THIS DRAFT DOCUMENT IS BEING RELEASED TO SUPPORT THE FEBURARY 18, 2022, ADVISORY COMMITTEE ON REACTOR SAFEGUARDS (ACRS) 10 CFR PART 50/52 RULEMAKING ACTIVITIES SUBCOMMITTEE PUBLIC MEETING. THE NRC STAFF IS NOT REQUESTING OR ACCEPTING PUBLIC COMMENTS ON THIS DRAFT DOCUMENT. THIS DRAFT DOCUMENT HAS NOT BEEN SUBJECT TO NRC MANAGEMENT OR LEGAL REVIEWS AND APPROVALS, AND ITS CONTENTS SHOULD NOT BE INTERPRETED AS OFFICIAL AGENCY POSITIONS. FOLLOWING THE PUBLIC MEETING WITH THE ACRS, THE NRC STAFF PLANS TO CONTINUE WORKING ON THIS DOCUMENT AND TO CONSIDER OPTIONS FOR INVITING PUBLIC PARTICIPATION IN THE RULEMAKING ACTIVITY.

U.S. NUCLEAR REGULATORY COMMISSION

DRAFT REGULATORY GUIDE DG-13991.206, ~~REVISION 1~~

Proposed Revision 2 to Regulatory Guide 1.206

Issue Date: XXXX~~October 2018~~
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APPLICATIONS FOR NUCLEAR POWER PLANTS

A. INTRODUCTION

Purpose

This regulatory guide (RG) provides guidance on the format and content of applications for nuclear power plants submitted to the U.S. Nuclear Regulatory Commission (NRC) under Title 10 of the *Code of Federal Regulations* (10 CFR) Part 52, "Licenses, Certifications, and Approvals for Nuclear Power Plants" (Ref. 1), which specifies the information to be included in an application.

Applicability

This RG applies to power reactors with light-water reactor (LWR) technology. The NRC staff also considers this RG to generally apply to other types of power reactors (e.g., non-LWRs). The NRC staff considers this guidance acceptable to support preparation of applications for early site permits (ESPs), standard design certifications (DCs), and combined licenses (COLs) under 10 CFR Part 52 and generally acceptable to support its review of other types of applications under 10 CFR Part 52.

This RG is being issued in draft form to involve the public in the development of regulatory guidance in this area. It has not received final staff review or approval and does not represent an NRC final staff position. Public comments are being solicited on this draft regulatory guide (DG) and its associated regulatory analysis. Comments should be accompanied by appropriate supporting data. Comments may be submitted through the Federal-rulemaking Web site, http://www.regulations.gov, by searching for draft regulatory guide DG-1399 or Docket ID NRC-2009-0196. Alternatively, comments may be submitted to Office of the Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, ATTN: Rulemakings and Adjudications Staff. Comments must be submitted by the date indicated in the *Federal Register* notice.

Electronic copies of this DG, previous versions of DGs, and other recently issued guides are available through the NRC's public Web site under the Regulatory Guides document collection of the NRC Library at https://nrcweb.nrc.gov/reading-rm/doc-collections/reg-guides/. The DG is also available through the NRC's Agencywide Documents Access and Management System (ADAMS) at http://www.nrc.gov/reading-rm/adams.html, under Accession No. ML21222A223. The regulatory analysis is associated with a rulemaking and may be found in ADAMS under Accession No. MLXXXXXXXXX.

Applicable Rules and Regulations

The following regulations are germane to the development of applications for DCs, ESPs, and COLs:

- 10 CFR Part 50, "Domestic Licensing of Production and Utilization Facilities" (Ref. 2). The regulations in this part provide for the licensing of production and utilization facilities pursuant to the Atomic Energy Act of 1954, as amended and Title II of the Energy Reorganization Act of 1974.

- 10 CFR Part 51, "Environmental Protection Regulations for Domestic Licensing and Related Regulatory Functions" (Ref. 3). The regulations in this part set forth the activities and processes for determining the potential environmental impact from the proposed action based on the requirements of the National Environmental Policy Act (NEPA) of 1969, as amended.

- 10 CFR Part 52, "Licenses, Certifications, and Approvals for Nuclear Power Plants." The regulations in this part govern the issuance of early site permits, standard design certifications, combined licenses, standard design approvals, and manufacturing licenses for nuclear power facilities pursuant to the Atomic Energy Act of 1954, as amended and Title II of the Energy Reorganization Act of 1974.

- 10 CFR Part 52, Subpart A – Early Site Permits, §52.17, "Contents of applications, technical information." The regulations in this part govern what technical information must be included in applications for ESPs.

- 10 CFR Part 52, Subpart B –Standard Design Certifications, §52.47, "Contents of applications, technical information." The regulations in this part govern what information must be included in applications for DCs.

- 10 CFR Part 52, Subpart C –Combined Licenses §52.79, "Contents of applications, technical information in final safety analysis report." The regulations in this part govern what information must be included in final safety analysis reports (FSARs) for COL applications.

- 10 CFR Part 72, "Licensing Requirements for the Independent Storage of Spent Nuclear Fuel, High-Level Radioactive Waste, and Reactor-Related Greater than Class C Waste" (Ref. 4). The regulations in this part establish requirements, procedures, and criteria for the issuance of licenses to receive, transfer and possess power reactor spent fuel, power reactor-related Greater than Class C (GTCC) waste and other radioactive materials associated with spent fuel storage in an independent spent fuel storage installation (ISFSI) and the terms and conditions under which the Commission will issue these licenses.

Related Regulations and Guidance

- 10 CFR Part 2, "Agency Rules of Practice and Procedure" (Ref. 5). This part governs the conduct of all proceedings, other than export and import licensing described in 10 CFR Part 110, under the Atomic Energy Act of 1954, as amended, for granting, suspending, revoking, amending, or taking other action with respect to any license, construction permit, or application to transfer an license; and standard design approvals under 10 CFR Part 52 of this chapter.

- 10 CFR Part 20, "Standards for Protection against Radiation" (Ref. 6). The regulations in this part establish standards for protection against ionizing radiation resulting from activities conducted under licenses issued by the Nuclear Regulatory Commission.

- 10 CFR Part 21, "Reporting of Defects and Noncompliance" (Ref. 7). The regulations in this part establish procedures and requirements for any individual director or responsible officer of a firm constructing, owning, operating or supplying the components of any facility or activity licenses under the Atomic Energy Act of 1954, as amended, who obtains information reasonably indicating that the facility, activity or basic component supplied to such facility or activity fails to comply with the Atomic Energy Act of 1954, as amended, or the facility, activity or basic component supplied to such facility or activity contain defects, to immediately notify the Commission of such failures.

- 10 CFR Part 25, "Access Authorization" (Ref. 8). The regulations in this part establish procedures for granting, reinstating, extending, transferring, and terminating access authorizations of licensee personnel, licensee contractors or agents, and other persons who may require access to classified information.

- 10 CFR Part 26, "Fitness for Duty Programs" (Ref. 9). The regulations in this part prescribe requirements and standards for the establishment, implementation, and maintenance of fitness-for-duty (FFD) programs for all persons granted access to nuclear power reactor protected areas.

- 10 CFR Part 30, "Rules of General Applicability to Domestic Licensing of Byproduct Material" (Ref. 10). The regulations in this part prescribe rules applicable to all persons in the United States governing domestic licensing of byproduct material under the Atomic energy Act of 1954, as amended.

- 10 CFR Part 40, "Domestic Licensing of Source Material" (Ref. 11). The regulations in this part establish procedures and criteria for the issuance of licenses to receive title to, receive, possess, use, transfer, or deliver source and byproduct material materials, and establish and provide for the terms and conditions upon which the Commission will issue such licenses.

- 10 CFR Part 50, Appendix A, "General Design Criteria for Nuclear Power Plants." The General Design Criteria (GDC) establish minimum requirements for the principal design criteria for water-cooled nuclear power plants similar in design and location to plants for which construction permits have been issued by the Commission. The NRC issued RG 1.232, "Guidance for Developing Principal Design Criteria for Non-Light-Water Reactors" (Ref. 12), to provide guidance on how the GDC in 10 CFR Part 50, Appendix A, may be adapted for non-LWR designs.

- 10 CFR Part 50, Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Processing Plants." Appendix B sets forth the requirements for quality assurance programs for nuclear power plants and is applicable to applications for ESPs, DCs, and COLs as per 10 CFR 52.17(a)(1)(xi), 10 CFR 52.47(a)(19) and 10 CFR 52.79(a)(25) and 10 CFR 52.79(a)(27).

- 10 CFR Part 70, "Domestic Licensing of Special Nuclear Material" (Ref. 13). The regulations of this part establish procedures and criteria for the issuance of licenses to receive title to, own, acquire, deliver, receive, possess, use, and transfer special nuclear material; and establish and provide for the terms and conditions upon which the Commission will issue such licenses.

- 10 CFR Part 73, "Physical Protection of Plants and Materials" (Ref. 14). The regulation in this part prescribe requirements for the establishment and maintenance of a physical protection system which

will have capabilities for the protection of special nuclear material at fixed sites and in transit and of plants in which special nuclear material is used.

- 10 CFR Part 74, "Material Control and Accounting of Special Nuclear Material" (Ref. 15). This part has been established to contain the requirements for the control and accounting of special nuclear material at fixed sites and for documenting the transfer of special nuclear material.

- 10 CFR Part 100, "Reactor Site Criteria" (Ref. 16). The regulations in this part establish approval requirements for proposed sites for stationary power and testing reactors subject to Part 50 or Part 52 of this chapter.

- 10 CFR Part 140, "Financial Protection Requirements and Indemnity Agreements" (Ref. 17). The regulations in this part provide requirements and procedures for (a) licensee financial protection and indemnification pursuant to section 170 of the Atomic Energy Act of 1954, as amended; and (b) the liability insurance required of uranium enrichment facility licensees pursuant to section 193 of the Atomic Energy Act of 1954, as amended.

- RG 1.70, "Standard Format and Content of Safety Analysis Reports for Nuclear Power Plants (LWR Edition)" (Ref. 18), provides detailed guidance in preparing applications for construction permits and operating licenses for new nuclear power plants under 10 CFR Part 50.

- RG 1.232, "Guidance for Developing Principal Design Criteria for Non-Light-Water Reactors," provides guidance on how the GDC in 10 CFR Part 50, Appendix A may be adapted for non-LWR designs.

- RG 4.2, "Preparation of Environmental Reports for Nuclear Power Stations" (Ref. 19), provides guidance for the format and content of environmental reports (ER).

- NUREG-0800, "Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants (LWR Edition)" (Ref. 20), is the standard review plan (SRP) for the NRC staff. It contains guidance related to safety reviews of applications and describes methods or approaches that the staff previously has found acceptable for meeting NRC requirements.

- NUREG/BR-0298, "Nuclear Power Plant Licensing Process" (Ref. 21), gives a high level overview of available application processes for nuclear power plants.

- NUREG-1520, "Standard Review Plan for the Review of a License Application for a Fuel Cycle Facility" (Ref. 22), supplements the SRP and lists technical information that Materials Licenses for COLs should include in the FSAR and other parts of the application. NUREG-1520 is cited in Section C.2.13.

- NUREG-1555, "Standard Review Plans for Environmental Reviews for Nuclear Power Plants," including Supplement 1 for reactor operating license renewal (Ref. 23), provides guidance to the NRC staff for review of ERs. NUREG-1555 is cited in Section C.1.3.

- NUREG-1556, "Consolidated Guidance about Materials Licenses" (Ref. 24), supplements the guidance by further identifying the technical information that the applicant should include in its

FSAR and other parts of the application related to materials licenses. NUREG-1556 is cited in Section C.2.13.

- COL/ESP-ISG-026, "Environmental Issues Associated with New Reactors" (Ref. 25), provides NRC staff guidance, for the review of all ESPs and combined license applications (COLAs) and includes those applicants seeking a limited work authorizations (LWAs). COL/ESP-ISG-026 is cited in Section C.1.3.

- COL/ESP-ISG-027, "Specific Environmental Guidance for Light Water Small Modular Reactor Reviews" (Ref. 26), provides supplemental guidance to the staff for environmental reviews in areas unique to small modular reactor (SMR) applications. COL/ESP-ISG-027 is cited in Section C.1.3.

Purpose of Regulatory Guides

The NRC issues RGs to describe to the public methods that the staff considers acceptable for use in implementing specific parts of the agency's regulations, to explain techniques that the staff uses in evaluating specific problems or postulated events, and to provide guidance to applicants. Regulatory guides are not substitutes for regulations and compliance with them is not required. Methods and solutions that differ from those set forth in RGs will be deemed acceptable if they provide a basis for the findings required for the issuance or continuance of a permit or license by the Commission.

Paperwork Reduction Act

This[EM1] RG provides voluntary guidance for implementing the mandatory information collections in 10 CFR Parts 50, 51, 52, 72, and 140 that are subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et. seq.). These information collections were approved by the Office of Management and Budget (OMB), under control numbers 3150-0011, 3150-0021, 3150-0151, 3150-0132 and 3150-0039, respectively. Send comments regarding this information collection to the Freedom of Information Act (FOIA), Library, and Information Collections Branch ((T6-A10M), U.S. Nuclear Regulatory Commission, Washington, DC 20555 0001, or by e-mail to Infocollects.Resource@nrc.gov, and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-10202 (3150-0011, 3150-0021, 3150-0151, 3150-0132 and 3150-0039) Office of Management and Budget, Washington, DC, 20503.

Public Protection Notification

The NRC may neither conduct nor sponsor, and a person is not required to respond to, a request for information or an information collection requirement unless the requesting document displays a currently valid OMB control number.

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B. DISCUSSION

Reason for Revision

This revision of the guide (Revision 2) ~~(Revision 1)~~ reflects changes resulting from the rulemaking to align of licensing requirements of 10 CFR P~~p~~arts 50 and 52 ~~of title 10 of the *Code of Federal Regulations* (10 CFR), "Domestic Licensing of Production and Utilization Facilities" and "Licenses, Certifications, and Approvals for Nuclear Power Plants,"~~ respectively to incorporate lessons learned from recent new power reactor licensing reviews. ~~lessons learned regarding the review of large light-water nuclear power plant applications under Title 10 of the *Code of Federal Regulations* (10 CFR) Part 52, "Licenses, Certifications, and Approvals for Nuclear Power Plants," since the initial issuance of RG 1.206 in June 2007. As such, it satisfies the two remaining action items from NRC's April 2013 Lessons Learned Report (Ref. 27) by 1) revising RG 1.206 to reflect lessons learned and 2) incorporating DC/COL-ISG-011, "Finalizing Licensing Basis Information" (Ref. 28), in the revised RG 1.206. In addition, the NRC staff has adjusted the scope of this RG in response to these lessons learned as described below.~~[GD2]

Background[GD3]

~~The staff has expanded the scope of this revision beyond COLAs addressed in~~ RG 1.206 ~~Revision 0 to more explicitly~~ addresses the current application process related to applications for COLAs, DCs, ESPs, and LWAs, as well as other applicable NRC regulations referenced in 10 CFR Part 52 (e.g., portions of 10 CFR Part 50, and 10 CFR Part 51). The RG provides ~~more~~ integrated guidance on the overall format and content for COLAs and DC and ESP applications. The guidance conforms with that given in other RGs pertaining to nuclear power plant licensing and operation. Consistent with RG 1.206, Revision 0, this revision does not cover processes in Subpart E, "Standard Design Approvals," and Subpart F, "Manufacturing Licenses," of 10 CFR Part 52. In addition, the NRC staff believes that several of the topics discussed in this RG may be used in applications for any type of power reactor technology.[GD4]

~~Another major change from RG 1.206, Revision 0, is the removal of a description of the technical information to be included in the safety analysis report (SAR). There is substantial overlap between RG 1.206, Revision 0, and the NRC staff's SRP in NUREG-0800, which contains guidance for the NRC staff to perform safety reviews of applications and describes methods or approaches that the staff previously has found acceptable for meeting NRC requirements.~~

~~The technical application guidance for a SAR that was previously included in RG 1.206, Revision 0, is being updated to reflect lessons learned and will be developed into interim staff guidance (ISG), a NUREG, or other knowledge management document. Stakeholders will be provided an opportunity for input to the document via an FRN requesting public comments. The document is expected to be useful to both applicants and to staff working on future updates to the SRP and related RGs; however, direct incorporation of applicant guidance in the SRP is not expected.~~[GD5]

The regulatory guidance in Section C of this guide is ~~divided into~~in two parts. Section C.1 supplies guidance for the organization, content, and format of an application under 10 CFR Part 52, which includes an applicant's transmittal letter and a series of multiple parts developed based on lessons learned from submitted applications to date. Sections C.1.1 through C.1.11 address each of the multiple parts of an application under 10 CFR Part 52, discuss the applicability and parts for different types of applications, and contain guidance for format and content of applications.

Section C.2 contains information and guidance on selected regulatory topics related to the preparation, submittal, acceptance, and review of applications under 10 CFR Part 52. This section is intended to facilitate the public's understanding of the NRC's requirements and expectations and to provide guidance to those engaged in the application process. The topics are varied and cover key issues of interest to applicants (e.g., additional licenses under 10 CFR Part 30, 10 CFR Part 40, and 10 CFR Part 70, as well as consensus standards; and information change processes).

~~Several regulatory topics update previous guidance that was originally issued as ISG that were subsequently retired upon issuance of this revised RG (e.g., Sections C.2.11, C.2.16, and C.2.18).~~

~~Regulatory Guide 1.206, Revision 1, replaces the following interim staff guidance which will be withdrawn upon issuance of Revision 1:~~

~~COL/ESP-ISG-04, "Definition of Construction and on Limited Work Authorizations" (Ref. 29).~~

~~DC/COL-ISG-08, "Necessary Content of Plant-Specific Technical Specification When a Combined License is Issued" (Ref. 30). See sections C.1.4 and C.2.11 of this guidance.~~

~~DC/COL-ISG-11, "Finalizing Licensing Basis Information."~~

~~ESP/DC/COL-ISG-015, "Post Combined License Commitments" (Ref. 31). See Section C.2.11 of this guidance.~~[GD6][EM7]

There are appendices to this RG and supplements contained within sections of this RG. Appendices A, B and C, referenced in Section C.1, present examples of several SARs and are found at the end of this RG. Other shorter supplements associated with application regulatory topics are collocated with the associated sections, Sections C.2.7 and C.2.18. These supplements which are embedded in the relevant section are entitled "Supplement to C.2.7" and "Supplement to C.2.18."

Background on License, Certification, and Approval Processes under 10 CFR Part 52

The regulations in Title 10 CFR Part 52 provide options for early resolution of safety and environmental issues before authorizing construction. Issuance of a COL authorizes both construction and conditional operation of a nuclear power plant. Before issuing the findings that allow the COL licensee to load fuel and operate the facility, the NRC verifies that the inspections, tests, analyses, and acceptance criteria (ITAAC) stated in the COL have been completed to ensure that the plant has been constructed and will be operated as designed and licensed. Sections C.1.4 and C.2.9 provide guidance on ITAAC. Subpart C, "Combined Licenses," of 10 CFR Part 52 establishes the requirements and processes applicable to issuance of COLs for nuclear power plants. Subpart A, "Early Site Permits," of 10 CFR Part 52 provides the requirements for obtaining an ESP, which the NRC issues to approve a site or sites for future placement of one or more nuclear power facilities. Subpart B, "Standard Design Certifications," of 10 CFR Part 52 provides the requirements for obtaining a DC, which is the NRC's certification through rulemaking of a final standard design for a nuclear power facility. Each DC rule is codified in an appendix to 10 CFR Part 52. As provided in 10 CFR Part 52, the applications for and issuance of ESPs and DCs are processes that are separate from the licensing process for COLs. A COL review does not consider the issues resolved by the DC rulemaking process and during the ESP hearing process, with limited exceptions (see, for example, 10 CFR 51.50(c)(1)(iii)).

