 2015 (ADAMS accession No. ML15152A297) represents to a great degree the practices that have evolved via the DCRA. An "integrated FSAR" that represents further enhancements to the DCRA must be associated with an actual COLA and the COLA must fully comply with all requirements before issuance of a COL. Based on the experiences with COLA reviews to date, an integrated FSAR may not be a "final product" due to additional changes in later COLAs and COLs that represent desirable shared content. Similarly, future COLAs would still need to rely on additional referencing related to site specific issues that need to be included in the plant-specific FSAR for their application.

Any COL application, including the FSAR, must be complete and sufficient to support the required NRC's safety, security and environmental findings. If an applicant wishes to take advantage of previous NRC staff findings and other applicant or licensee submissions, the applicant needs to clearly articulate that desire and provide justification as to why the staff's previous findings are appropriate precedence. This can be accomplished by using and/or refining current referencing practices that include left margin annotation (LMA) and endorsement letters related to RAI responses by previous COL applicants. There is no regulatory requirement that future COLAs adopt standard content solely from a DCWG-identified R-COLA as demonstrated in the William States Lee III (WLS) COLA which references content from the Levy Nuclear Plant (LNP) COLA. Similarly, there is no regulatory requirement to constrain future COL applicants from further refinement of approaches to referencing previous NRC staff findings to best meet their needs as an applicant.

It is essential that an S-COL applicant provide clear referencing of any information related to previous NRC reviews whether it be related to an R-COLA, another S-COLA, or post-licensing actions such as LARs and post-license departures and exemptions. Referencing such material should be an important part of pre-application meetings with NRC staff. Transparent communications with NRC regarding such referencing should continue throughout the COLA review process. It is recommended that COL applicants further increase review efficiency whenever possible by explaining how the referenced material is applicable to their application. For example, the applicant should explain how the assumptions used are the same as the referenced material, and clearly demonstrate that any differences do not impact safety.

¹ Nuclear Power 2010 Program, Combined Construction and Operating License & Design Certification Demonstration Projects, Lessons Learned Report, August 30, 2012

The use of the term reference COL and subsequent COL is somewhat of a misnomer since an S-COLA must explicitly reference detailed “standard content” in their COLA. The S-COLA cannot simply reference the previous R-COLA as a whole and must instead provide sufficient detail to support the NRC staff’s safety finding. Based on the evolution of the DCRA, current reviews include a referencing system presented by the applicant involving LMA, endorsement letters by S-COL applicants of RAI responses by the R-COLA applicant and in some cases, other S-COL applicants.

Left Margin Annotation in COL Applications

A key referencing approach associated with the DCRA utilized by current applicants in the AP1000 and ESBWR design centers involves LMA of the FSAR and associated acronyms that have become standardized through practice.

The following notations have been used by applicants for the departures and/or supplements in their site-specific DCD:

STD – standard (STD) information that is identical in each COLA referencing the certified design.

Plant name or abbreviation – plant-specific information that is specific to this application (e.g. LNP for Levy, WLS for Lee, etc.)

DEP – represents a departure (DEP) from the DCD.

COL – represents a COL information item identified in the DCD.

VAR – represents a variance from an ESP

SUP – represents information that supplements (SUP) information in the DCD.

CDI – represents design information replacing conceptual design information (CDI) included in the generic DCD but not addressed within the scope of the DCD review.

For example, Section 1.1 of the Bellefonte COLA FSAR indicated that the section incorporated the AP1000 generic DCD by reference with specific departures and/or supplements. There was a supplement to Subsection 1.1.6.3 marked with LMA stating STD SUP 1.1-3 indicating that it represented R-COL standard content (STD), that it was a supplement (SUP), and that it was the third supplement in Section 1.1. This supplement referenced Table 1.1-202 which described the LMA used in the FSAR. The same supplement, using the same LMA was used in the Levy COLA FSAR. Similar notation was included in the North Anna Unit 3 COLA FSAR (revision 8, submitted 6/24/14) which referenced the standard content of the Fermi Unit 3 COLA for the ESBWR DC.