A COL applicant, as stated in 10 CFR Part 52, has the option to reference an ESP, a DC, both an ESP and DC, or neither (10 CFR 52.73, "Relationship to Other Subparts"). Thus, the COL applicant has the option to: (1) identify a "custom" nuclear plant design (i.e., a COL that does not reference a DC and contains all of the required information directly in the application) for a site identified in the application,

(2) reference a DC for placement at the site identified in the application, (3) identify a custom nuclear plant design in the application and reference an ESP, or (4) reference both a DC and an ESP. For a COL applicant, the application process is the same for each option; however, the application content depends on the option selected at the time the application is tendered because information can be incorporated by reference from either a referenced DC or ESP and would thereby not be repeated. In addition, an applicant may ask that an LWA under 10 CFR 50.10, "License Required; Limited Work Authorization," be issued in conjunction with an ESP in accordance with 10 CFR 52.17(c) or before issuance of a COL in accordance with 10 CFR 52.80(c). Section C.2.18 provides detailed guidance related to LWAs. Section C.2.6 and several other portions of Section C.2 (e.g., Sections C.2.7, C.2.8, C.2.11, C.2.14, C.2.15, and C.2.16) provide detailed guidance on requirements for a COL that reference a DC, ESP, or both.

A holder of a COL issued under 10 CFR Part 52 obtains materials licenses issued under 10 CFR Parts 30, 40, and 70 in order to support facility construction and operation. Section C.2.13 provides guidance regarding COL applicant requests for materials licenses. In addition, when the license for a nuclear power plant is issued under 10 CFR Part 52, a general license for an independent spent fuel storage installation is also issued in accordance with Subpart K of 10 CFR Part 72. A brochure prepared by the NRC staff, NUREG/BR-0298, gives a high level overview of application processes under 10 CFR Part 50 and 10 CFR Part 52 with a focus on opportunities for public engagement in the review processes.

Regardless of what portions of a COLA are incorporated by reference rather than included directly in the application, Subpart C of 10 CFR Part 52 requires comprehensive and detailed information sufficient to meet all requirements before a COL can be issued. For example, 10 CFR 52.79, "Contents of Applications; Technical Information in Final Safety Analysis Report," addresses the contents of a COL applicant's FSAR, and the FSAR should meet all requirements either through information that is incorporated by reference or through information included directly in the FSAR. Similarly, requirements related to the environmental report in 10 CFR 51.50, "Environmental Report—Construction Permit, ESP, or Combined License Stage," is satisfied through material incorporated by reference or information included directly in the environmental report. The COLA that references an ESP or DC, or both, contains only the supplemental information necessary to address issues that were not resolved as a part of the ESP or DC, or both, that is incorporated by reference. A COL applicant referencing a DC would have a significant portion of the proposed facility design and design characteristics already reviewed by the NRC before submitting the COLA. Correspondingly, a COL applicant referencing an ESP would have a significant portion, if not all, of the site characteristics already reviewed by the NRC before submitting the COLA.

With some limited exceptions, the NRC does not intend for a COL applicant to resubmit information previously submitted, reviewed and approved. Accordingly, the COLA would include the remaining portions of the facility design and site characteristics information that require review. For example, 10 CFR 52.79(b) specifies the FSAR content if the COLA references an ESP, and 10 CFR 52.79(d) specifies the FSAR content if the COLA references a DC. If the referenced ESP or DC application is under concurrent review, a COL cannot be issued until the ESP has been finalized or the DC has been certified (or both).

Consideration of~~Harmonization with~~ International Standards

The[EM8] International Atomic Energy Agency (IAEA) works with member states and other partners to promote the safe, secure, and peaceful use of nuclear technologies. The IAEA develops Safety Requirements and Safety Guides for protecting people and the environment from harmful effects of ionizing radiation. This system of safety fundamentals, safety requirements, safety guides, and other

relevant reports reflects an international perspective on what constitutes a high level of safety. To inform its development of this RG, the NRC considered IAEA Safety Requirements and Safety Guides pursuant to the Commission's International Policy Statement (Ref. 27) and Management Directive and Handbook 6.6, "Regulatory Guides" (Ref. 28). ~~The International Atomic Energy Agency (IAEA) has established a series of safety guides and standards constituting a high level of safety for protecting people and the environment. IAEA safety guides present international good practices and increasingly reflect best practices to help users striving to achieve high levels of safety. The NRC was involved in the development of the original~~ IAEA Safety Guide No. GS-G-4.1, "Format and Content of the Safety Analysis Reports for Nuclear Power Plants," issued May 2004 (Ref. 29~~32~~) was considered in the development/update of the Regulatory Guide. ~~and has provided significant input into IAEA's efforts on a revision of that guide, which is currently under development. This RG contains principles similar to those in IAEA Safety Guide No. GS-G-4. The revision of GS-G-4.1 is being developed using insights from both RG 1.70 and RG 1.206, as well as the SRP. NRC staff does not intend to endorse or accept use of any specific international standards via this regulatory guide.~~

C. STAFF REGULATORY GUIDANCE

This section provides guidance on the format and content of applications for nuclear power plants submitted to the NRC under ~~Title 10 of the *Code of Federal Regulations* (~~10 CFR~~)~~ Part 52.

C.1 Application Format and Content

Each application under 10 CFR Part 52 shall comply with the requirements in Subpart A, "Early Site Permits"; Subpart B, "Standard Design Certifications"; or Subpart C, "Combined Licenses," of 10 CFR Part 52. Each application shall be submitted to the NRC in accordance with 10 CFR 50.30, "Filing of Applications for Licenses; Oath or Affirmation," and 10 CFR 52.3, "Written Communications." Furthermore, NRC staff recommends that an application adhere to the standard format and content identified herein. Though the standard format facilitates the application and review processes and is useful for organizing guidance, adherence to the standard format is not required by regulation.

Applications consist of a comprehensive collection of documented information and data that should be organized in multiple parts consistent with the standard parts addressed in Section C.1 of this RG and submitted to the NRC through a formal transmittal letter. Where practicable, applications should be submitted using the NRC's electronic submittal process. Section C.2.3 includes guidance on the electronic submittal process.

The NRC staff considers the guidance in Section C.1 on application format and content is applicable to any type of reactor including non-LWRs. The organization, standard parts, and electronic submittal process for an application, as well as site characterization information, applicant-specific information (e.g., financial, business-related, proprietary), and certain other types of information, are independent of the reactor technology.

Application Transmittal Letter

The formal transmittal letter accompanying each application should be in standard business format and do the following:

a. Identify the applicant (e.g., business entity).

b. State the type of application and the appropriate 10 CFR Part 52 subpart.

c. Summarize the information in the application. The summary should include the site location and description, reactor design, relation to other applications anticipated or currently undergoing NRC review, and relevant prior correspondence with the NRC (e.g., preapplication interactions and submittal of topical reports).

d. State the parts of the application being submitted by part number and title.

e. State which parts of the application contain the following types of information and describe how such information is being addressed:

   (1) restricted data that require information separation in accordance with 10 CFR 50.33(j);
   (2) Safeguards Information that requires protection as specified in 10 CFR 52.17(d), 10 CFR 52.47(d), and 10 CFR 52.79(d);

(3) security-related information withheld under 10 CFR 2.390(d)(1) that does not require an affidavit;

(4) sensitive information, such as trade secrets, privileged, or confidential commercial or financial information, requested to be withheld from public disclosure in accordance with 10 CFR 2.390, "Public Inspections, Exemptions, Requests for Withholding," requiring an affidavit; and

(5) export control information (ECI): NRC is subject to the requirements of the CUI Rule (32 CFR Part 2002, Controlled Unclassified Information) (Ref. 3~~03~~), issued in September 2016 by the National Archives and Records Administration (NARA), which identifies several categories or subcategories of information on which existing federal law or regulation places control meant to prevent unauthorized transfer of sensitive information, such as ECI. The CUI Registry defines ECI as:

> "Unclassified information concerning certain items, commodities, technology, software, or other information whose export could reasonably be expected to adversely affect the United States national security and nonproliferation objectives. To include dual use items; items identified in export administration regulations, international traffic in arms regulations and the munitions list; license applications; and sensitive nuclear technology information."

Based upon the CUI Rule, the NRC lacks authority itself to designate information in its possession as ECI under these various statutes or regulations in the CUI Registry. If an applicant submits information that qualifies as ECI, the applicant should inform the NRC of the information's designation. The applicant should identify any information that has been designated as ECI under another federal agency's criteria so that it can be protected as ECI. NRC staff is required to handle information designated as ECI in accordance with the requirement of the CUI Rule and the NRC's CUI Policy.

f. Note the means by which the application is being submitted (e.g., electronic).

g. State the applicant's designated point(s) of contact (e.g., name, address, and telephone numbers).

h. Include additional explanatory information that may help the NRC in understanding any unique aspects of the application.

i. Include the signature of the applicant or a duly authorized officer under oath or affirmation (in accordance with 10 CFR 50.30(b)).

Application Parts

The parts of an application are standardized by number, title, and content. The type of application (i.e., COL, an ESP, or a DC) and the applicant's selection of regulatory options (e.g., a COLA may or may not reference an ESP or DC, or both) determine which standard parts are to be included in a specific application. Table 1 illustrates this guidance by the use of a checkmark (✓) to reflect mandatory parts, "Not Applicable," or "Optional" designations for each type of application. Though use of the standard format is not required by regulation, organization of content by the parts described in Table 1 facilitates the application and review processes as well as the organization of guidance. The subsequent portions of Section C.1 provide detailed guidance for the format and content of each application part.

C.1.1 General and Financial Information

Part 1 of the application under 10 CFR Part 52 includes the administrative, general, and financial information related to the applicant. The regulations in 10 CFR 52.77, "Contents of Applications; General Information"; 10 CFR 52.46, "Contents of Applications; General Information"; and 10 CFR 52.16, "Contents of Applications; General Information," establish the information requirements for a COLA, DC application, and ESP application, respectively.

In summary, 10 CFR 52.77 requires a COLA to contain all of the information required by 10 CFR 50.33, "Contents of Applications; General Information"; 10 CFR 52.46 requires a DC application to contain the information required by 10 CFR 50.33(a)–(c) and (j); and 10 CFR 52.16 requires an ESP application to contain the information required by 10 CFR 50.33(a)–(d) and (j).

Several requirements pertain to the treatment of nonpublic information in the application. For example, 10 CFR 50.33(j) requires applicants to separate all restricted data or other defense information from the unclassified information in the application. In addition, 10 CFR 2.390 identifies the requirements for all information (e.g., trade secrets, confidential commercial, financial, security-related information (but not Safeguards Information)) that the applicant requests to be withheld from public disclosure. Applicants should include all information requested to be withheld from public disclosure in Part 9 of the application.

Specific requirements and guidance addressing Part 1 information include the following:

a. requirements in 10 CFR 50.75, "Reporting and Recordkeeping for Decommissioning Planning";
b. Appendix C, "A Guide for the Financial Data and Related Information Required To Establish Financial Qualifications for Construction Permits and Combined Licenses," to 10 CFR Part 50, "Domestic Licensing of Production and Utilization Facilities"[1];
c. RG 1.159, "Assuring the Availability of Funds for Decommissioning Nuclear Reactors" (Ref. 3<u>14</u>); and
d. NUREG-1577, "Standard Review Plan on Power Reactor Licensee Financial Qualifications and Decommissioning Funding Assurance" (Ref. 3<u>25</u>~~5~~).

Part 1 should include an introduction to the overall application and should be presented in a logical and organized manner. The introduction should include the purpose and summary of the application and should address the application's organization and content. For example, the introduction should address the application labeling conventions, pagination, notation scheme for incorporating by reference a DC or ESP, references, and revision markings. As practicable, Part 1 should include tables that list information such as financial data and names and addresses. Part 1 may include reports submitted to other regulatory authorities that contain current information required by 10 CFR 50.33, along with an explanation for the inclusion of such reports.

[1] The Commission's Staff Requirements memorandum (SRM)-SECY-13-0124, "Policy Options for Merchant (Non-Electric Utility) Plant Financial Qualifications," April 25, 2014, (Ref. 3<u>36</u>~~6~~) instructed the NRC staff to engage in rulemaking to amend the financial qualification requirements. NRC finalized the regulatory basis for the rulemaking on October 14, 2016 (Ref. 3<u>47</u>~~7~~).

Table 1. Application Format and Content

APPLICATION PART	COMBINED LICENSE	EARLY SITE PERMIT	DESIGN CERTIFICATION
Transmittal Letter	✓*	✓	✓
Part 1: General and Financial Information	✓	✓(financial information not required)	✓(financial information not required)
Part 2: Safety Analysis Report	✓	✓	✓
Part 3: Environmental Report	✓	✓	✓
Part 4: Technical Specifications	✓	Not Applicable	✓
Part 5: Emergency Plans	✓	✓ (Variable Scope)†	Optional (Limited Scope)
Part 6: Security Plans	✓	Optional (Limited Scope)	Optional (Limited Scope)
Part 7: Exemptions, Departures, and Variances	Yes, if Applicable	Yes, if Applicable	Yes, if Applicable
Part 8: License Conditions; Inspections, Tests, Analyses and Acceptance Criteria	✓	Yes, if Applicable	✓ (only ITAAC, no license conditions)
Part 9: Withheld Information	✓	✓	✓
Part 10: Quality Assurance Program Description	✓	✓	✓
Part 11: Supplemental Information (e.g., Limited Work Authorization)	Yes, if Applicable	Yes, if Applicable	Yes, if Applicable

* The symbol "□" denotes mandatory information.

† Applicant must address significant impediment criteria under 10 CFR 52.17(b)(1), and contacts and arrangements and may address major features, or prepare a complete and integrated EP.

The provisions of the Price-Anderson Act (Section 170 of the Atomic Energy Act of 1954, as amended) and the Commission's implementing regulations in 10 CFR Part 140, "Financial Protection Requirements and Indemnity Agreements," require, in part, that each holder of a COL issued pursuant 10 CFR Part 52, "Licenses, Certifications, and Approvals for Nuclear Power Plants," have and maintain financial protection. Additionally, as required by 10 CFR 50.54(w), a power reactor licensee must obtain insurance to stabilize and decontaminate the reactor and the reactor station site in the event of an incident that requires financial protection.

The COL application must address the following regulations:

- 10 CFR 140.9, "Modification of indemnity agreements,"
- 10 CFR 140.11, "Amounts of financial protection for certain reactors,"
- 10 CFR 140.13, "Amount of financial protection required of certain holders of construction permits and combined licenses under 10 CFR Part 52,"
- 10 CFR 140.15, "Proof of financial protection,"
- 10 CFR 140.20, "Indemnity agreements and liens,"
- 10 CFR 140.21, "Licensee guarantees of payment of deferred premiums,"
- 10 CFR 140.22, "Commission guarantee and reimbursement agreements," and
- 10 CFR 50.54, "Conditions of licenses."

An explanation of each of the above mentioned regulations is provided in Section C.2.19 of this RG and addressed in the chronological order experienced during licensing (vice numerical order). All proof of financial protection provided to the Commission shall be filed in the manner specified in 10 CFR 140.15, "Proof of financial protection."

C.1.2 Safety Analysis Report

Part 2 of the application under 10 CFR Part 52 includes the safety analysis report (SAR). The requirements address the scope and content of the FSAR of a COLA in 10 CFR 52.79(a), the site safety analysis report (SSAR) of an ESP application at 10 CFR 52.17(a)(1) and (b), and the DC FSAR of a DC application in 10 CFR 52.47(a). In addition, the appendices to 10 CFR Part 52 that contain the design certification rules (DCRs) identify additional requirements specific to the FSAR for a COLA referencing a certified design.

The DCR appendices A through E to 10 CFR Part 52 are similarly structured and contain a common set of definitions and terminology. These include the generic design control document (DCD) by which technical information was submitted by DC applicants prior to a 2007 revision of 10 CFR Part 52 that required a DC applicant to submit similar content in an FSAR under 10 CFR 52.47, "Contents of Applications; Technical Information." Some DC applicants continue to use the term DCD to describe portions of their applications and this guidance uses the terms DCD or generic DCD to also describe content in DC FSAR for a future DCR. Any future DCRs are expected to have similar structures and definitions to the current DCRs but may vary. ~~Additionally~~[TO9]~~, the DCRs establish a two-tier hierarchy of design-related information (Tier 1 and Tier 2).~~

Table 2 identifies the standard SAR chapters for a COLA and denotes, for both DC and ESP applications, those chapters that are either mandatory (✓), "Optional," or "Not Applicable." Appendices A, B and C to this RG provide illustrative examples of the table of contents for the SARs from applications for the DC, COL, and ESP associated with the Vogtle Electric Generating Plant (VEGP) Units 3 and 4 COL which incorporates by reference the AP1000 DC and the Vogtle ESP and which includes an associated LWA. Appendix A presents the SAR table of contents (TOC) for the AP1000 advanced passive pressurized-water reactors from the following documents: "Westinghouse AP1000

Design Control Document, Revision 19- Introduction" (Ref. 358), "Westinghouse AP1000 Design Control Document, Revision 19, Tier 1" (Ref. 369) , and "Westinghouse AP1000 Design Control Document, Revision 19, Tier 2 – Master Table of Contents" (Ref. 3740). The SAR TOCs for the VEGP COLA (Ref. 3841), and the Vogtle ESP application (Ref. 3942) appear in Appendices B and C respectively. The examples in Appendix A are not intended to be prescriptive but serve as a sample of how the required information may be organized. Variations are a function of the DC that is incorporated by reference, the details of the ESP or LWA if applicable, regulatory requirements or guidance at the time of submission of the application as well as preferences of the applicant.

Table 2. Safety Analysis Report Format

	COL	ESP	DC
Chapter 1: Introduction and Interfaces	✓*	✓	✓
Chapter 2: Site Characteristics and Site Parameters	✓	✓	✓ [Limited Scope]
Chapter 3: Design of Structures, Components, Equipment, and Systems	✓	✓ [Limited Scope]	✓
Chapter 4: Reactor	✓	Not Applicable	✓
Chapter 5: Reactor Coolant System and Connected Systems	✓	Not Applicable	✓
Chapter 6: Engineered Safety Features	✓	Not Applicable	✓
Chapter 7: Instrumentation and Controls	✓	Not Applicable	✓
Chapter 8: Electric Power	✓	Not Applicable	✓
Chapter 9: Auxiliary Systems	✓	Not Applicable	✓
Chapter 10: Steam and Power Conversion System	✓	Not Applicable	✓
Chapter 11: Radioactive Waste Management	✓	✓ [Limited Scope]	✓
Chapter 12: Radiation Protection	✓	✓ [Limited Scope]	✓
Chapter 13: Conduct of Operations	✓	✓ [Variable Scope]	✓ [Limited Scope]
Chapter 14: Initial Test Program and Inspections, Tests, Analyses and Acceptance Criteria	✓	[Optional]	✓
Chapter 15: Transient and Accident Analysis	✓	✓ [Limited Scope]	✓
Chapter 16: Technical Specifications	✓	Not Applicable	✓
Chapter 17: Quality Assurance	✓	✓	✓
Chapter 18: Human Factors Engineering	✓	Not Applicable	✓
Chapter 19: Severe Accidents	✓	Not Applicable	✓

* The symbol "□" denotes a mandatory chapter.

~~and C respectively. The examples in Appendix A are not intended to be prescriptive but serve as a sample of how the required information may be organized. Variations are a function of the DC that is incorporated by reference, the details of the ESP or LWA if applicable, regulatory requirements or guidance at the time of submission of the application as well as preferences of the applicant.~~

Combined License Application

The FSAR, as required by 10 CFR 52.79(a) regardless whether the COL references an ESP, a DC, neither, or both, describes the facility, presents the design bases and the limits on its operation, and presents the safety analysis of the structures, systems, and components (SSCs) of the facility as a whole. It includes the detailed site-specific and design-specific information sufficient to support issuance of a COL. The FSAR should contain the technical information of the scope and level of detail described in the SRP.

Further, in NRC Management Directive (MD) 8.4, "Management of Backfitting, Forward Fitting, Issue Finality, and Information Requests" (Ref. 40~~???~~) in Section I.B.2(e) of the Directive Handbook, the Commission has stated that for light-water reactor (LWR) facilities, applicants should be anticipated to reasonably rely upon in the development of their applications the version of the SRP or a Design-Specific Review Standard (DSRS), as applicable, in effect 6 months before the docket date of the application. The Commission further directed the NRC staff that any change in requirements or regulatory staff positions from that version of the SRP or DSRS, as applicable, interpreting the Commission's requirements should follow the same reasoned decisionmaking process as a forward fit.

~~Further, as required by 10 CFR 52.79(a)(41), the FSAR documents an evaluation of the facility against the SRP revision in effect 6 months before the docket date of the application. The evaluation should identify and describe all differences in design features, analytical techniques, and procedural measures proposed for the facility and those corresponding features, techniques, and measures given in the SRP acceptance criteria. Where a difference exists, the evaluation should discuss how the proposed alternative provides an acceptable method of complying with the Commission's regulations, or portions thereof, that underlie the corresponding SRP acceptance criteria.~~ [GD10]
[GD11]

For a COLA referencing a DC, the FSAR is similar in both format and content. However, a key distinction is that the detailed site-specific information should describe all interfaces with the referenced certified design, as well as all departures, supplements, or exemptions from the referenced DC.

In addition, for information that is wholly unchanged from the referenced DC FSAR, the phrase "incorporated by reference" is inserted in the appropriate COL FSAR chapter and section in lieu of duplication of the information. Alternatively, the COLA FSAR may incorporate the DC FSAR (or DCD) content directly into the FSAR, however, it continues to describe all interfaces with the DC as well as all departures, supplements, and exemptions as specified in 10 CFR 52.79(d)(2).

For a COLA referencing both a DC and an ESP, the FSAR is similar in both format and content. However, a key distinction is that the detailed site-specific information should: (1) describe all interfaces with the referenced reactor design and all departures, supplements, or exemptions from the referenced DC and (2) address all variances from the ESP. In addition, for information that is wholly unchanged either from the referenced DC FSAR or from the ESP SSAR, the phrase "incorporated by reference" is inserted in the appropriate COL FSAR chapter/section in lieu of duplication of the information. Alternatively, a COLA FSAR may incorporate the DC FSAR (or DCD) content and ESP SSAR content directly into the FSAR, however, the same requirements of 10 CFR 52.79(b) and 10 CFR 52.79(d)(2) apply.

Section C.2.6 provides guidance on FSAR information and specific regulatory issues for COL applicants referencing a DC or ESP, or both. The guidance includes specific organization and format requirements for such an FSAR, the use of an appropriate administrative scheme to identify FSAR information on the referenced DC and/or ESP, as well as numerous issues (e.g. COL action items, design interface requirements, departures and variances) that are reflected in the FSAR. Applicants should note the terms "COL action item" and "COL information item" have been used interchangeably. However, the

NRC staff has typically used the term "COL action item" in regulations and SE reports, and DC applicants have typically included the term "COL information item" in application DCDs. This RG uses the term "COL action item" throughout the document.

Design Certification Application

As required by 10 CFR 52.47(a), the application includes an FSAR that describes the facility, presents the design bases and the limits on its operation, and presents a safety analysis of the SSCs and the facility as a whole. The FSAR should contain the technical information of the scope and level of detail described in the SRP.

Further, in NRC MD 8.4, in Section I.B.2(e) of the Directive Handbook, the Commission has stated that for LWR facilities, applicants should be anticipated to reasonably rely upon in the development of their applications the version of the SRP or a DSRS, as applicable, in effect 6 months before the docket date of the application. The Commission further directed the NRC staff that any change in requirements or regulatory staff positions from that version of the SRP or DSRS, as applicable, interpreting the Commission's requirements should follow the same reasoned decisionmaking process as a forward fit.

~~Further, as required by 10 CFR 52.47(a)(9), the FSAR documents an evaluation of the design against the SRP revision in effect 6 months before the docket date of the application. The evaluation should identify and describe all differences in design features, analytical techniques, and procedural measures proposed for the design and those corresponding features, techniques, and measures given in the SRP acceptance criteria. Where a difference exists, the evaluation should discuss how the proposed alternative provides an acceptable method for complying with the Commission's regulations, or portions thereof, that underlie the corresponding SRP acceptance criteria.~~ [GD12]

~~[GD13]~~

The FSAR for a DC application differs in scope and content but is similar in format to a COL FSAR. The design-related information identifies and discusses interfaces for SSCs that a COL applicant's plant-specific design should address, and the site-related information includes postulated site parameters for the design, in lieu of site-specific characteristics, that the COL applicant should address.

Early Site Permit Application

As required by 10 CFR 52.17(a)(1) and (b), the application includes an SSAR that contains detailed information on the possible facilities to be located at the site and a comprehensive characterization and safety assessment of the site. The SSAR should contain the technical information of the scope and level of detail described in the SRP.

Further, in NRC MD 8.4, in Section I.B.2(e) of the Directive Handbook, the Commission has stated that for LWR facilities, applicants should be anticipated to reasonably rely upon in the development of their applications the version of the SRP or a DSRS, as applicable, in effect 6 months before the docket date of the application. The Commission further directed the NRC staff that any change in requirements or regulatory staff positions from that version of the SRP or DSRS, as applicable, interpreting the Commission's requirements should follow the same reasoned decisionmaking process as a forward fit.

~~Further, as required by 10 CFR 52.17(a)(1)(xii), the SSAR documents an evaluation of the site against applicable sections of the SRP revision in effect 6 months before the docket date of the application. The evaluation should identify and describe all differences in analytical techniques and procedural measures proposed for a site and those corresponding techniques and measures given in the SRP acceptance criteria. Where such a difference exists, the evaluation should discuss how the proposed~~

~~alternative provides an acceptable method of complying with the regulations, or portions thereof, that underlie the corresponding SRP acceptance criteria.~~[GD14]

[GD15]

The SSAR is similar in format to a COL FSAR. The SSAR content includes detailed site-specific characteristics and the potential reactor facility information that applies to the issuance of an ESP. An ESP that is issued prior to selection of a reactor design will follow the plant parameter envelope (PPE) approach which establishes postulated values of design parameters that provide design information to support the NRC staff's review of an ESP application. A controlling PPE value, or bounding parameter value, is one that necessarily controls the value of a site characteristic in the context of site suitability (e.g. X/Q values established within the PPE for the purposes of evaluating the postulated design performance). As the PPE is intended to bound multiple reactor designs, the actual design selected in a COLA referencing an ESP must fit within the bounding parameter values. Following selection of a design, if a design value exceeds the PPE bounding value, an applicant must request and justify a variance from the ESP. As illustrated in Table 2, the SSAR contains a subset of the chapters in a COL FSAR. The following summarizes the scope of the SSAR chapters:

a. Chapter 1 is analogous to a COL FSAR for the potential future facility and reactor designs.
b. Chapter 2 is analogous to a COL FSAR. For an ESP that uses a PPE instead of specific reactor facility information, the PPE is given here.
c. Chapter 3 is generally limited to Section 3.5 on aircraft hazards.
d. Chapter 11 is limited to addressing whether effluent releases and public dose limits can be met for the site.
e. Chapter 12 is limited to addressing doses to construction workers, especially from onsite sources of direct radiation, and possible direct dose contributors to offsite members of the public.
f. Chapter 13 is generally limited to Section 13.3 on emergency planning (EP) and Section 13.6 on site characteristics for adequate security planning.
g. Chapter 14 is optional and addresses ITAAC that apply to EP or an LWA.
h. Chapter 15 is analogous to a COL FSAR for the potential reactor designs but is limited to Section 15.0.3 addressing the evaluation of the radiological consequences of design basis
i. ~~.~~Chapter 17 is analogous to a COL FSAR but addresses the quality assurance applied to site-related activities for the design, construction, and testing of the potential future facility.

C.1.3 Environmental Report

Part 3 of the application under 10 CFR Part 52 includes the environmental report (ER). Requirements for the ER related to a COLA and ESP and DC applications are set forth in 10 CFR 52.80(b), 10 CFR 52.17(a)(2), and 10 CFR 52.47(b)(2), respectively, which reference the applicable sections of 10 CFR Part 51.

The scope and content of the ER varies by the type of application. A COLA includes the section entitled, "Applicant's Environmental Report-Combined License Stage," which contains information in accordance with 10 CFR 51.50(c) or in accordance with both 10 CFR 51.49(a) and 10 CFR 51.50(c) if an LWA is requested. Section C.2.18 includes additional guidance on an LWA. An ESP application includes the section entitled, "Applicant's Environmental Report - Early Site Permit Stage," which contains information in accordance with 10 CFR 51.50(b) or in accordance with both 10 CFR 51.49(c) and 10 CFR 51.50(b) if an LWA is sought. A DC application includes the section entitled, "Applicant's Environmental Report—Standard Design Certification," which contains information in accordance with 10 CFR 51.55, "Environmental Report-Standard Design Certification."

A COLA ER referencing an ESP need not contain information or analyses submitted to the NRC in the ESP stage or resolved in the ESP EIS, but it must contain, in addition to the environmental

information and analyses otherwise required by Part 51, the information required by 10 CFR 51.50(c)(1)(i)-(v). Section C.2.15 addresses the finality of environmental issues for a COLA that references an ESP or DC.

RG 4.2, "Preparation of Environmental Reports for Nuclear Power Stations," provides guidance for the format and content of ERs. NUREG-1555, provides guidance to the NRC staff for review of ERs.

Current ISG addresses the NRC staff's review of ERs. COL/ESP-ISG-026 is applicable to the review of all ESPs and COLAs and includes those applicants seeking an LWA. COL/ESP-ISG-027, offers supplemental guidance to the staff for environmental reviews in areas unique to small modular reactor (SMR) applications. Section C.2.17 provides additional guidance related to SMRs. The NRC staff plans to retire COL/ESP-ISG-026 and COL/ESP-ISG-027 once it completes its updates to RG 4.2 and NUREG-1555.

C.1.4 Technical Specifications

Part 4 of the application under 10 CFR Part 52 includes the technical specifications and the technical specifications bases. Requirements for technical specifications and the associated bases related to a COL and DC are set forth in 10 CFR 52.79(a)(30) and 10 CFR 52.47(a)(11), respectively, which reference the requirements of 10 CFR 50.36, "Technical Specifications," and 10 CFR 50.36a, "Technical Specifications on Effluents from Nuclear Power Reactors." There are no technical specification requirements for an ESP application; therefore, Part 4 is not applicable to an ESP application.

For DCs, the technical specifications required under 10 CFR 52.47(a)(11) that have been incorporated by reference in the DCR Appendices A, B, C, D and E of 10 CFR Part 52 are referred to as "generic technical specifications." A DC application shall include proposed generic technical specifications, as required by 10 CFR 50.36(a)(2), which should be derived from the analyses and evaluations included in the proposed DC FSAR. Throughout this guidance, it should be understood, when referring to the DC, that both the specifications and associated bases are encompassed in the term "generic technical specifications." In accordance with the DCR appendices of 10 CFR Part 52, departures from the generic technical specification bases are treated the same as departures from the associated generic technical specifications.

The NRC has published Standard Technical Specifications (STS) for various reactor designs as NUREG publications in response to the "Final Commission Policy Statement on Technical Specifications Improvement for Nuclear Power Plants," dated July 22 1993 (76 FRN 39132) (Ref. 4143). The STS represented by NUREGs 1430, "Standard Technical Specifications, Babcock and Wilcox Plants" (Ref. 4244), 1431, "Standard Technical Specifications, Westinghouse Plants" (Ref. 435), 1432, "Standard Technical Specifications, Combustion Engineering Plants" (Ref. 446), 1433, "Standard Technical Specifications, General Electric BWR/4 Plants" (Ref. 457), and 1434, "Standard Technical Specifications, General Electric BWR/6 Plants" (Ref. 468), as well as NUREG-2194, "Standard Technical Specifications, Westinghouse Advanced Passive 1000 Plants" (Ref. 479), were developed with extensive public technical meetings with owners groups and vendors for each reactor type. They are maintained for each of the Nuclear Steam Supply Systems owners groups. The NRC's Office of Nuclear Reactor Regulation's (NRR) Office Instruction LIC-600, "Review of Technical Specifications Task Force (TSTF) Travelers and Creation of "CLIIP" Model Applications" (Ref. 4850) provides information on this process. A DC application's proposed generic technical specifications should conform to the format and be consistent with the content of the most recent version of the STS appropriate to the design proposed for certification to the extent that existing STS apply.

A COLA referencing a DC should include proposed plant-specific technical specifications and bases. The plant-specific technical specifications should be derived from the analyses and evaluations included in the proposed SAR. They should encompass the generic technical specifications and bases of the certified design, the departures from the DC FSAR (or DCD) of the certified design, and site-specific information included in the proposed SAR. A COL applicant departing from any portion of the generic technical specifications needs an exemption from the generic technical specifications to include the departure in the plant-specific technical specifications or associated bases that are issued with the COL.

A COLA not referencing a DC should include proposed plant-specific technical specifications and associated bases as required by 10 CFR 50.36 and 50.36a. The plant-specific technical specifications should be derived from the analyses and evaluations included in the proposed SAR and should conform to the format and be consistent with the content of the most recent version of the STS appropriate to the reactor plant design proposed in the COLA.

The Atomic Energy Act of 1954, as amended (AEA), requires technical specifications issued with the COL to contain all the information mandated by 10 CFR 50.36 and 10 CFR 50.36a. Technical specifications serve the purpose, under Section 182a of the Act, of allowing the NRC to make its operational safety finding. Section 182a also requires the issued license to include technical specifications. Moreover, Section 185b specifically requires the NRC to make its finding of safe operation when issuing the COL. Therefore, compliance with these statutory provisions requires including a complete set of technical specifications in the COL to support the Commission's safety findings for granting a COL. Plant-specific technical specifications, issued with a combined license, must be acceptable for governing plant operation within its design basis, and therefore, must be final.

Part 4 of the application should include the following:

a. technical specifications,
b. technical specification bases, and
c. additional information intended for NRC review that relates to the applicant's proposed technical specifications and bases, as follows:

(1) A DC application should include an introductory section that does the following:

- describes the process the applicant used to assess the design's safety analyses and design features against the selection criteria for limiting conditions for operation (LCOs) in 10 CFR 50.36(c)(2)(ii),
- describes the COL action items (as described in Section C.2.11) to be denoted by square brackets in the proposed generic technical specifications and associated bases with appropriate guidance to COL applicants for completing COL action items needing such guidance,
- describes how and why the proposed generic technical specifications and bases differ from the STS and bases and other precedents for technical specification requirements from which the applicant states it derived the proposed generic technical specifications and bases,

- describes any NRC-approved (or pending NRC approval) generic changes to operating reactor STS and bases that the applicant proposes to incorporate in the generic technical specifications and bases, and

- states the reasons for including requirements in the proposed generic technical specifications, if any, that are not required by 10 CFR 50.36.

(2) A COLA that references a DC should include an introductory section that does the following:

- describes how the applicant proposes to resolve each COL action item included in the generic technical specifications and associated bases to complete the plant-specific technical specifications and associated bases,

- summarizes where the COLA describes supplemental information proposed for incorporation as additional requirements in the proposed plant-specific technical specifications and associated bases, and

- summarizes where the application describes standard and site-specific departures from the generic technical specifications and associated bases that are included in the proposed plant-specific technical specifications and associated bases.

(3) A COLA that does not reference a DC should include an introductory section that does the following:

i. describes how the applicant developed the proposed plant-specific technical specifications, especially how it assessed the design's safety analyses and design features against the selection criteria for LCOs in 10 CFR 50.36(c)(2)(ii),
ii. describes how and why the proposed plant-specific technical specifications and bases differ from the STS and bases and other precedents for technical specification requirements from which the applicant states it derived the proposed plant-specific technical specifications and bases,
iii. describes any NRC-approved (or pending NRC approval) generic changes to operating reactor STS and bases that the applicant proposes to incorporate in the plant-specific technical specifications and bases, and
iv. states the reasons for including requirements in the proposed plant-specific technical specifications, if any, that are not required by 10 CFR 50.36.

C.1.5 Emergency Plans

Dependent on what an applicant is seeking, Part 5 of an application for a COL or an ESP includes the applicant's onsite emergency plan and additional information, such as offsite emergency plans, an evacuation time estimate, a description of the emergency planning zones, and a description of contacts and arrangements made with offsite officials, that supplements the onsite emergency plan. For a DC application, Part 5 is optional and may include design-specific emergency plan information.

The specific EP requirements vary, depending on whether the applicant submits: (1) a COLA, (2) an ESP application with a complete and integrated emergency plan, (3) an ESP application with a "major features" (i.e., partial) emergency plan, (4) an ESP application that only identifies physical characteristics of the proposed site that could pose a significant impediment to the development of an

emergency plan, or (5) a DC application that may, or may not, address very limited (generic design-specific) aspects of the emergency plan supporting the reactor design.

The EP requirements related to a COLA are included in 10 CFR 50.33(g); 10 CFR 50.34(f); 10 CFR 50.47; Appendix E, "Emergency Planning and Preparedness of Production and Utilization Facilities," to 10 CFR Part 50; 10 CFR 52.77; 10 CFR 52.79(a)(21); 10 CFR 52.79(a)(22); 10 CFR 52.79(a)(29)(ii); 10 CFR 52.80, "Contents of Applications; Additional Technical Information"; and 10 CFR 100.21(g). The EP requirements related to an ESP application are included in 10 CFR 52.17, "Contents of Applications; Technical Information"; and 10 CFR 100.21(g); additional requirements are included in 10 CFR Part 50, depending on the extent that the ESP application addresses EP. The EP requirements related to a DC application are included in 10 CFR 50.34(f) and 10 CFR 52.47 and will vary depending on the extent that the DC application addresses EP. In addition, 10 CFR 30.32(i)(1), 10 CFR 40.31(j)(1), and 10 CFR 70.22(i)(1) provide EP requirements associated with the receipt, possession, and use of byproduct, source, and special nuclear materials (SNMs).