There is no regulatory requirement that would restrict a COL applicant from creating a site specific supplement (i.e. XXX 1.1-3 for a plant named XXX) that modifies the standard supplement, SUP 1.1-3 by adding additional terms. For example, acronyms from specific S-COLs could be included in addition to XXX and STD, and other forms of referenced decisions (e.g. LARs from previous COLs that the applicant wants to list as a departure). In this way, a COL applicant can deviate in their notation and adopt a modification of the LMA to efficiently reference FSAR material from a later subsequent COL and even post-licensing decisions if appropriate. As this LMA has so far proved useful, staff recommends that it be continued but modified as appropriate to reflect applicant and/or DCWG preferences. The primary

importance is clarity of the COL applicant in its application so that the NRC, the applicant and the public clearly understand the content of the application.

Endorsement Letters and RAI Responses in the R-COLA

Endorsement letters from S-COL applicants indicate acceptance of R-COL responses to NRC RAI's associated with standard content. This approach involves identification in the R-COLA of RAI responses submitted as either "Expected to be Standard for the S-COLAs" or "Plant Specific" which are then summarised in a table. An endorsement letter from an S-COL applicant confirms the applicability of standard content RAI response by including an evaluation of the R-COL RAI responses. The evaluation typically includes:

- A table listing R-COL RAIs including RAI identification numbers
- A copy of the R-COL determination of the RAI as to whether the RAI was standard or site-specific
- A determination as to whether the RAIs designated as Standard are endorsed by the S-COL applicant

The S-COLA endorsement letters are also referred to as "me-too" letters and reflect a commitment by the S-COL applicant to make standard changes identical to the R-COL applicant changes. Where an S-COL applicant response differs from the R-COLA standard response, the S-COL applicant typically notifies NRC. Additional S-COLA endorsement letters may be submitted later as necessary.

Though this practice was initially limited to referencing R-COL standard content, the practice has now evolved to include referencing RAI responses of S-COLAs. For example, the WLS applicant, referenced a series of RAI response letters from the LNP S-COL applicant (ADAMS Accession No. ML16049A411) in a February 12 letter requesting an exemption associated with a departure for the WLS COLA. Enclosure 1 of that letter lists the NRC's number designation for the Levy RAI and the corresponding response to the LNP RAI. Enclosure 1 states that the Levy RAI response letters had been reviewed and found to be applicable to WLS. Though the WLS letter differs slightly from earlier letters that endorse R-COL responses to RAIs (e.g. Progress Energy letter of December 7, 2009, ADAMS Accession No. ML093450351), both are initiated by the applicant and facilitate review by NRC staff in the same way. The primary importance is that the response to the RAI be clear and transparent to the NRC, the COL applicant and the public and that the COLA including the FSAR be updated with the appropriate information on each COLA docket.

R-COL and S-COL Application Referencing in Departure and Exemptions Reports

Part 7 of a COLA includes exemptions, departures, and variances applicable to an application as discussed in Section C.1.7 of this regulatory guide. Departures are listed cumulatively in Part 7 and typically rely on the same LMA conventions used in the site-specific FSAR that identifies the departure as either a site-specific departure or a standard departure. For each departure, detailed information is provided in Part 7 on the departure supporting whether NRC approval or an exemption is required and making specific exemption requests. There are no regulatory requirements that would restrict a future COL applicant from including other notations

in the departure report in order to reference previously reviewed departures and exemptions from an S-COL. Referencing should be clear and correlate with any revised LMA used in the FSAR in order to facilitate efficient review.

Post-licensing departures will not appear as modifications to Part 7 of the application. During the interval from the date of application for a license to the date the Commission makes its findings required by 10 CFR Part 52.103(g), COL applicants and licensees must submit a report to the NRC semi-annually as required by Section X.B.3.b under the relevant appendix to 10 CFR Part 52. The semi-annual report must contain a brief description of any plant-specific departures from the DCD with a summary of the evaluation for each departure, as required under Section X.B.1 under the relevant appendix. These semi-annual reports from previous COLs may be of value to S-COL applicants wishing to reference a post-licensing departure. As discussed in Section C.2.16 of this regulatory guide, a number of departures and license amendments may be deferred by a COL applicant who chooses to finalize licensing-basis information at a point during the licensing review via a “freeze-point”. This may result in additional post-licensing departures that a later S-COL may wish to reference. There are no regulatory requirements that would restrict such a practice though efficient review would depend on clear and properly qualified referencing.