Part 5 of the COLA, or as applicable in an ESP application, should include the following or provide cross-references to other parts of the application as indicated:

a. a table of contents;
b. the applicant's onsite emergency plan;
c. a description of the size and configuration of the emergency planning zones;
d. State and local (offsite) emergency plans or an offsite utility emergency plan;
e. a description of contacts and arrangements with Federal, State, and local governmental agencies with EP responsibilities, including letters of agreement or certificates of approval, or both;
f. an evacuation time estimate;
g. for an ESP application, identification of physical characteristics of the proposed site that could pose a significant impediment to the development of an emergency plan, including measures that would, when implemented, mitigate or eliminate the significant impediment (to be included in Part 2);
h. if an ESP (or DC) is referenced in a COLA, any required information to update the information that was previously reviewed (to be included in Part 2);
i. EP program implementation milestones, including a discussion of implementation of the proposed emergency plan at a site with an operational emergency plan supporting an existing reactor(s) (to be included in Part 2);
j. an evaluation of the applicability and implementation of EP requirements associated with the receipt, possession, and use of source, byproduct, and SNMs (to be included in Part 2);
k. for an ESP application that includes the PPE approach for choosing a reactor technology, a description of how this will affect the emergency plan at the COLA stage (to be included in Parts 2 and 5);
l. requested exemptions, departures, and variances related to EP (to be included in Part 7);
m. EP ITAAC (to be included in Part 8); and
n. proposed EP-related COL license conditions or ESP permit conditions (to be included in Part 8).

C.1.6 Security Plans

Part 6 of the application under 10 CFR Part 52 includes the security plans and relevant supplemental information. The security plans, as described in 10 CFR 73.55(c)(1), consist of the physical security plan (PSP), training and qualification plan (T&QP), safeguards contingency plan (SCP), and cybersecurity plan (CSP). For a COLA, the PSP, T&QP, SCP, and CSP are required by 10 CFR 52.79(a)(35)(i) and 10 CFR 52.79(36)(i), (ii), and (iii).

An ESP application has no security plan requirements. However, 10 CFR 52.17(a)(1)(x) requires the application to contain "information demonstrating that site characteristics are such that adequate security plans and measures can be developed." The applicant may include such information in Part 6 of the application.

A DC application has no security plan requirements. However, the applicant may include design-specific security plan information (e.g., cybersecurity features and security-informed design features) in Part 6 of the application.

Part 6 contains Safeguards Information as defined in 10 CFR 73.2, "Definitions." The applicant shall protect the plans and other related Safeguards Information against unauthorized disclosure in accordance with the requirements of 10 CFR 73.21, "Protection of Safeguards Information: Performance Requirements." Accordingly, Part 6 must be submitted to the NRC separate from other parts of the application in accordance with the requirements for submitting safeguards information.

Part 6 of the COLA should include the following:

a. ~~–~~a table of contents;
b. the PSP;
c. the SCP;
d. the T&QP;
e. the CSP;
f. a description of the implementation of the SCP, T&QP, and CSP;
g. a description of the SNM control and accounting program;
h. the ITAAC containing Safeguards Information;
   Note: Part 8 of the application includes ITAAC related to security and safeguards. ITAAC that contain Safeguards Information as defined in 10 CFR 73.2 are included in this Part 6 and cross-referenced in Part 8.
i. a new fuel shipping plan;
j. a description and plan to address loss of large areas of the plant due to explosions or fire, as required by 10 CFR 52.80(d); and
k. Safeguards Information in support of any requested materials licenses under 10 CFR Part 30, 10 CFR Part 40, and 10 CFR Part 70, for which additional guidance is provided in Section C.2.13.

C.1.7 Exemptions, Departures, and Variances

Part 7 of the application under 10 CFR Part 52 includes the exemptions, departures, and variances applicable to a specific application. The regulations in 10 CFR 52.7, "Specific Exemptions"; 10 CFR 52.63, "Finality of Standard Design Certifications"; 10 CFR 52.93, "Exemptions and Variances"; and the appendices to 10 CFR Part 52 that contain the DCRs include the requirements related to exemptions. The regulations in 10 CFR 52.63 and the DCR appendices to 10 CFR Part 52 include the requirements related to departures. The regulations in 10 CFR 52.39, "Finality of Early Site Permit Determinations," and 10 CFR 52.93 include the requirements related to variances.

An applicant for a COL, DC, or ESP may request an exemption from one or more of the requirements of 10 CFR Part 52. Exemptions from the requirements of other parts of the regulations that apply by virtue of 10 CFR Part 52 are governed by the exemption requirements of those parts (e.g., 10 CFR 50.12, "Specific Exemptions," governs exemptions from 10 CFR Part 50 requirements).

A COL applicant that references a DC may make departures from the design as provided in 10 CFR 52.63, 10 CFR 52.93, and Section VIII, "Processes for Changes and Departures," of the referenced DCR appendix to 10 CFR Part 52.

A COL applicant that references an ESP may ask for a variance from the permit or the SSAR as provided in 10 CFR 52.39 and 10 CFR 52.93.

Part 7 of the application should include a table listing the identifying number, title, and brief description of each requested exemption, departure, and variance.

Section X of Appendices A-E of 10 CFR Part 52 applies to COL applicants who reference the relevant certified designs. Section X.A.1 of each appendix states that the applicant shall prepare and maintain written evaluations which provide the bases for making plant-specific departures under Section VIII of the certification appendix. These evaluations must be retained throughout the period of application and for the term of the license (including any period of renewal). Section, X.B.1 requires each COL applicant to provide in its initial application submittal a report that contains a brief description of any plant-specific departures from the referenced DCD including a summary of the evaluation of each. This report should be included in Part 7. Section X.B.1 of the DCR additionally requires that the reports be updated semi-annually, as per Section X.B.3, until the date the Commission makes its findings required by 10 CFR 52.103(g). These summary reports should be similar in format and level of detail as reports submitted by operating reactors as required by 10 CFR 50.59. For departures that do not require prior NRC approval per Section VIII of Appendices A-E of 10 CFR Part 52, no additional departure description information needs to be included in Part 7.

For a COLA that is a "subsequent" COLA (or S-COLA), as discussed in Section C.2.7, it is anticipated that previous COL applicants (i.e., a reference COLA, or R-COLA) or COL holders referencing the same DC will have developed reports under Section X.B.1 for "standard" departures approved per Section VIII which are presumably applicable to all applications that reference the same design. A COL applicant may incorporate by reference these reports in lieu of repeating the information in Part 7, provided that each departure evaluation is properly referenced in Part 7 consistent with requirements under Section X.B.1 and information is provided that it has been reviewed and found applicable to the COL applicant's site/plant. If, because of plant-specific considerations, additional evaluation of the departure is necessary, the COL applicant should supplement the referenced reports with a summary of the plant-specific evaluation.

For departures/exemptions requiring prior NRC approval, Part 7 should include the following information:

a. The scope and summary of the request;
b. Justification relative to the specific application with cross-references to applicable regulatory guidance and/or requirements;
c. A technical and regulatory evaluation relative to safety significance and regulatory acceptance criteria (e.g., 50.12, Section VIII of referenced DC rule);
d. For exemptions, an evaluation against the applicable exemption criteria; and
e. A statement identifying the need for NRC approval or need for an exemption.

However, if a COL holder referencing the same DC has obtained NRC approval for the same departures or exemptions, the S-COL applicant may incorporate by reference into Part 7 the evaluations submitted in those license amendment/exemption requests (i.e. item c from the list above), in lieu of repeating this information in Part 7, and also reference the NRC letter enclosing the applicable safety evaluation. Applicants should include necessary supplemental plant-specific

information. This information will aid the NRC staff in determining that no additional staff review of these changes is necessary.

With respect to requests for variances, Part 7 should include the following information:

a. description of the variance
b. justification for the variance

C.1.8 License Conditions and Inspections, Tests, Analyses, and Acceptance Criteria

Part 8 of the application under 10 CFR Part 52 includes the applicant's proposed ITAAC and the applicant's proposed license conditions, if any. The requirements for ITAAC related to an application for a COL, DC, and ESP are set forth in 10 CFR 52.80(a), 10 CFR 52.47(b)(1), and 10 CFR 52.17(b)(3), respectively. Section C.2.9 provides guidance on ITAAC development and format.

Inspections, Tests, Analyses, and Acceptance Criteria

As required by 10 CFR 52.80(a), a COLA includes the proposed inspections, tests, and analyses, including those applicable to EP, that the applicant should perform and the acceptance criteria that are necessary and sufficient to provide reasonable assurance that, if the inspections, tests, and analyses are done and the acceptance criteria met, the facility has been constructed and will be operated in conformity with the COL, the provisions of the Atomic Energy Act of 1954, as amended (AEA), and the Commission's rules and regulations. The COL applicant should include the proposed selection method and criteria for establishing ITAAC in FSAR Section 14.3 and include the proposed ITAAC in Part 8 of the COLA.

For a holder of a COL, successful completion of all ITAAC is a prerequisite for fuel load and a condition of the license. After the Commission makes its finding in accordance with 10 CFR 52.103(g) and authorizes fuel load, the ITAAC are no longer license requirements nor do they have legal standing. In recognition of the finite nature of the ITAAC, 10 CFR 52.80 identifies ITAAC as additional technical information required in the application. Therefore, Part 8 of the application containing the ITAAC will not become part of the facility's FSAR.

As required by 10 CFR 52.47(b)(1), a DC application includes the proposed ITAAC that are necessary and sufficient to give reasonable assurance that, if the inspections, tests, and analyses are done and the acceptance criteria met, a facility that references the DC has been constructed and will be operated in conformity with the DC, the provisions of the AEA, and the Commission's rules and regulations. DC applicants using the document hierarchy convention of "Tier 1" and "Tier 2" should include the ITAAC along with the required design descriptions, significant interface requirements, and significant site parameters in the Tier 1 information. In this hierarchy, Tier 1 is the portion of the design-related information ~~included within the DCR~~ that is certified (i.e. each appendix to 10 CFR Part 52), and Tier 2 is the portion of the design-related information that is approved but not certified ~~in the DCR~~. The applicant may: (1) include the entirety of Tier 1 information in Part 2 of the application or, (2) include the Tier 1 design descriptions, significant interface requirements, and significant site parameters in Part 2 of the application and provide the ITAAC in Part 8.

For an ESP applicant that does not seek an LWA, the ITAAC requirements are limited to EP. Under 10 CFR 52.17(b)(3), the ESP applicant has three alternatives:

a. EP ITAAC shall be included if the application contains proposed complete and integrated emergency plans in accordance with 10 CFR 52.17(b)(2)(ii).

b. EP ITAAC may be included if the application contains the proposed major features of the emergency plans in accordance with 10 CFR 52.17(b)(2)(i).
c. EP ITAAC do not apply if the application is limited to addressing physical site characteristics that could pose significant impediments to the development of emergency plans in accordance with 10 CFR 52.17(b)(1).

ITAAC other than those related to EP or an LWA (if requested) are not applicable to an ESP application.

License Conditions

A COL issued under 10 CFR Part 52 shall contain the terms and conditions that the Commission deems necessary and appropriate. For example, 10 CFR 50.54, "Conditions of Licenses," identifies conditions that apply to every COL, some of which only apply after the Commission has made its finding under 10 CFR 52.103(g). In addition, 10 CFR 50.55, "Conditions of Construction Permits, Early Site Permits, Combined Licenses, and Manufacturing Licenses," identifies conditions applicable to every COL until the date of the Commission finding under 10 CFR 52.103(g). The NRC staff typically identifies proposed license conditions as part of the application review process. However, a COL applicant may propose additional license-specific conditions in their application. Part 8 of the application is the appropriate location to document license-specific conditions.

An ESP issued under 10 CFR Part 52 must specify the terms and conditions that the Commission deems appropriate and 10 CFR 50.55 identifies conditions applicable to each ESP. An ESP applicant may propose permit-specific additional conditions in coordination with the NRC staff review of the application. Part 8 of the application is the appropriate location to document permit-specific conditions.

For both COL and ESP applications, 10 CFR 51.50, "Environmental Report—Construction Permit, Early Site Permit, or Combined License Stage," requires the ER to state procedures for reporting and keeping records of environmental data and any conditions and monitoring requirements for protection of the terrestrial and aquatic environment for possible inclusion in the license as environmental conditions in accordance with 10 CFR 50.36b, "Environmental Conditions." The ER should include the environmental license conditions (Part 3 of the application). A COL or ESP issued under Part 52 may include appropriate environmental license conditions in an environmental protection plan.

C.1.9 Withheld Information

Part 9 of an application for a COL, DC, or ESP under 10 CFR Part 52 contains the information considered by the applicant to be "sensitive unclassified[2] non-Safeguards[3] information," or other unclassified information that is required to be withheld from public disclosure. As provided in 10 CFR 2.390, information may be made available to the public at the NRC Web site at http://www.nrc.gov or at the NRC Public Document Room in the absence of an NRC determination for withholding the information. Accordingly, the applicant should redact from other parts of the application all information requested to be withheld from public disclosure and include such information in Part 9.

[2] National security information and restricted data are addressed in 10 CFR Part 25, "Access Authorization." Pursuant to 10 CFR 50.33(j), the application shall be prepared in such manner that all restricted data and other defense information are separated from the unclassified information.

[3] Safeguards Information, as defined in 10 CFR 73.2, is addressed in 10 CFR 73.21 and 10 CFR 73.22, "Protection of Safeguards Information: Specific Requirements."

The information may include commercial trade secrets, financial data, proprietary information, State and local governmental agency sensitive information (e.g., emergency plans), and security-related information not designated as Safeguards Information or classified information. The applicant shall comply with the provisions of 10 CFR 2.390 at the time of application submittal for the information requested to be withheld, including specific identification and marking of documentation and any applicable affidavit requirements. For example, consistent with NRC guidance in Regulatory Issue Summary (RIS) 2005-26, "Control of Sensitive Unclassified Nonsafeguards Information Related to Nuclear Power Reactors," dated November 7, 2005 (Ref. 4951), applicants are not required to make an affidavit for sensitive information withheld under 10 CFR 2.390(d) and related to: (1) physical protection or (2) material control and accounting.

The applicant may, consistent with guidance for application electronic submittal (Section C.2.3 of this guide), elect to submit two complete electronic files (e.g., compact disk/read-only memory (CD-ROM) format) of the SAR; one file intended for NRC staff review that includes complete information, and a second file intended for public availability that excludes the information to be withheld. For this option, the applicant should submit the version intended for public availability in Part 2 of the application and submit the version containing withheld information in Part 9 of the application.

The Part 9 contents should be logically organized and presented in a manner supportive of an efficient review. Accordingly, Part 9 should include the following:

a. an introductory statement(s) relative to 10 CFR 2.390 (e.g., "Part 9 of the application contains the proprietary, sensitive, and security-related information that is to be withheld from public disclosure in accordance with 10 CFR 2.390");
b. table of contents that clearly identifies the redacted information and the specific application part, chapter, or section from which the information was redacted; and
c. a description of the marking convention used throughout the application, an explanation of whether such convention is consistent with 10 CFR 2.390(b)(1) (e.g., using triple brackets {{{ }}}, square brackets [ ], or other appropriate designation) to identify the information redacted and to explain the absence of the information at its source location in the application; this should include header and footer page designations if they are used.

C.1.10 Quality Assurance Program Description

Part 10 of the application under 10 CFR Part 52 includes the quality assurance program description (QAPD). Requirements for a COL, ESP, and DC QAPD are set forth in 10 CFR 52.79(a)(25), 10 CFR 52.17(a)(1)(xi), and 10 CFR 52.47(a)(19), respectively.

The type of application determines the scope and content of the QAPD. The COL applicant describes quality assurance applied to the design, fabrication, construction, testing, and operation of the facility; the ESP applicant describes quality assurance applied to site-related activities for the design, fabrication, construction, and testing of the future facility or facilities; and the DC applicant describes quality assurance applied to the facility design and testing.

Part 10 of the application should contain the applicant's QAPD as a separate standalone document. If the applicant previously submitted the QAPD to the NRC for review (e.g., prior submittal as a topical report), it should identify the transmittal correspondence, should incorporate by reference the QAPD into the application, and should not resubmit the QAPD with the application.

C.1.11 Supplemental Information

An application for a COL, DC, or ESP under 10 CFR Part 52 may need to include information that supplements the standard information identified in Parts 1 through 10 of the application. Part 11 of the application for a COL, DC, or ESP contains this supplemental information.

The supplemental information may address the following:

a. a regulatory option selected by the applicant (e.g., LWA or site redress plan);
b. an application-specific regulatory issue (e.g., geotechnical subsurface investigation report, site-specific seismic analysis report, or topical report(s) not previously submitted); and
c. other information specifically identified by the NRC or deemed appropriate by the applicant for a complete application and timely NRC review (e.g., a COL applicant's position on a request for additional information (RAI) issued by the NRC to another COL applicant with the same referenced DC or a COL applicant's position on a subsequent combined license (S-COL) about commitments by the reference-COL applicant for which guidance is provided in Section C.2.7).

Part 11 should not include information designated for inclusion in Parts 1- 10 of the application. In particular, Part 11 should not be used for providing information that is required to be contained in the SAR in Part 2 of the application.

C.2 Application Regulatory Topics

Applications submitted under 10 CFR Part 52 should be complete, sufficiently detailed, technically defensible, and accurate to support an effective and efficient NRC staff review. Further, applicants should support preapplication activities, the application acceptance review, and the application detailed technical review. To this end, Section C.2 includes information on selected topics related to the preparation, submittal, acceptance, and review of applications that is intended to: (1) facilitate the understanding of NRC requirements and expectations and (2) offer useful guidance to those engaged in the application process.

The NRC staff considers the guidance in Section C.2 to generally apply to LWR and to potentially apply to other types of power reactors. The topics addressed in Section C.2 primarily relate to the regulatory processes identified in 10 CFR Part 52, most of which are independent of reactor technology. For example, guidance on preapplication activities, the preapplication readiness assessment, the acceptance review process, RAIs, environmental issue finality, and the option for a COLA to reference a DC or ESP, or both, applies to all applicants independent of reactor technology. However, the guidance on specific regulatory and technical issues (e.g., 10 CFR Parts 30, 40, and 70 material licenses for COLs and design-specific review standards (DSRS) for SMRs) focuses on LWR technology and may have limited applicability to non-LWR applicants.

C.2.1 Preapplication Activities

"Preapplication activities" is the term used to encompass all the communications, correspondence, meetings, document submittals/reviews, and other interactions that occur between the NRC staff and a prospective applicant before the tendering of an application under 10 CFR Part 52. The NRC considers preapplication activities to be mutually beneficial to both the staff and prospective applicants and encourages prospective applicants to initiate interactions early in the application planning process. Preapplication activities, although encouraged and recommended by the NRC, are not required and are voluntary by prospective applicants. This section of the RG provides an explanatory overview of preapplication activities and provides guidance to prospective applicants for initiating and

carrying out the varied activities.