COL Applications Referencing Post-licensing Information

Consistent with guidance provided in Section C.2.16 of this regulatory guide, COL applicants, may choose to define a “freeze point” during the application review process at which the licensing-basis information is considered final. If a COL applicant then defers making changes until after COL issuance, there may be a number of departures and license amendment requests (LAR)s that NRC staff will need to review in order to support eventual construction of the facility. In addition, resolving constructability issues encountered during construction or start up issues immediately after the 10 CFR Part 52.103(g) finding by the Commission may result in additional post-licensing departures, exemption requests or LARs.

The DCRA has focused on referencing standard content that was established during the review of a COLA. There is no regulatory requirement that would restrict a COL applicant from referencing either post-licensing departures and changes or license amendment requests. As discussed related to LMA in this regulatory topic, refining LMA could be used for efficient referencing of post-licensing departures. The semi-annual reporting of changes, tests, and experiments required by 10 CFR 50.59 and departures under Section VIII of the relevant 10 CFR Part 52 appendix (e.g. letter related to Summer Nuclear Station, August 1, 2016, ADAMS accession No. ML16214A157), provides detailed information that may be useful to applicants.

Information on post-licensing LARs is readily accessible and could also be useful in the development of departures for a COLA. License amendment requests, such as the December 17, 2015 letter from SCE&G requesting a license amendment and exemption (LAR 15-15) (ADAMS Accession No. ML15351A165) provide detailed information that could be used for a departure in future COLAs or to support similar LAR if identified after an S-COLA’s freeze-point.

SUMMARY

NRC's design-centered review approach (DCRA) increased efficiencies associated with standardization of license applications associated with 10 CFR Part 52. The development of the DCRA was partially in response to an unprecedented increase in projected licensing and design certification application reviews. The DCRA has relied historically on the use of left margin annotation of the FSAR, identification of a reference COLA that would be a carrier of "standard content" that would be shared by subsequent COLAs, and use of endorsement letters related to R-COLA responses to RAIs on standard content. This referencing system has functioned well as demonstrated by the ability of the DCRA to adapt to significant market-driven changes that have impacted schedules for COLAs. Both industry and NRC staff have effectively taken advantage of the efficiency associated with the standardization via the referencing practices. This process also lends itself positively to the interested public who can focus their scarce resources on important issues during the one issue, one review, one position process of the DCRA.

Future COL applicants must provide complete information and need to clearly identify previous safety reviews which they want to reference regardless of whether an active DCWG chooses to support specific additional refinement of standard content or refinements in referencing procedures to take better advantage of S-COLAs and post-licensing actions of COLs. The DCRA, in practice, has evolved and can be expected to continue to evolve.

Future COL applicants should discuss their plans to rely on previously established NRC safety findings with NRC staff in public meetings during the pre-application phase and throughout the review phase. These discussions should include both the material the COL applicant plans to reference as well as specific methods of identifying and referencing the relevant materials. Preapplication discussions will inform NRC's planning for the review and allow NRC input regarding opportunities to refine the approach. NRC further recommends that COL applicants provide analysis, as appropriate, that demonstrates that the material referenced is applicable to their application. NRC further recommends that COL applicants suggest refinements to the referencing practices rather than develop an entirely new approach since the current use of LMA and endorsement letters is familiar, effective and adaptable.

Appendix A - Background Information on the History of the DCRA

Constraints on applicants, NRC staff, and public resources were an important impetus for RIS 2006-06, based on an unprecedented increase in projections of near-term COLAs related to the Energy Policy Act of 2005 and the Department of Energy's (DOE) Nuclear Power 2010 program. Before issuing RIS-2006-06, NRC presented the proposed DCRA at a public meeting (ADAMS accession number ML060650413) in February 2006. RIS-2006-006 also indicated that NRC planned to make annual requests for voluntary information to support future resource scheduling for information on potential future COLAs, associated information on DCWG participation and any R-COL application that might be referenced. These requests for voluntary information have been made (e.g. RIS-2016-08) and responses have been critical to resource planning for reviews.