OVERVIEW

Commission Policy

The NRC encourages interactions between the staff and those entities considering the submittal of an application under 10 CFR Part 52. As stated in the Commission's Final Policy Statement on the Regulation of Advanced Reactors (Ref. 5052), the Commission encourages the earliest possible interaction with applicants, vendors, and other Government agencies to provide for early identification of regulatory requirements and to provide all interested parties, including the public, with a timely, independent assessment of the safety and security characteristics of the designs. The Commission foresees that such interaction early in the design process will contribute to stability and predictability in the licensing and regulation of new reactors. The policy further states that in "the absence of a significant history of operating experience on an advanced concept reactor, plans for the innovative use of proven technology and/or new technology development programs should be presented to the NRC for review as early as possible, so that the NRC can assess how the proposed program might influence regulatory requirements."

NRC Staff Position

Consistent with agency policy, the NRC staff encourages early and continuing communications and interactions with prospective applicants in varying type, scope, formality, and frequency as a prospective applicant progresses toward tendering an application. Preapplication activities support NRC readiness to conduct licensing reviews in a predictable timeframe, and major policy, technical, and licensing issues should be identified and progress should be made in understanding how such issues can be resolved before the NRC receives the application.

The NRC staff supports differing approaches for preapplication activities, and the staff has no expectations for standardization of interactions with prospective applicants.

Public and Nonpublic Meetings

To facilitate regulatory transparency and to ensure coordination between the NRC and its stakeholders, agency policy is to maximize the use of public meetings to address generic approaches for resolving the policy, licensing, and key technical issues for new reactor technologies. NRC's MD 3.5, "Attendance at NRC Staff-Sponsored Meetings," provides information on the NRC's implementation of this policy. In addition, consistent with the agency's mission, the NRC staff is precluded from performing, or being perceived as performing, the role of advisor or consultant to any prospective applicant or stakeholder. To this end, the staff will ensure that as many preapplication interactions as practicable are carried out in the public domain.

The NRC staff recognizes that certain information (e.g., applicable to innovative technologies) provided by prospective applicants includes proprietary information, pending patents, and other information not appropriate for release to the public. For this reason, nonpublic (i.e., closed) meetings may be appropriate for addressing such information. However, the NRC intends to minimize closed meetings and, where feasible, arrange meeting agendas such that meetings can be divided into open and closed portions to allow public participation.

GUIDANCE

The following sections provide guidance to prospective applicants on; (1) familiarity with the NRC's regulatory requirements and processes, (2) application-related plan and schedule information of interest to the NRC, (3) regulatory engagement plans (REPs), (4) staff's enhanced safety-focused review approach (ESFRA), (5) preapplication meetings with the NRC staff (public and nonpublic meetings), (6) application-related documents that may be submitted for the NRC staff's review, (7) application-related safety and environmental regulatory issues, (8) information requested by the NRC in regulatory issue summaries, and (9) the NRC staff's preapplication readiness assessment.

Regulatory Familiarity

Prospective applicants may initiate communications (e.g., by telephone, written correspondence, or e-mail) with the NRC staff at their discretion. However, early in the application planning process, a prospective applicant should become familiar with the NRC's regulatory structure, policies, requirements, and processes. The NRC public Web site at http://www.nrc.gov/ is a resource for such information and the site http://www.nrc.gov/reactors/new-reactors.html is the source for current requirements, guidance, and information on new reactors and applications. In addition, the site provides extensive information on applications currently undergoing staff review and the licenses, certifications, and permits recently issued. The advanced reactors Web site at http://www.nrc.gov/reactors/advanced.html is the source for current regulatory and technical issues concerning advanced reactors and SMRs. In addition, the advanced reactors Web site provides specific information on the business entities currently engaged in preapplication activities and the respective reactor designs.

Prospective applicants should be familiar with the identification and resolution of regulatory and technical issues encountered by prior applicants/preapplicants. The new reactors and advanced reactors Web sites provide electronic links to the comprehensive publicly available information authored by both applicants/preapplicants and the staff throughout the application submittal and review process (e.g., preapplication public meetings, applicant-authored topical reports and FSARs, staff RAIs and applicant responses, and staff safety evaluation (SE) reports). The NRC staff recommends that prospective applicants review relevant information for insights into policy, regulatory, and technical issues.

Plans and Schedules

Prospective applicants should determine the appropriate preapplication activities relative to their respective plans, needs, and schedules. The preapplication activities should focus on what would be most beneficial both to the preparation and submittal of the application and to the NRC's acceptance and detailed review of the application including the identification of long lead-time issues such as exemptions and site-specific data collection needs. Further, the activities should focus on what would achieve the most efficient use of both staff and applicant resources.

Preapplication activities should address information on plans and schedules (see the discussion below under "NRC Information Requests—Regulatory Issue Summaries") and on the specific design and application-specific regulatory issues. Early in the planning process, information will be preliminary; however, the information will become more defined and detailed as the design and planning progress. During the preapplication timeframe, the NRC will seek information such as the following:

a. What applications (e.g., ESP, DC, and COL) are planned and when?
b. What is the status of the plant design?
c. What is the status for the qualification of fuel and other major systems and components?

d. What is the status of computer codes and models for design and licensing analyses?
e. What is the status of a quality assurance program?
f. What is the status of probabilistic risk assessment (PRA) models?
g. What is the status of a control room simulator?
h. What are the plans for submittal of white papers, technical reports, and topical reports?
i. What is the status of first-of-a-kind components, including their design, qualification, and testability in accordance with NRC regulations?
j. What is the status of interactions with other agencies from which permits or authorizations will be required?
k. What is the status of environmental studies necessary to support preparation of the environmental report?
l. What is the status of the development of emergency plans both onsite and offsite?
m. What exemptions, site-specific data collections or other long lead time issues are expected?

Regulatory Engagement Plans for Non-LWR Applicants and Implications for LWR Applicants

Pre-application activities for non-LWRs are described in NRC's document entitled "A Regulatory Review Roadmap for Non-Light Water Reactors," dated December, 2017 (Ref. 5153). The roadmap builds on recent experience with LWRs and past experience with non-LWRs to help non-LWR developers prepare REPs. Though recommended, development of an REP for non-LWR is optional. Though the roadmap and the concept of REPs were designed to support interactions with non-LWR developers, the approach is relevant for preapplication activities related to LWR technologies and interactions similar to those of an REP can facilitate the development of a shared understanding of the review process. Of particular relevance to LWR applicants, Sections 5 and 6 of the roadmap describe flexible regulatory review processes applicable to early phases of development characteristic of non-LWR reactor technologies as well as later stages of application preparation more characteristic of LWR reactor technologies.

Section 5 of the roadmap includes a description of possible outcomes from regulatory interactions such as information exchange, initial feedback, conditional staff findings, conclusive NRC staff findings and final agency position. An applicant's understanding of the range of results from interactions is important to ensure that the NRC staff and the applicant have the same understanding of the desired outcome of each interaction that will affect schedules and review costs. Section 5 of the roadmap additionally describes licensing, certification and approval options for applicants including options not covered in this RG such as standard design approvals issued under 10 CFR Part 52, Subpart E, which can provide incremental progress towards licensing or certification in what can be referred to as a staged-licensing process, as well as construction permits and operating licenses issued under 10 CFR Part 50.

An REP, as presented in section 6 of the roadmap, describes a potential applicant's plan to engage with the NRC during the development and review of an application for a license, certification, or approval. The development of the REP will include interactions with the NRC staff to reach mutual agreement on the desired outcomes or defined interactions and estimated costs and schedules for defined reviews. The plans and related discussions should identify the expected meetings, correspondence, and submittal of documents for review and issuance of NRC staff findings or final agency positions. The development of a REP should address expected outcomes, priorities, resources, and schedules. Routine interactions between the applicant and the NRC staff should ensure the goals of the review and licensing plans are being met, monitor the costs and schedules, and identify and implement appropriate changes to the plans. The plans will need to reflect the resource and schedule limitations facing both NRC staff and applicants and appropriately prioritize expected outcomes.

Enhanced Safety-Focused Review Approach

In order to enhance the effectiveness and efficiency of reviews, staff developed the ESFRA, which was first implemented in the review of the NuScale SMR DC application "NuScale Power, LLC Submittal of the NuScale Standard Plant Design Certification Application (NRC Project No. 0769)," December 31, 2016 (Ref. 5254). ESFRA is a collection of tools and strategies designed to help NRC staff optimize the scope and depth of their review. One of the ESFRA tools is the SSC review tool, which was described in SECY-17-0112, November 13, 2017, "Plans for Increasing Staff Capabilities to Use Risk Information in Decision-Making Activities" (Ref. 5355) and its development and use were discussed in various presentations or briefings to the ACRS, the Commission and at various other conferences.

As discussed in Section C.2.17 of this guidance, SRP Introduction - Part 2 describes the framework for categorizing an SSC or its function(s) into four safety-significance categories. These categories are A1 (safety-related and risk significant), B1 (nonsafety-related and risk significant), A2 (safety-related and not risk significant), and B2 (nonsafety-related and not risk significant), that correlate to the safety classification and risk significance of the SSC under review. Using a graded approach, the staff applies the most rigorous review techniques to SSCs with the highest safety significance (analogous to the typical review process using the SRP), and a progressively less-detailed review to other SSCs as the assigned safety-significance declines. The SSC review tool includes considerations beyond SRP Introduction - Part 2 regarding how to further implement the graded approach, such as novel design, regulatory compliance issues, risk insights, relationship to defense-in-depth, and relationship to safety margins. An example of the implementation of staff's ESFRA SSC tool is recorded in the transcripts of the May 3, 2017, meeting of the NuScale Subcommittee of the ACRS (Ref. 546). The transcript includes presentation slides and discussion as well as detailed tables that categorize SSC review topics for either "review emphasis" or "reduced effort reviews." While the SSC review tool is focused on categorization and review planning for SSC, other ESFRA tools are designed to be used on non-SSC and programmatic review areas.

While ESFRA is a staff activity, in order for it to be most effective, the staff engages with the applicant during preapplication, including auditing the PRA to gather risk insights. An applicant's willingness to share SSC categorization and other risk insights is crucial for staff to initiate ESFRA.

Meetings

The prospective applicant should request an initial meeting with the NRC staff early in the application planning process and should continue to initiate and/or support appropriate subsequent meetings. The meetings (depending on the purpose, scope, and subject matter) may or may not include attendance by external stakeholders and the public (i.e., public or nonpublic), and the NRC staff's participation may or may not include a fee billable to the prospective applicant.

Introductory Meetings

Typically, the initial meeting is introductory in nature and intended to provide overview information to the NRC staff. Topics include the prospective applicant's business structure, reactor design features, siting considerations, preliminary application plans/schedules, and potential regulatory issues. For example, the initial meeting may be a planning/scheduling "drop-in" meeting. The prospective applicant's management requests the opportunity for a "drop in" with NRC management to share information on its design and application intentions. The meeting is limited to a general exchange of information that is not directly related to any regulatory action or decision. The meeting is not a public meeting and is not billable to the prospective applicant. The initial meeting may also include information of increased detail with greater certainty regarding the design and

application intentions.

Subsequent Meetings

Typically, after the initial introductory-type meetings, the prospective applicant and the NRC staff agree to engage in follow-on preapplication activities intended to result in the submittal of an application. At this time, the staff establishes a project designation for the prospective applicant that initiates the agency's administrative and business process (e.g., correspondence control or fee-billable account) for subsequent preapplication activities. The NRC staff's participation in subsequent activities specifically in support of the prospective applicant is billable to the prospective applicant.

The needs of the prospective applicant primarily determine the purpose, subject matter, and frequency of subsequent meetings as the application is developed and prepared for submittal as well as the level of documentation or desired outcome using interactions similar to the REPs discussed in this regulatory topic. Topics include, for example, application-specific approaches for resolution of generic regulatory issues and application-specific submittal issues. The meetings typically address, in an increasing level of detail, application-specific regulatory and technical issues and the prospective applicant's plans and schedules. Whenever practicable, the meetings include participation by external stakeholders and the public.

In addition to meetings initiated by the prospective applicant, the prospective applicant should support NRC-requested meetings. Though strongly recommended, additional meetings requested by the NRC staff are at the discretion of the pre-applicant. The NRC staff may find the conduct of meetings appropriate in support of its preparations for the acceptance and technical review of the anticipated application. Such meeting requests would typically be based on the staff's need for clarification of certain application-specific information (e.g., proposed resolution of generic regulatory or technical issues, revised application plans or schedules, first-of-a-kind components, and proprietary or security-related information issues).

Documents

During the preapplication timeframe, the prospective applicant should determine both the type of documents and the schedule for their submittal to the NRC staff as well as the level of feedback documentation or desired outcome and schedule related to NRC staff reviews using interactions similar to the REPs discussed in this regulatory topic. Preapplication documents vary in both purpose and formality, and they may or may not be made publicly available. For example, under 10 CFR 2.390, a prospective applicant may request that its preliminary application plans and schedules, intended to inform the NRC staff, that include proprietary information (including trade secrets and privileged or confidential commercial or financial information) be withheld from public availability. Alternatively, a topical report that addresses the approach for regulatory resolution of design technical issues and that is submitted for formal staff review and preparation of a SE report by the staff would be fee billable and would likely be made publicly available.

This section of this guidance provides detailed information on three types of formal documents (topical reports, technical reports, and white papers) that the prospective applicant may author and submit for staff consideration in addition to formal letters and the application itself. Less formal documents may include letters, schedules, and other documents relevant to the planned application submission and review.

The intended purpose of these documents is to address application-related regulatory or technical issues, or both. As determined by the prospective applicant, the documents may be submitted during the preapplication timeframe, in parallel with, and/or subsequent to application submittal.

Topical Reports

A prospective applicant may, at its option, submit topical reports for the NRC staff's review. The NRC sponsors a topical report program to increase the efficiency of the licensing process and reduce the burden on applicants and licensees. Details of the program, including NRC requirements and the administrative process, are available on the NRC Web site at http://www.nrc.gov/about-nrc/regulatory/licensing/topical-reports.html.

A topical report addresses a technical topic related to nuclear plant safety that may apply to multiple applicants or licensees. For example, a topical report may address the quality assurance program, instrument set point methodology, or severe accident evaluation for the DC. Submittal of a topical report allows for a single review by the NRC staff and, if appropriate, approval of a safety-related topic, thereby increasing the efficiency of the licensing process by minimizing the time and resources that both industry and the NRC staff could expend on serial reviews of the same topic in multiple applications. The schedule for the staff's review depends on the scope and complexity of the topical report. The staff typically documents and publishes its evaluation in a topic-specific SE report.

Applicants may incorporate by reference into an application topical reports for which a topic-specific SE report has been published. Topic-specific reports include nonproprietary topical reports, nonproprietary versions of proprietary topical reports, and nonproprietary correspondence about the review of topical reports are made publicly available.

A topical report should meet all of the following criteria:

a. It addresses a specific safety-related subject that requires a safety assessment by the NRC staff that can be evaluated independently of a specific license application.
b. It can be referenced by multiple applicants and licensees or is expected to improve regulatory efficiency for new reactors or novel designs by addressing singular but critical technical issues.
c. It contains complete and detailed information on the specific subject presented.

Use of the NRC-approved topical report will increase the efficiency of the review process for those applications referencing the report.

Technical Reports

A prospective applicant may, at its option, submit technical reports for the NRC staff's review in advance of the application submittal and may submit technical reports in parallel with or subsequent to the application submittal. Technical reports address application-specific technical safety topics and are generally intended to support and augment information contained in the application, typically the FSAR. Technical reports may contain a level of detail (e.g., test data) beyond that considered appropriate for inclusion in the application and may be incorporated by reference into the application to support its completeness. For example, a technical report may include design-specific features to address a regulatory issue, the safety/security interface, or may address the design-specific vibration assessment program. A technical report may be used for sections of the application that contain proprietary information.

The NRC staff will typically review technical reports submitted by a prospective applicant as part of the preapplication process. The staff may issue RAIs, but typically does not publish issue-specific SE reports; instead, the staff will incorporate the technical reports and its associated evaluation into the overall review/evaluation of the application. The applicant should discuss the level of feedback documentation (e.g. a letter, public meeting summary, or SE) or desired outcome and schedule related to NRC staff reviews of technical reports to ensure mutual understanding of expectations using interactions similar to the REPs discussed in this regulatory topic. Similarly, the NRC staff will review technical reports submitted in parallel with or subsequent to the application as part of the overall review/evaluation of the application. Section C.2.6 discusses the incorporation by reference of reports in applications.

White Papers

A prospective applicant may, at its option, submit white papers in advance of the application submittal. White papers can be, for example, publicly available information reports that address application-specific regulatory and/or technical issues and may document a prospective applicant's proposed position on a regulatory issue. The intent of white papers is to provide explanatory information to enhance the understanding of the NRC staff; for this reason, they are not formally incorporated into the 10 CFR Part 52 application. For example, a white paper may address: (1) a proposed alternative for compliance with a requirement that is not considered applicable because of the innovative features of the design, (2) an approach for risk-informing plant systems/components, (3) an approach for using a PRA to enhance the design, (4) a methodology for a design-specific EP zone, or (5) the prospective applicant's perspective on the industry's position on a generic regulatory issue (e.g., a Nuclear Energy Institute (NEI) template).

The NRC staff will typically review white papers only for familiarization and enhanced understanding. To support this review, the staff may informally request clarification or supplemental information, or both. Depending on the paper content, the staff may perform a formal review and evaluation of white papers, however, this is not typical and the staff will generally not issue formal RAIs or perform a formal review or evaluation of white papers. The applicant should discuss the level of feedback documentation or desired outcome and schedule related to NRC staff reviews of white papers to ensure mutual understanding of expectations using interactions similar to the REPs discussed in this regulatory topic.

Safety and Environmental Issues

The NRC's application acceptance review and detailed technical review focus on the regulatory issues pertaining to safety and the environment. The prospective applicant should ensure that preapplication activities encompass the identification and proposed resolution of issues necessary to support an effective and efficient safety review and environmental review.

As development of the application progresses, the prospective applicant should take steps to address application-specific safety and environmental issues. For example, the prospective applicant may discuss the potential resolution of issues in meetings with the NRC staff and, subsequently, document the proposed resolution in a technical report. The NRC staff will seek information at a level of detail commensurate with significance, to support its required safety and environmental findings on issues such as the following:

a. proposed exemptions from the regulations;
b. innovative and/or advanced reactor design features;
c. for a COLA referencing a DC:

(1) potential departures from the certified design and
(2) plans to address COL action/information items;

d. for a COLA referencing an ESP:
(1) potential variances from the ESP and
(2) plans for addressing COL action items and conditions in the permit;

e. a quality assurance program;

f. a PRA; and

g. a reliability assurance program.

Environmental Preapplication Activities

Prospective COL and ESP applicants are encouraged to participate in environmental preapplication activities to ensure the NRC staff's effective and timely review of the application's ER. It is recommended that the prospective applicant and the staff begin discussions on environmental preapplication activities soon after completion of the introductory meetings. A site tour and discussions on design features that will directly affect environmental resources such as rivers, wetlands, terrestrial and aquatic habitats, threatened or endangered species, and ground water should be completed early in the preapplication process. Though strongly recommended, a site tour is at the discretion of the pre-applicant and may be deferred until after submission of the application. Numerous environmental guidance documents that are available on the NRC public Web site address information that must be included in the ER.