The NuStart Energy Development, LLC consortium was formed in 2004 by six member companies focused on the Advanced Passive 1000 (AP1000) reactor and the Economic Simplified Boiling Water Reactor (ESBWR). NuStart developed a cooperative agreement with the Department of Energy (DOE) under DOE's Nuclear Power 2010 program. DOE also developed cooperative agreements with the two reactor vendors. The Nuclear Power 2010 program represented a market driven, industry cost shared approach that brought vendors and utilities into close cooperation during the DC finalization phase and COL application development phase. NuStart identified TVA's Bellefonte site and Entergy's Grand Gulf site for initial COLAs for the AP1000 and the ESBWR, respectively, via letter on November 17, 2005 (ADAMS accession number ML053270434). NuStart played a key role in NRC's development of the DCRA and formation of the AP1000 and ESBWR DCWGs. NuStart was later disbanded in 2012 upon the issuance of the first two COLs that referenced the AP1000 DC.

The DCRA evolved via DCWG meetings and public meetings in which the details of how S-COL applicants would reference previous staff decisions on the standard content of an R-COL were developed. The original development of LMA was proposed by industry and specifically by the DCWGs. NuStart presented referencing approaches to the AP1000 ACRS subcommittee in October 2007 (ADAMS accession number ML073190611) and clarified that having a single R-COL was preferable for the AP1000 due to the challenge of referencing standard content in multiple parallel COLA reviews. The decision to restrain referencing COLs other than a COLA identified as an R-COLA by a DCWG was primarily to avoid confusion and problems associated with multiple COLAs referencing each other². Alternatively, NuStart, Dominion, and Entergy indicated initially that for the ESBWR, standard content would be developed without identifying an R-COLA (ADAMS accession No. ML062000032) and described planning to submit the two first COLAs to reference the ESBWR simultaneously. The use of endorsement letters from S-

² In a letter dated April 28, 2009, the NuStart Energy Development, LLC, consortium informed the NRC that it had changed the R-COL designation for the AP1000 design center from Bellefonte Nuclear Plant (BLN) Units 3 and 4 to the Vogtle Electric Generating Plant (VEGP) Units 3 and 4. The transition of the R-COL from BLN Units 3 and 4 to VEGP Units 3 and 4 occurred after the issuance of the BLN Units 3 and 4 safety evaluation (SE) with open items. Standard content material from the SE for the R-COL (VEGP) application and referenced in later SE includes evaluation material from the SE for the BLN COL application. Similar changes have occurred relevant to the ESBWR R-COLA designation.

COL applicants was proposed by NuStart in an AP1000 DCWG category 1 public meeting on 10/9/08 (ADAMS Accession No. ML083050649).

In addition to evolution in the practices of COL applicants and DC vendors, the NRC staff has expanded the use of this approach to other areas with essentially identical information for regulatory purposes. Final Safety Evaluation Reports (FSER) on S-COLs have relied upon and directly referenced earlier FSERs for COLAs referencing the same design. This practice has not been restricted to referencing of standard content in the relevant R-COLA. The FSERs for SCOLAs have instead directly incorporated excerpts from FSERs from previous COLA reviews that were relied upon in the staff's analysis of the application in question. The WLS FSER, directly referred to the Levy Nuclear Plant (LPN) as the reference COLA for several design issues that were resolved after issuance of the Vogtle and Summer COLs due to Levy's role as default reference COLA that carried standard content related to more recently resolved issues in section 21.0 (ADAMS accession # ML16137A123). Various sections of the WLS FSER (e.g. section 21.1.4) describe how the staff used material from LPN in the review of the WLS COLA which included a comparison between the WLS and LNP FSARs and verification that site-specific differences were not relevant.