The NRC staff will seek information, in sufficient detail, to support the required environmental findings on issues such as the following:

a. historical site information for land use, ecology, cultural/historic resources, hydrology, hydrogeology, geology, meteorology, and socioeconomic data;

b. site-specific information needed for the environmental review;

c. alternative site-selection process and narrowing of the selection of the alternative sites and the proposed site;

d. information on the applicant's monitoring plans, such as 1 year of aquatic ecology surveys in waterways adjacent to the site;

e. preapplication interactions with other State and Federal agencies; and

f. information on socioeconomics characteristics of the site and surrounding area, cultural/historic resources, hydrology and geohydrology, aquatic and terrestrial threatened and endangered species, meteorology, and other resource areas.

The applicant's response to NRC staff preapplication environmental review requests is up to the discretion of the pre-applicant. The pre-applicant is not required to submit information in advance of the submission of the application.

For prospective COL and ESP applicants, the NRC typically will request that the U.S. Army Corps of Engineers (USACE) be a cooperating agency in the preparation of the EIS for the application. For construction activities detailed in COL and ESP applications, USACE develops an EIS for the issuance of licenses that cover those construction activities in U.S. jurisdictional waters. To be cost effective, the NRC and USACE work together on the NRC's EIS, and USACE adopts the EIS for its action. The prospective applicant should brief USACE on its planned activities so that USACE can begin its work planning and funding activities. Additionally, the NRC staff will brief other Federal, State, and local government agencies, as well as appropriate tribal authorities (if applicable) on the agency's scope and schedule for the license application no later than 1 year before submission of the application. It is recommended that the prospective applicant brief these Federal, State, and local

agencies and tribal authorities (if applicable) before the NRC does because the prospective applicant is more knowledgeable about the site and the surrounding environs, the reactor design, and the application schedule. NEI 10-7 "Industry Guidelines for Effective Pre-Application Interactions with Agencies Other Than the U.S. Nuclear Regulatory Commission during the Early Site Permit Process" (Ref. 557) provides guidance for applicants to engage other Federal and State agencies early in the process which was endorsed by NRC.

The NRC staff may request a tour of the proposed site and proposed alternative sites and the opportunity to review nearly completed sections of the ER. The tours and meetings may begin as early as 2 years before submission of the application in order to support timelines for any data collection surveys as well as coordination regarding other State and Federal requirements. Other Federal, State, and local government agencies that have a regulatory or enforcement interest in the project may attend some or all of these tours and meetings. The prospective applicant would benefit from maintaining open communications with all Government entities that may have an interest and/or regulatory responsibility associated with the project.

NRC Information Requests—Regulatory Issue Summaries

To support the agency's process for planning, budgeting, and resource allocations, the NRC requests that prospective applicants provide application-related planning and scheduling information commencing approximately 3 years before the intended application submittal date. As a Federal agency, the NRC must prepare its budget, which includes plans for application reviews and associated resource estimates, several years in advance. To support this effort, the NRC seeks planning information on, for example, the intended use of topical reports to resolve regulatory issues, the schedules for application submittals, and preliminary technical designs. The NRC issues updated information requests annually in the form of a Regulatory Issues Summary (RIS) (e.g., RIS 2017-08, "Process for Scheduling and Allocating Resources for Fiscal Years 2020 through 2022 for the Review of New Licensing Applications for Light-Water Reactors and Non-Light-Water Reactors," dated December 21, 2017 (Ref. 568). Prospective applicants should respond to these information requests.

In addition to application plan/schedule information, the NRC is especially interested in the extent of standardization related to the application. The NRC promotes the standardization of applications to enhance the safety and reliability of nuclear power plants and facilitate a predictable and consistent method for application review. The agency's design-centered review approach (DCRA) is a strategy based on industry standardization of COLAs referencing a particular reactor design. When such standardization is achieved, the NRC staff intends to conduct one technical review for each reactor design issue and use this one decision to support its decision on the DC application and on multiple COLAs. NRC's RIS 2006-06, "New Reactor Standardization Needed to Support the Design-Centered Licensing Review Approach," dated May 31, 2006 (Ref. 579), initially addressed the DCRA strategy, which continues to be a subject of the annual RIS information requests.

C.2.2 Pre-application Readiness Assessment

OVERVIEW

The voluntary preapplication readiness assessment is intended to inform and benefit both the prospective applicant and the staff. The NRC staff anticipates conducting an assessment of each prospective applicant's readiness to tender an application under 10 CFR Part 52 for a COL, DC, or ESP approximately 6 months before the planned submittal date. Although a readiness assessment is voluntary, the report entitled, "New Reactor Licensing Process Lessons Learned Report: 10 CFR Part 52," issued April 2013 (Ref. 5860), identified it as one of the means of enhancing the

quality of applications. The NRC staff highly recommends a readiness assessment for each prospective applicant. Applicants should discuss with the NRC any activities they wish to have included in the preapplication readiness assessment, including the schedule, level of documentation or desired outcome using interactions similar to the REPs discussed in Section C.2.1 of this guidance.

The readiness assessment allows the NRC staff to: (1) identify information gaps between the draft application and the technical content that should be included in the application submitted to the agency, (2) identify major technical or policy issues that may adversely impact the acceptance or technical review of the application, and (3) become familiar with the application, particularly in areas involving proposed new concepts or novel design features.

The readiness assessment allows the prospective applicant an opportunity to interface directly with the NRC staff on application-specific regulatory and technical issues and gain a better understanding of NRC requirements and guidance. For example, the prospective applicant may: (1) discuss a planned request for an exemption from the regulations, (2) discuss potential departures from the certified design, (3) better understand the need for a variance from the ESP, (4) discuss the significance of a site-specific environmental issue, (5) better understand the necessary coordination between the NRC as the lead Federal agency and cooperating Federal agencies, and/or (6) develop an effective approach for facilitating cooperation between State and Federal agencies involved in the review.

The assessment results: (1) inform the prospective applicant in finalizing the application and (2) support the NRC's process for planning and budgeting and for allocating resources by providing the staff with better clarity on the application's content and schedule. The assessment does not provide regulatory determinations nor any guidance to the prospective applicant. The NRC staff documents the assessment results in a report that is issued to the prospective applicant and made publicly available though the meetings and detailed materials shared at meetings is not made public.

GUIDANCE

Each prospective applicant should support the NRC staff's planning, preparations, and conduct of the preapplication readiness assessment. The staff will plan and schedule the readiness assessment in coordination with, and consistent with, the application development schedule of the prospective applicant.

The staff typically engages with prospective applicants to conduct the assessment at least 6 months before the planned application submittal date. The staff coordinates both the schedule and scope of the assessment with the prospective applicant. Ideally, the scope of the assessment should include the overall application. Alternatively, the assessment scope may be limited to selected parts of the application such as those topics identified as challenging areas in prior application reviews (e.g., instrumentation and controls (I&Cs), seismic analysis, long-term cooling, and human factors engineering (HFE)). The prospective applicant should support the staff's assessment preparations (e.g., availability of appropriate documentation) and the conduct of the assessment (e.g., availability of appropriate personnel and subject matter experts). Further, the prospective applicant should support, as requested, the staff's preparation of the assessment report to ensure the report's accuracy and clarity.

The prospective applicant should consider the results of the readiness assessment while finalizing the application and should reevaluate, as appropriate, the application submittal date based on the time required to address the readiness assessment observations. Prospective applicants should be aware that although not part of the NRC acceptance review, the NRC uses results from the readiness assessment to focus on identified topics, evaluate if changes have been made to specific sections of the

application, and confirm the identified topics from the readiness assessment have been adequately addressed for purposes of the acceptance review. The readiness assessment does not predetermine whether the application will be accepted and docketed.

~~NRO-REG-104~~LIC-116 "Pre-application Readiness Assessment"

The ~~NRC's Office of New Reactors (NRO)~~NRR Office Instruction ~~NRO-REG-104~~LIC-116, "Pre-Application Readiness Assessment," Revision 0, dated ~~October 8, 2014~~August 3, 2020 (Ref. 59~~61~~), [GD16][EM17]provides detailed guidance to the staff in preparing and conducting preapplication readiness assessments for ESP and DC applications and COLAs. Although it was developed for use by the staff, this publicly available document is a resource that gives: (1) all stakeholders a general understanding of the preapplication readiness assessment process and (2) applicants a detailed understanding of the staff's preapplication readiness assessment activities and schedule and the staff's expectations of applicants.

C.2.3 Application Electronic Submittal

OVERVIEW

An applicant for a COL, DC, or ESP should submit all correspondence, reports, applications, and other written communications to the NRC in accordance with the provisions of 10 CFR Part 52.3. Where practicable, the communications should be submitted electronically in a manner that enables the NRC to receive, read, authenticate, distribute, and archive the submission and to process and retrieve it a single page at a time.

GUIDANCE

The NRC provides specific guidance on acceptable procedures for electronic submissions on its public Web site at http://www.nrc.gov/site-help/e-submittals.html. Users new to the process should select the "getting started" link to http://www.nrc.gov/site-help/e-submittals/getting-started.html and access the "reference materials for electronic submissions" link at http://www.nrc.gov/site-help/electronic-sub-ref-mat.html. The "reference materials for electronic submissions" link also provides a link to the current version of the primary guidance document entitled, "Guidance for Electronic Submissions to the NRC." The NRC staff plans to update the guidance periodically to reflect changes in technology and agency experience and post the latest version of the document. Applicants should use the most recent processes and guidance when submitting documents in electronic format. The presentation from the public meeting entitled, "Electronic Document Submittal Process," March 18, 2014 (Ref. 60~~62~~) is also a useful reference.

In accordance with the provisions of 10 CFR Part 52.3, all correspondence, reports, applications, and other written communications from an applicant, licensee, or holder of a standard design approval to the NRC concerning regulations, individual license conditions, or the terms and conditions of an ESP or standard design approval must be sent either by mail to the NRC's Document Control Desk, by hand delivery to the NRC office, or electronic submission where practicable (e.g., CD-ROM). Table 3 summarizes the distribution requirements for specific correspondence, given in 10 CFR 52.3(b).

Table 3. Submission of Documentation under 10 CFR 52.3

TYPE OF SUBMISSION	ADDRESSEES AND COPIES (CD-ROM OR PAPER)	REGULATION(S)
Application for amendments of permits and licenses, reports,	NRC Document Control Desk (if on paper, include signed original) 1 copy to the appropriate regional office	10 CFR 52.3(b)(1) and 10 CFR 50.30

TYPE OF SUBMISSION	ADDRESSEES AND COPIES (CD-ROM OR PAPER)	REGULATION(S)
and other communications	1 copy to the resident inspector, if applicable (to be provided under oath or affirmation)	
Application and amendment to application	NRC Document Control Desk (if on paper, include signed original) 1 copy to the appropriate regional office 1 copy to the resident inspector, if applicable (to be provided under oath or affirmation)	10 CFR 52.3(b)(2) and 10 CFR 50.30
Acceptance review application	NRC Document Control Desk (if on paper, include signed original) 1 copy to the appropriate regional office	10 CFR 52.3(b)(3)
Security plan and related submissions	NRC Document Control Desk (if on paper, include signed original) 1 copy to the appropriate regional office	10 CFR 52.3(b)(4)
Emergency plan and related submissions	NRC Document Control Desk (if on paper, include signed original) 1 copy to the appropriate regional office 1 copy to the resident inspector, if applicable	10 CFR 52.3(b)(5)
Updated FSAR	NRC Document Control Desk (if on paper, include signed original) 1 copy to the appropriate regional office 1 copy to the resident inspector, if applicable	10 CFR 52.3(b)(6)
QA-related submissions	NRC Document Control Desk (if on paper, include signed original) 1 copy to the appropriate regional office 1 copy to the resident inspector, if applicable	10 CFR 52.3(b)(7), 10 CFR 50.54(a)(3), or 10 CFR 50.55(f)(3)
Certification of permanent cessation of operations	NRC Document Control Desk (to be provided under oath or affirmation)	10 CFR 52.3(b)(8)
Certification of permanent fuel removal	NRC Document Control Desk (to be provided under oath or affirmation)	10 CFR 52.3(b)(9)

Referencing a Design Certification Rule or Early Site Permit

The COL applicant that incorporates a DC by reference includes the DC FSAR or the plant-specific DCD under Appendices A through E of 10 CFR Part 52 in its FSAR in accordance with the applicable DCR. The plant-specific DCD, as defined in Section II.C of 10 CFR Part 52 Appendices A through E consists of the information in the generic DCD, as modified and supplemented by the plant-specific departures and exemptions. However, in accordance with 10 CFR 52.79(d)(1), the plant-specific DCD portion of the COL applicant's FSAR incorporates by reference the generic DCD. Any incorporation by reference should be clear and should specify the section number(s) containing the

relevant information to be incorporated by reference. To facilitate the NRC staff's review and support features such as hyperlinks between electronic files, the applicant should identify the actual generic DCD, which is complete and is current to the revision referenced in the COLA, as a reference document when an electronic medium is used for the COLA. When an application includes hyperlinks to the DCD and other reference documents, these files should be the files within the Agencywide Documents Access and Management System (ADAMS). The ADAMS links will not be automatically updated when the ADAMS file is superseded by a newer version; therefore, the applicant would need to resubmit all files that would be impacted with updated links to the newer version. Likewise, a COLA may incorporate by reference documents related to an ESP, and the electronic applications may include hyperlinks to the ESP references in ADAMS.

COL applicants should facilitate the NRC's review of COLAs that incorporate a DC by reference. For example, the applicant should integrate the plant-specific DCD into the FSAR included in the COLA by inserting the information from the generic DCD into the FSAR or, for electronic submittals, by providing hyperlinks from the COLA to the appropriate section of the generic DCD. Regardless of the approach selected the applicant should clearly distinguish information quoted directly from the generic DCD from the plant-specific departures and exemptions to the generic DCD that the NRC will review in the COLA. In addition, site-specific information and operational programs should also be distinguished from information in the generic DCD. Applicants should clearly identify the information in the application and the FSAR in terms of its role in addressing COL action items, proposed departures or variances, replacement of conceptual design information, and supplemental information provided in a generic DCD or ESP. Applicants should identify information that is specific to the subject application and information that is referencing or will be referenced by another COLA (e.g., reference or standard information).

The staff anticipates that, as described in 10 CFR 52.55(c), some COLAs will reference a design for which a DC application has been docketed but not granted. Such COLAs may use the above guidance to incorporate by reference the DC application's FSAR under review by the NRC and clearly indicate relevant departures, COL action items, and other information that correlates the application to the proposed design. The NRC staff, DC applicant, and COL applicant need to closely coordinate their activities related to the reviews of the proposed design and COLAs. In some cases, it may be appropriate for a COL applicant to submit revisions to major COL documents (e.g., the FSAR) to reflect intermediate revisions to the DC application's FSAR. The COL applicant should submit a letter following each revision to the referenced DC application's FSAR to supplement the COLA and acknowledge the related activities in the design review. In all cases, the COL applicant should submit a revision to its application, including the FSAR and other affected documents, upon the completion of the NRC's review and certification of the referenced design.

The staff additionally anticipates that some COLAs may incorporate a DC by reference that has been renewed. Guidance relevant to incorporating a DC by reference applies and the plant-specific DCD portion of the COL applicant's FSAR incorporates by reference the generic DCD for the renewed DC. The existence of a renewed DC does not preclude a COL applicant from incorporating the original DC by reference if it has not yet expired. Similarly, a COLA may reference a design for which an application for renewal has been docketed and is pending while under review, as described in 10 CFR 52.57, "Application for Renewal." The NRC staff, DC renewal applicant, and COL applicant need to closely coordinate their activities related to the reviews of the proposed design and COLAs.

The agency expects some COLAs to reference DCRs for which an amendment to the applicable DC has been requested but not yet granted by the NRC. The COL applicant has the following three options in such cases, and its decision on which option to choose will depend on the specific circumstances related to the DCR and COLAs:

a. The COLAs may be prepared based on the expected outcome of the rulemaking related to the proposed changes to the generic DCD under review by the NRC. This approach is similar to the above approach for cases involving a new DC application.
b. The COLAs may be prepared independent from the petition to amend the DCR. The outcome of the rulemaking could then be addressed by a revision to the COLA or as otherwise required by the provisions of change processes related to maintaining the relationship between generic and plant-specific DCDs.
c. COLAs may include, within the identified departures from the existing DCR, those changes related to the requested amendment to the DCR. The report addressing departures from the certified design may refer to the request for an amendment to the certified design. In this way, the COLA may then incorporate by reference the DCD under review by the NRC. Within the FSAR and other parts of the application, the COL applicant may correlate the proposed departures, COL action items, and other information to the version of generic DCD under review by the NRC.

As mentioned above, there are several ways to handle the coordination of activities related to the reviews of the DCD and COLAs. The COL applicant should submit a revision to its application, including the FSAR and other affected documents, upon issuance by the NRC of its decision on the request to amend the referenced DC.

Revised or Additional Information

During the application review process, the applicant may submit revisions of applications, or portions thereof, as the review progresses. The guidance on electronic submissions includes information explaining the process used to submit changes to electronic documents. Applicants should submit a complete revised document (e.g., an FSAR) even if only a portion of the document has been revised. If the revised document includes hyperlinks to other documents within the application and those documents are not being revised (e.g., a revised FSAR with hyperlinks to the same generic DCD), the referenced documents may be identified as reference documents on the CD-ROM or DVD and are not to be entered as new records into ADAMS (even if the CD-ROM or DVD includes the reference documents). The updated version of a document should include a list of changes from the previous version. Each page should include a change indicator (e.g., a bold vertical line at the margin adjacent to the portion of the text that has been changed) and a page change identification, including either the date of change or revision number, or both. Alternative means may be acceptable when designating changes to drawings and pictures.

The licensing process will likely involve general correspondence, responses to RAIs, and other submittals. The agency expects that the supplemental submittals will involve a combination of electronic information exchange, additional CDs or DVDs, and paper correspondence. Applicants should ensure that these various submittals are addressed and submitted in accordance with 10 CFR 52.3. These should also include the docket number and subject, and applicants should ensure that copies are provided to the NRC project manager.

C.2.4 Application Acceptance Review

OVERVIEW

The regulations in 10 CFR Part 2, prescribe the requirements for applicants to file COLAs and ESP and DC applications and for NRC staff to determine whether a filed application is complete and acceptable for docketing. Applicants file COLAs and ESP applications in accordance with 10 CFR 2.101,

"Filing of Application," and DC applications in accordance with 10 CFR 2.811, "Filing of Standard Design Certification Application; Required Copies." Under 10 CFR 2.101 for COLs and ESPs and 10 CFR 2.815, "Docketing and Acceptance Review," for DCs, the NRC staff determines whether a tendered application is acceptable for docketing.

The acceptance review process is the means by which the staff determines the acceptability of an application. Consistent with Commission direction, provided in Staff Requirements Memorandum for COMDEK 07 0001/COMJSM-07-0001, "Report of the Combined License Review Task Force," dated June 22, 2007 (Ref. 6163), the staff determines the acceptability of an application based on its completeness and technical sufficiency within a period of 60 days. The completeness review ensures that the applicant has submitted the information required by applicable requirements, and the technical sufficiency review ensures that the application contains sufficient information in scope and level of detail for the staff to conduct its detailed technical review within a predictable timeframe. The goal is to determine with a high level of certainty that the staff can complete the detailed technical review within a predictable timeframe.

Although not part of the acceptance review, preapplication interactions between the applicant and the NRC staff before submittal of the application and the results of the preapplication readiness assessment support a more effective and efficient acceptance review. The NRC staff's familiarity with the applicant's approach to technical and regulatory issues and proposed new methodologies and/or innovative design features, before submittal of the application, enhances its capabilities to evaluate both the application's completeness and its technical sufficiency. Section C.2.1 provides guidance on preapplication interactions.

~~NRO-REG-100~~LIC-117, "Acceptance Review Process for New Nuclear Facility Licensing Applications~~Acceptance Review Process for Early Site Permit, Design Certification, and Combined License Applications~~"

~~NRO-~~NRR Office Instruction ~~NRO-REG-100~~LIC-117, "Acceptance Review Process for New Nuclear Facility Licensing Applications~~Acceptance Review Process for Early Site Permit, Design Certification, and Combined License Applications~~," Revision 2, dated ~~December 18, 2014~~January 28, 2021 [GD18](Ref. 6264), provides detailed guidance to the staff in preparing and conducting acceptance reviews for ESP and DC applications and COLAs. Although it was developed for use by the staff, this publicly available document is a resource that gives: (1) all stakeholders a general understanding of the acceptance review process and (2) applicants a detailed understanding of the staff's acceptance review activities and schedule, the staff's expectations of applicants, and the docketing decision process.

GUIDANCE

Acceptance Review Process

The applicant should be familiar with the overall acceptance review process and the staff's approach for implementation of the process as documented in ~~NRO-REG-100~~LIC-117. In addition, as discussed in ~~NRO-REG-100~~LIC-117,[GD19] the applicant should anticipate interactions with the staff throughout the acceptance review process that include both oral and written communications and the potential need for submittal of documentation supplemental to the initial application.

Further, the applicant should be aware that the initial steps of the acceptance review process include the staff's actions to: (1) ensure the application adheres to the agency's guidelines for electronic submittal and (2) make the application publicly available (less withheld information). Section C.1.9 and

Section C.2.3 provide guidance on withheld information and the electronic submittal, respectively, of an application.

Completeness and Sufficiency

The applicant should understand that the acceptance review, although encompassing the entire application, focuses on the SAR and the ER and comprises both a "completeness" element and a "sufficiency" element. As prescribed in ~~NRO-REG-100~~LIC-117, [GD20]the staff reviews and evaluates the application in terms of technical content identified in the SRP, DSRSs (if applicable), NUREG-1555, RG 4.2, and other application-related guidance. The staff will typically perform the acceptance review with the version of the SRP or DSRS, as applicable, in effect 6 months before the docket date of the application. [GD21]The staff performs the completeness portion of the review to verify that the application contains all the information required by applicable regulations. It completes the technical sufficiency portion to verify that the application contains sufficient technical information in scope and level of detail to conduct the detailed technical review of the application within a predicable timeframe.

During the review process, the applicant should understand that a key component of the staff's review is the identification of any technical deficiencies. ~~NRO-REG-100~~LIC-117 [GD22]defines a technical deficiency as missing, improper, inadequate, or incorrect technical information needed by the NRC staff to conduct the detailed technical review of the application. A minor technical deficiency is defined as missing, improper, inadequate, or incorrect technical information that a reasonable round of RAIs can address after the application is accepted for docketing without notably impacting the overall detailed technical review schedule (e.g., the applicant possesses the relevant information but omitted the information in the application). A significant technical deficiency is defined as missing information that does not allow the staff to evaluate detailed technical information against the acceptance criteria (e.g., the SRP) or to conduct its review within a predictable timeframe (e.g., the applicant neglected to perform a required analysis that is critical to the staff's understanding of a safety system).

Communication

The applicant should be prepared to respond to any staff-initiated communications in a timely and accurate manner and to proactively initiate communication with the staff when warranted. The NRC staff, consistent with the agency's "Effective Policy Issue #1: Transparency and Openness" (Ref. 6~~3~~5), initiates and maintains communication with the applicant throughout the acceptance review process. These communications typically include a combination of teleconferences, meetings, and formal correspondence. Communications concerning application issues and deficiencies provide the applicant an opportunity to address and potentially resolve the acceptability-related items before the staff makes a docketing decision.

Throughout the acceptance review process, the applicant should maintain an awareness of the staff's progress and acquire an understanding of any potential acceptance issues. The applicant should initiate communications with the staff as necessary to ensure a mutual understanding of potential issues and the appropriate path to resolution. When requested by the staff, the applicant should provide timely and substantive information to support the review and the docketing decision.

Results and Docketing Decision

As discussed in ~~NRO-REG-100~~LIC-117[GD23], the docketing decision has three possible outcomes: (1) the application is acceptable for docketing, (2) the application is not acceptable for docketing, or (3) the application is acceptable for docketing contingent on specific supplemental information.

Following the guidance in ~~NRO-REG-100~~LIC-117[GD24], the NRC staff compiles the acceptance review results in a manner to clearly identify the significant deficiencies that the staff needs to consider in the decision to docket the application. For areas in which significant deficiencies are identified, the staff communicates the findings with the applicant for specific technical areas and describes the nature of the deficiencies. The applicant is responsible for having a clear understanding of the deficiencies in the application identified by the staff and the capability to address these deficiencies within an acceptable timeframe.

If the application is acceptable for docketing, the NRC staff issues a letter of acceptance to the applicant followed by the staff's schedule for conducting the detailed technical review of the application. The applicant should support the staff's detailed technical review consistent with the agreed upon schedule.

If the application is acceptable for docketing contingent on specific supplemental information or is not accepted for docketing, the staff notifies the applicant and identifies the deficiencies and the applicant's options concerning the application. If the application is accepted with contingencies, the applicant should address the contingencies and submit supplemental information necessary to resolve the identified deficiencies. If the application is not accepted for docketing, the applicant may withdraw the application and resubmit it at a later date after it addresses the identified deficiencies.

C.2.5 Application Review and Requests for Additional Information

OVERVIEW

The NRC staff conducts detailed technical reviews of COLAs and ESP and DC applications subsequent to completion of the acceptance review process and docketing of the applications. Under 10 CFR 2.102, "Administrative Review of Application," the staff may require an applicant to supply additional information to support its review. Under 10 CFR 2.108, "Denial of Application for Failure To Supply Information," the NRC may deny an application if the applicant fails to respond to an RAI within 30 days of the date of the request or within such other time as may be agreed upon between the NRC staff and the applicant.

Consistent with the regulations, the NRC staff issues RAIs to acquire additional information from an applicant to determine the safety of the application design, operation, and siting and to address environmental issues. RAIs are issued to verify, supplement, or clarify information that is not available in the initial application submittal or other docketed correspondence or is not reasonably inferred from the information available to the staff. RAIs are intended to enable the NRC staff to obtain information needed to make a regulatory decision on an application. The RAI process allows for safety and environmental evaluations that are fully informed, technically correct, and legally defensible. RAIs may address varied regulatory and technical subject matter as needed to make regulatory decisions on the application.

The NRC staff employs a computer-based system and internal Web site to prepare, issue, process, and track RAIs. The computer-based system and internal Web site are not used for RAIs that contain sensitive information such as Safeguards Information, sensitive unclassified non-Safeguards Information, export control information, or critical electric infrastructure information but can be used for internal tracking of RAI that include such content. The NRC staff issues RAIs to applicants electronically in the form of e-mails and saves them as official records, publicly available, in the agency's recordkeeping system (ADAMS).

~~NRO-REG-101~~LIC-115, "Processing Requests for Additional Information"

~~NRO~~ NRR Office Instruction ~~NRO-REG-101~~LIC-115, "Processing Requests for Additional Information," Revision ~~2~~0, issued ~~August 2018~~November 6, 2019 [GD25](Ref. 6~~4~~6), provides comprehensive and detailed guidance to the staff on the RAI process, including the preparation and issuance of RAIs, communication and interactions with applicants regarding RAIs, evaluation of applicants' responses, resolution and closure of RAIs, and issuance and posting of RAI reports on the Web site. Although developed for use by the staff, this publicly available document is a resource that gives: (1) stakeholders a general understanding of the RAI process and (2) applicants a detailed understanding of the staff's RAI-related activities and schedule, the staff's communications with applicants and expectations of applicants, and the process for RAI closure and reporting.

GUIDANCE

The guidance herein correlates to the contents of ~~NRO-REG-101~~LIC-115 [GD26]and focuses on RAI-related information of importance to applicants. The intent of the guidance is to assist applicants in achieving a more efficient application review by enhancing their understanding and support of the NRC staff's review process.

Application Review and RAIs

The applicant should be familiar with the application review and RAI process. Further information about these can be found in ~~NRO-REG-101~~LIC-115[GD27]. The applicant should understand that, although the review and RAI process encompasses the entire application (e.g. ITAAC and quality assurance program description), it focuses on the SAR and the ER. The staff conducts a detailed review and evaluation against the acceptance criteria in the SRP, DSRSs (if applicable), the guidance in NUREG-1555, and other application-related guidance. The staff generates RAIs to acquire the information necessary to fill data gaps by addressing missing, incomplete, inconsistent, or unclear information in order to complete the evaluation and determine whether reasonable assurance of adequate protection of public health and safety exists. Often, the requested information is contained in reports that are cited in the application but not publically available (e.g., contractor reports). To enhance both the efficiency of the NRC staff's review and the transparency of the technical basis in the application, the applicant should consider providing NRC staff with copies of certain references cited in the application, but not readily available. Such courtesy copies are typically not considered part of the docketed application but may become Federal records. The applicant should be mindful of requirements and limitations on providing such copies, such as copyright restrictions.

The applicant should anticipate communications and interactions with the staff pertaining to RAIs throughout the application review to include both oral and written communications, participation in public meetings, and the potential need for revision of the application and submittal of documentation supplemental to the application. The applicant should be aware that RAIs and any substantive correspondence between the staff and applicant related to the RAIs are made publicly available unless they contain withheld information or Safeguards Information.

The applicant should understand that the RAI process is a structured, formal, and regulation-based process. Each RAI undergoes a multilevel review and approval sequence, and the applicant should expect to receive RAIs that are succinct, include a regulatory basis, and clearly identify the requested information (e.g., the methodology, equation, assumption, and other such information) and its significance. RAIs vary in scope, content, and level of technical detail depending on the issue being addressed; however, the applicant should anticipate that all RAIs address information needed for staff to either: 1) make a determination that the proposed activity is not inimical to the common defense and

security or to the health and safety of the public, 2) determine how the applicant meets the regulations, or 3) complete a safety finding that is clearly tied to a regulation. Information provided in an RAI will vary but typically includes: 1) a brief explanation of the relevant regulatory requirements, relevant guidance documents and/or SRP acceptance criteria, 2) a discussion of where the application does not meet the regulatory requirements, 3) identification of the safety, risk, or environmental significance, and 4) the type of information needed to complete the technical review. Where appropriate, the RAI will include specific examples of why the application does not meet the regulatory requirements (e.g., failure to meet a regulation) and what the staff expects the applicant to provide.

Communications

The applicant should understand that proactive communications and interactions with the NRC staff are key to an efficient application review. The applicant should expect the staff, as prescribed in ~~NRO-REG-101~~LIC-115[GD28], to initiate and maintain communications with the applicant throughout the review. The communications include a combination of teleconferences, e-mails, meetings, and formal correspondence. The applicant should be prepared to respond to staff-initiated communications in a timely manner with substantive and accurate information and to proactively initiate communication with the staff when warranted.

Throughout the application review, the applicant should maintain an awareness of the staff's progress and acquire a detailed understanding of any potential issues. When necessary, to ensure a mutual understanding of potential issues and the path to resolution, the applicant should initiate appropriate communication with the staff to support a timely and efficient review.

Project Manager

The applicant should understand that the safety project manager and the environmental project manager with lead responsibility for the review is its primary interface with the NRC staff. The applicant should expect the project manager (or designated alternate) to initiate and coordinate the review-related communications and interactions, including issuance and follow-up of RAIs, on behalf of the staff. Accordingly, the applicant should coordinate review-related telephone, electronic, and correspondence communications; meeting arrangements; and other staff interactions with the project manager. Questions related to an RAI (e.g., schedule, clarification information, or regulatory basis) should be directed to the project manager (or designated alternate) who will arrange for a public meeting if appropriate.

The applicant should confirm with the project manager the applicant's primary/alternate points of contact and contact information, and should reach an agreement on protocols related to RAIs. The applicant should verify the acceptability of its planned method for receipt of issued RAIs and the submittal of RAI responses and other review-related material.

Conference Calls

The applicant should understand that public conference calls are an element of the RAI process that is mutually beneficial and efficient for the staff and the applicant. For example, the staff may initiate public conference calls early in the application review to discuss review issues before generating RAIs; such public teleconferences provide the applicant with a general idea of what informational areas the staff considers deficient and with an opportunity for the applicant to address and potentially resolve the staff's issues. The applicant also may initiate public conference calls through the NRC project manager to proactively discuss a potential review issue. Public conference calls may include a portion the calls that is closed to the public to allow discussions of proprietary material or other sensitive material withheld from disclosure.

During the application review, the staff may initiate nonpublic conference calls, for example, to clarify impending RAI questions before issuance of the RAIs and/or to clarify the intent of issued RAIs. The applicant also may initiate nonpublic conference calls, for example, to ensure a clear understanding of RAI questions before submitting its responses to the RAIs. The technical aspects of the RAIs or possible responses to the RAIs may not be discussed during a nonpublic conference call. The NRC staff will document that the nonpublic conference call only involved clarification of the RAIs.

Meetings

The applicant should be prepared to participate in RAI-related public meetings throughout the application review. For example, the staff may request a public meeting if the staff determines that the information provided in a RAI response has not resolved the identified issue. At the public meeting, the staff and applicant would discuss the information in the RAI response and how the applicant would address supplemental response information. The applicant may volunteer to submit a supplement to the RAI response or may ask the staff to provide additional information that describes the specific information that it must submit.

The staff may request a public meeting early in the application review to give the applicant an opportunity to develop an understanding of the questions being developed by the staff and to begin work on the responses before the official RAI is issued.

Nonpublic meetings may be conducted to discuss proprietary material or other sensitive material withheld from disclosure. The staff will prepare a summary of these meetings that will be made publicly available.

Advance Requests for Additional Information

The applicant should understand that the staff, as provided in ~~NRO-REG-101~~LIC-115[GD29], will issue an Advance RAI (ARAI). Issuance of the ARAI starts the clock for the 30 day time-period. In general, an ARAI is an RAI that has received internal review and approval. Staff transmits the ARAI to the applicant and includes three specific questions regarding the presence of sensitive information in the ARAI, the expected response time to the ARAI, and whether a clarification phone call is needed. Once any applicant concerns have been addressed, the RAI can be generated in final form and all non-sensitive content is finalized in ADAMS and made public.

Issuance of Requests for Additional Information

The applicant should understand that the NRC staff uses e-mail as the vehicle to transmit RAIs that do not contain sensitive information to applicants. The project manager transmits RAIs in the form of letters or PDF files as attachments to e-mails. Accordingly, the applicant should coordinate with the project manager to ensure the applicant's capabilities for timely and accurate receipt of RAIs sent through e-mail.

The applicant should understand that it supports the timeliness of the review by providing answers to individual RAI questions as soon as it has prepared the answers and is reasonably confident of their accuracy. The applicant's response should be comprehensive and address any other technical aspects relevant to its response to the specific RAI request. The applicant should indicate the resolution of all applicable aspects identified by the specific RAI in its response. In coordination with the project manager, the applicant may transmit initial and partial RAI responses through e-mail.

When preparing an RAI response, the applicant should determine whether a revision to its SAR is necessary as part of the RAI response. If a revision is necessary, the applicant should provide a markup of the applicable pages along with the RAI response. The applicant should note that a revision is not always necessary if the RAI response simply clarifies information currently contained in the document. However, to the extent that the NRC staff is relying on the information to make its finding or that clarity is necessary to ensure that the licensing basis documents are clear, the applicant will need to modify the FSAR. Although there is no requirement for the applicant to revise its ER, it may decide that such a revision is prudent or practical if RAI responses indicate that significant changes in the report are necessary to prevent miscommunication.

The applicant should be aware of the availability of RAI-related information on the NRC's public Web site that may assist the applicant in understanding of the received RAIs and in preparing its responses. On the Web site, the NRC maintains publicly available information for each 10 CFR Part 52 application, including: (1) safety-related RAIs and the applicant's responses, (2) environmental-related RAIs and the applicant's responses, (3) the final safety evaluation report (FSER), and (4) the final EIS. The applicant may find it useful to review similar RAIs and the accepted responses from previous applications. In addition, the applicant may find value in reviewing the staff's SE reports or EISs prepared for previous applications.

The applicant should understand that formal RAI responses are typically required within 30 days of receipt of the ARAI and should coordinate any variations in the schedule with the project manager. The applicant should transmit its official RAI responses by mail to the NRC's Document Control Desk. The RAI responses are entered in ADAMS and are made publicly available unless, as noted by the applicant, they contain proprietary information, Safeguards Information, security related or other sensitive information.

Status and Resolution of Requests for Additional Information

The applicant should be familiar with the RAI status and tracking system and the RAI publicly available reports discussed in ~~NRO-REG-101~~LIC-115[GD30]. Throughout the application review, the applicant should maintain awareness of the status of each RAI and understand that "resolved-closed" is the status requisite for completion of the application review. The applicant should initiate communication with the safety project manager or environmental project manager, or both, to address questions concerning RAI status or the publicly available RAI report.

C.2.6 Combined License Application Referencing a Design Certification or Early Site Permit, or Both

OVERVIEW

A COLA may, as allowed by 10 CFR 52.73, "Relationship to Other Subparts," reference an ESP issued under Subpart A of 10 CFR Part 52 or a DC issued under Subpart B of 10 CFR Part 52. By referencing an ESP, the COL applicant acquires the established level of regulatory finality regarding the site as provided by 10 CFR 52.39. By referencing a DC by reference, the COL applicant acquires the established level of regulatory finality associated with the design as provided by 10 CFR 52.63.

COL applicants that reference both a DC and an ESP will have a significant portion of the facility reviewed by the NRC before applying for a COL. The remaining portions of the facility requiring safety and environmental reviews will constitute the information contained in the plant-specific FSAR and the ER. The guidance herein pertains to regulatory matters specific to a COL applicant by referencing a DC or ESP, or both.

In SRM SECY-90-377 (Ref. 657), the Commission endorsed a two-tiered certification scheme. ~~10 CFR Part 52, Appendices A through E, describes Tier 1 information as the portion of the design related information contained in the generic DCD that is approved and certified by the appropriate appendix and Tier 2 information as the portion of the design-related information contained in the generic DCD that is approved but not certified by the appropriate appendix.~~

Additionally, as defined in ~~10 CFR Part 52, Appendices A through E,~~§52.1, ~~state~~ ~~that~~ Tier 1 information include~~s~~~~s~~:

1. Definitions and general provisions;
2. Design descriptions;
3. Inspections, tests, analyses, and acceptance criteria (ITAAC);
4. Significant site parameters; and
5. Significant interface requirements.

Tier 2 information includes:

1. Information required by §§ 52.47(a) and 52.47(c), with the exception of generic technical specifications and conceptual design information;
2. Supporting information on the inspections, tests, and analyses that will be performed to demonstrate that the acceptance criteria in the ITAAC have been met; and
3. COL action items (COL license information), which identify certain matters that must be addressed in the site-specific portion of the FSAR by an applicant who references this appendix. These items constitute information requirements but are not the only acceptable set of information in the FSAR. An applicant may depart from or omit these items, provided that the departure or omission is identified and justified in the FSAR. After issuance of a construction permit or COL, these items are not requirements for the licensee unless such items are restated in the FSAR.

Final Safety Analysis Report

For a COLA referencing a DC, 10 CFR 52.79(d) does not require the FSAR to contain information or analyses submitted to the Commission in connection with the DC as long as the FSAR incorporates by reference the DC FSAR and contains, in addition to the information and analyses otherwise required, information sufficient to demonstrate that the site characteristics fall within the site parameters specified in the DC.

For a COLA referencing an ESP, 10 CFR 52.79(b) does not require the FSAR to contain information or analyses submitted to the Commission in connection with the ESP as long as the FSAR incorporates by reference the ESP SSAR and contains, in addition to the information and analyses otherwise required, information sufficient to demonstrate that the design of the facility falls within the site characteristics and design parameters specified in the ESP.

For a COLA referencing both a DC and an ESP, collectively 10 CFR 52.79(d) and 10 CFR 52.79(b) do not require the FSAR to contain information or analyses submitted to the Commission in connection with the DC and ESP as long as the FSAR incorporates by reference the DC and ESP FSARs and contains, in addition to the information and analyses otherwise required, information sufficient to demonstrate that the site characteristics fall within the site parameters specified in the DC and that the design of the facility falls within the site characteristics and design parameters specified in the ESP.[GD31]

Environmental Report

For a COLA ~~incorporating by reference~~ referencing a DC[GD32], 10 CFR 51.50(c)(2) provides that the COL ER may incorporate by reference the EA previously prepared by the NRC for the referenced DC. If the DC EA is referenced, the COL ER contains information to demonstrate that the site characteristics for the COL site fall within the site parameters in the DC EA.

For a COLA referencing an ESP, 10 CFR 51.50(c)(1) does not require the COL ER to contain information or analyses submitted to the Commission in the ESP ER or resolved in the Commission's ESP EIS, however, in addition to the environmental information and analyses otherwise required it contains: (1) information to demonstrate that the design of the facility falls within the site characteristics and design parameters specified in the ESP, (2) information to resolve any potentially significant environmental issue that was not resolved in the ESP proceeding, and (3) any new and significant information for issues related to the impacts of construction and operation of the facility that were resolved in the ESP proceeding.

For a COLA referencing both a DC and an ESP, the COL ER contains the information stated in the previous two paragraphs.[GD33]

Sections C.1.3 and C.2.15 provide guidance for information to be included in the ER.

GUIDANCE

Material Referenced

Applications under 10 CFR Part 52 may reference other documents as part of the provisions for the specific application. However, the application should clearly indicate whether these documents are: (1) reference materials used to provide supplemental information or (2) legally binding requirements necessary as part of the design or licensing description or bases in accordance with a specific requirement of 10 CFR Part 52.

A document that provides supplementary information on a topic and is not intended to provide a unique provision or approach describing the plant design or operation is a "reference document." Conversely, a document "incorporated by reference" constitutes a requirement that is mandated as part of the design or operating provision or approach. If an applicant does not wish to incorporate by reference an entire document or section of a document, but instead to treat as a requirement only a particular issue or aspect discussed in a referenced document, the applicant should clearly identify the portion of material to be incorporated by reference. The NRC may rely on documents incorporated by reference in making determinations required by 10 CFR Part 52 for issuance of a certification or license. Deviations from documents incorporated by reference are controlled by the regulatory change processes set forth for the application. See Section C.2.14 for additional guidance on information change processes for COL applicants.

For example, if a document in a DC application is incorporated by reference, it could be either: (1) the actual description of the plant design or (2) information that demonstrates that the design meets applicable NRC requirements and is required by 10 CFR 52.47 to be in the DC FSAR. Such documents constitute requirements and are listed in the DCR as being approved for incorporation by reference.

Documents incorporated by reference in the DC FSAR[4] or DCD are considered by the NRC to apply as requirements to any COL applicant or licensee incorporating by reference the DCR. In addition, documents incorporated by reference are within the scope of issue resolution of the DCR and are accorded issue finality protection under 10 CFR 52.63. The *Federal Register* notice for the DCR for the Economic Simplified Boiling-Water Reactor (ESBWR) (79 FR 61944-61988) (Ref. 6~~8~~) describes the difference between a document incorporated by reference and a reference document.

A COLA should discuss reference material and material incorporated by reference, and FSAR Section 1.6 should present this discussion consistent with the SRP. Documents not intended to constitute requirements should be identified as references "for information only," and documents intended as requirements should be identified as "incorporated by reference." In addition, the applicant should make available public versions of referenced nonpublic documents.

Final Safety Analysis Report Information

The requirements at 10 CFR 52.79(a) identify the scope and contents of the FSAR. The SRP addresses the technical information and level of detail to be included in the FSAR. The organization and numbering of the FSAR should follow the same organization and numbering as the SRP if a COLA does not reference a DC. For a COLA referencing a DC, organization and content should be consistent with the organization and format of either SRP or the DC FSAR. The application should support clear understanding of the information that: (1) is incorporated by reference from the DC or ESP, (2) is supplemental to the DC or ESP (e.g., conceptual design information or COL action items), or (3) constitutes a departure from the DC or variance from the ESP.

COL applicants should facilitate the NRC staff's review of the FSAR wherever possible. The NRC staff, as part of the review process, will verify that the information provided in the FSAR of a COLA is consistent with the referenced certified design and the referenced ESP. The applicant's use of the standardized format and clear and definitive presentation of information supports an effective and efficient review of the FSAR.

COL applicants should include in FSAR Chapter 1 administrative information in addition to the technical information identified in the SRP to address the organization and format of the FSAR and the information on the DC and ESP. Applicants should do the following:

a. Use an administrative scheme (e.g., "left-margin" annotation (LMA) scheme analogous to that used by prior COL applicants) to identify FSAR information that has been incorporated by reference from a DC or ESP. Such a scheme would designate the FSAR information that: (1) is incorporated by reference from the DCD or SSAR, (2) replaces conceptual design information in the DCD, (3) supplements information in the DCD or SSAR, (4) addresses a COL action item in the DC or ESP, (5) is a departure from the DC or variance from the ESP, (6) involves an exemption from the regulations, (7) differentiates between a reference combined license (R-COL) and S-COL, and (8) should be annotated for clarity.

b. Discuss the consistency of the FSAR format with either this RG and the SRP or referenced certified design.

~~c. Address compliance with Section IV, "Additional Requirements and Restrictions," of the appendix to 10 CFR Part 52 codifying the referenced certified design that requires COL~~

[4] Several previous design certifications refer to a DCD which was a precursor to the DC FSAR required under 10 CFR Part 52.47(a) after the revision of 10 CFR Part 52, "Licenses, Certifications, and Approvals for Nuclear Power Plants; Final Rule," dated August 28, 2007, (72 FRN 49352) (Ref. 6~~7~~9).

~~applicants to follow the same organization and numbering as the certified design, as modified and supplemented by the applicant's exemptions and departures.~~

~~d.~~c. Discuss the pagination scheme and the format, content, and numbering for text, tables, and figures included in the FSAR.

~~e.~~d. Discuss the method used to identify and reference proprietary information (see Section C.1.9).

~~f.~~e. List the acronyms used in the application. For consistency, applicants that reference a certified design and an ESP should use the acronyms provided in the DCD and ESP and should provide a supplemental list of acronyms for items not included in the DCD and ESP, as necessary.

Design Acceptance Criteria

The NRC implemented the policy of approving design acceptance criteria (DAC) in the DC process in a limited number of design areas. Prior DCs have used DAC in the areas of radiation protection for the Advanced Boiling Water Reactor (ABWR), I&Cs, piping, and HFE.

A COL applicant referencing a DC that used DAC automatically incorporates the DAC when it incorporates the DC by reference. The COL applicant may include detailed design information in the design areas where DAC were used, if available. Section C.2.8 provides explanatory information and guidance on this topic.

Combined License Action Items

The COL action items identify certain matters that should be addressed in the FSAR by an applicant that submits a COLA that references a DC or an ESP, or both. The appendices to 10 CFR Part 52 contain the DCRs, and each appendix requires a COLA referencing the DC to include information that addresses the identified COL action items. These COL action items (COL license information items) are those regulatory matters that the DC vendor deferred to the COL applicant to address in the COLA. For example, these items include: (1) complete design information for the remainder of a proposed facility that references a DC, (2) verification of site parameters, (3) completion of analyses and design reports for as-built plant systems, (4) development and implementation of operational programs, and (5) completion of designs included in the DAC. Similarly, a COL applicant that references an ESP addresses any COL action items included as part of the ESP that were deferred to be addressed in the COLA. Section C.2.11 provides explanatory information and guidance on this topic.

Design Interfaces—Design Certification and Early Site Permit

The DC FSAR is required by 10 CFR 52.47(a)(25) to contain the interface requirements that are met for those portions of the nuclear power plant for which the DC application does not seek certification. Further, 10 CFR 52.47(a)(26) requires the DC FSAR to contain justification that compliance with the interface requirements is verifiable through inspections, tests, or analyses.

COLAs referencing a DC are required by 10 CFR 52.79(d) to contain information sufficient to demonstrate that the characteristics of the site fall within the site parameters specified in the DC and that the interface requirements established for the design under 10 CFR 52.47 have been met. If not demonstrated in the application, the COL applicant should include a request for departure that complies with the requirements of 10 CFR 52.63, 10 CFR 52.93, and/or Section VIII of the referenced DCR appendix to 10 CFR Part 52.

COLAs referencing an ESP are required by 10 CFR 52.79(b) to contain information sufficient to demonstrate that the design of the facility falls within the site characteristics and design parameters specified in the ESP. For an ESP that uses a PPE approach, the COLA should contain information

sufficient to demonstrate that the design of the facility falls within the site characteristics enveloped in the PPE. Note: If not demonstrated in the application, the COL applicant should include a request for variance that complies with the requirements of 10 CFR 52.39 and 10 CFR 52.93.

The COL applicant should provide information sufficient to demonstrate compliance with the requirements of 10 CFR 52.79(b) and 10 CFR 52.79(d) in FSAR Chapter 1. The information should be included in Section 1.8 and/or a cross-referenced tabulation highlighting the specific FSAR sections that contain the sufficient information.

Conceptual Design Information - Design Certification

The requirements of 10 CFR 52.47(a)(24), specify that the DC application contain a representative conceptual design for those portions of the nuclear power plant for which the application does not seek certification to aid the NRC in its review of the DC FSAR and to permit assessment of the adequacy of the interface requirements in 10 CFR 52.47(a)(25).

COL applicants that reference a DC should provide a complete design for the entire facility, including appropriate site-specific design information to replace any conceptual design portions for the referenced certified design. DC applicants facilitate the NRC staff's review of applications by including conceptual designs in the DCDs that offer a more comprehensive design perspective; these conceptual designs typically include portions of the balance of plant of the nuclear facility. However, because the conceptual portions of the design are not certified, the COL applicant needs to address them. The NRC does not consider replacement of the conceptual design information with actual design information to be a departure from the DC because the conceptual design was not certified. However, for those instances in which the actual design information differs from the conceptual design information, the COL applicant should explain how these differences will affect the NRC's evaluation of the certified design and the design PRA, as applicable.

The COL applicant should provide information to address the conceptual design information from the referenced DC in FSAR Chapter 1 and applicable FSAR sections. The level of detail needed for the site-specific designs that replace conceptual designs should be consistent with the level of detail provided in the DCD for the non-conceptual (or specific) designs and should be sufficient to resolve all safety issues.

Departures from the Design Certification

A departure is a plant-specific deviation from design information in a DCR. Section IV of Appendices A through E to 10 CFR Part 52 codifying the certified designs requires a COL applicant referencing a certified design to incorporate by reference, as part of its application, the applicable appendix. A COL applicant referencing a DC may make departures from the design as provided in 10 CFR 52.63 and 10 CFR 52.93 and Section VIII of the referenced appendix to 10 CFR Part 52 that contains the DCR.

The COL applicant requesting a departure that requires NRC approval, consistent with Section VIII of the relevant appendix to 10 CFR Part 52, should identify and discuss the departure in Part 7 of the application and should provide appropriate information in the FSAR to justify the departure as needed. The applicant should discuss the departure in the FSAR section that corresponds to the DCD section in which the topic is presented and should include, in FSAR Chapter 1, a tabular list of departures with reference to applicable FSAR sections. The applicant should provide sufficient information that allows the NRC staff to resolve all safety and security issues in its review of the departure.

Departures that do not require NRC approval also appear in Part 7 of the application. The applicant's determination regarding the need for NRC approval are made in accordance with Section VIII.B.5 of Appendices A through E, to 10 CFR Part 52. Under Section X.A of the relevant appendix to 10 CFR Part 52, the applicant maintains the plant-specific DCD and written evaluations that provide the bases for the determinations required by Section VIII of the relevant appendix to 10 CFR Part 52. These evaluations are retained throughout the period of application and for the term of the license (including any period of renewal). During the interval from the date of application for a license to the date the Commission makes its findings required by 10 CFR 52.103(g), COL applicants and licensees should submit a report to the NRC semiannually as required by Section X.B.3.b of the relevant appendix to 10 CFR Part 52. The semiannual report should 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 of the relevant appendix to 10 CFR Part 52.

The applicable DCR appendix to 10 CFR Part 52 requires COL applicants to provide a report to the NRC that contains a brief description of any plant-specific departures from the DCD with a summary of the evaluation for each departure. The DCR also requires each applicant to maintain and submit updates to its plant-specific DCD, which consists of the generic DCD and plant-specific departures. To fulfill these requirements, the applicant may provide a report separate from the FSAR with the description and evaluation for each departure and include a summary table in this section of the FSAR that lists each departure and the FSAR sections that address each departure.

Sections C.1.7 and C.2.14 contain explanatory information and guidance on this topic.

Variances from the Early Site Permit

A variance is a plant-specific deviation from one or more of the site characteristics, design parameters, or terms and conditions of an ESP or from the SSAR. As required by 10 CFR 52.79(b), if the application's FSAR does not demonstrate that the design of the facility falls within the site characteristics and design parameters of the ESP, the COLA should include a request for a variance that complies with the requirements of 10 CFR 52.39 and 10 CFR 52.93. In addition, the COL applicant may, at its option, request a variance from the permit terms and conditions or from the SSAR.

The COL applicant requesting a variance should identify and discuss the variance in Part 7 of the application and should provide detailed and sufficient information in the FSAR to justify the variance and enable the NRC staff to resolve all safety issues pertaining to the variance. Further, the applicant should identify or uniquely designate the information provided in the application, including the FSAR, which is a variance from the ESP. In addition, 10 CFR 51.50(c)(1)(i) requires the ER to contain information to demonstrate that the design of the facility falls within the site characteristics and design parameters specified in the ESP. Therefore, the ER should analyze the environmental impact of the variance.

Sections C.1.7 and C.2.14 contain explanatory information and guidance on this topic.

Exemptions from the Regulations

A COL applicant's intended departure from the referenced DC may constitute an exemption from NRC regulations as discussed in the appendices to 10 CFR Part 52 that contain the DCR that would require an exemption request. In addition, a COL applicant may request an exemption from one or more of the requirements of 10 CFR Part 52, as provided in 10 CFR 52.7.

COL applicants should discuss any departure from the referenced certified design that requires an exemption in the section of the FSAR that corresponds to the DCD section in which the topic is

presented. The COL applicant should include sufficient information for the NRC staff to resolve all safety and security issues related to the exemption and to determine the regulatory basis for the exemption, as described in 10 CFR 52.93.

Further, COL applicants should understand that the NRC staff regards an exemption from the referenced certified design as a potential critical path item in the review of a COLA. Accordingly, the COL applicant should inform the NRC of its intent to request exemptions, including the number and nature of these exemptions, during preapplication interactions.

Sections C.1.7 and C.2.14 contain additional and guidance on this topic.

Documentation of ~~Evaluation against the~~ Standard Review Plan Sections and Regulatory Guides Used to Develop the Application
~~**Standard Review Plan**~~

In NRC MD 8.4, in Section I.B.2(e) of the Directive Handbook, the Commission has stated that for LWR facilities, applicants should be anticipated to reasonably rely upon in the development of their applications the version of the SRP or a DSRS, as applicable, in effect 6 months before the docket date of the application. The Commission further directed the NRC staff that any change in requirements or regulatory staff positions from that version of the SRP or DSRS, as applicable, interpreting the Commission's requirements should follow the same reasoned decisionmaking process as a forward fit.

COL, DC, and ESP applicants should provide information on which SRP or DSRS Sections, as applicable, and RGs were ~~used~~relied upon to develop the applications and which SRP or DSRS Sections and RGs were not ~~used~~relied upon or were partially relied upon and an explanation as to why they were not ~~used~~relied upon. COL applicants that reference a DC should provide information on SRP~~s~~ or DSRS Sections and RGs used for site-specific portions of the facility design that are not included in the referenced DC and departures that require NRC approval from the referenced DC. COL applicants that reference an ESP should provide information on SRP~~s~~ or DSRS Sections and RGs used for variances from the ESP.

~~The regulation in 10 CFR 52.79(a)(41) requires that COL applicants for a LWR evaluate the facility against the SRP revision that is in effect 6 months before the docket date of the application. The evaluation should identify and describe all differences in design features, analytical techniques, and procedural measures proposed for the facility and those corresponding features, techniques, and measures given in the acceptance criteria in the application and review guidance.~~

~~In accordance with 10 CFR 52.47(a)(9), DC applicants for a LWR shall provide information addressing evaluation against the SRP that was in effect 6 months before the docket date of the DC application. The evaluation required by this section shall include an identification and description of all differences in design features, analytical techniques, and procedural measures proposed for the design and those corresponding features, techniques, and measures given in the SRP acceptance criteria. Where a difference exists, the evaluation shall discuss how the proposed alternative provides an acceptable method of complying with the Commission's regulations, or portions thereof, that underlie the corresponding SRP acceptance criteria. In accordance with 10 CFR 52.63, COL applicants that reference a DC are not required to re-evaluate the COLA against the SRP for those portions of the facility design included in the referenced DC. However, a COL applicant should evaluate against the SRP revision in effect 6 months before the submittal date of the COLA for the site-specific portions of the facility design that are not included in the referenced DC. In addition, the applicant should evaluate the operational aspects of the facility against the SRP revision in effect 6 months before the submittal date of the COLA. COL applicants that include departures from the referenced DC should evaluate these departures against the SRP revision in effect 6 months before the submittal date of the COLA. If an applicant wishes to~~

~~evaluate a part of the COLA that is subject to 10 CFR 52.79(a)(41) against a revision of the SRP other than the one in effect 6 months before the docket date of the COLA (e.g., an SRP revision in effect at the time of the earlier application for the referenced design certification), the applicant should inform the NRC in advance, request an exemption from 10 CFR 52.79(a)(41), and provide a justification.~~

~~Similarly, the regulation in 10 CFR 52.17(a)(1)(xii) requires ESP applicants to evaluate the site against applicable sections of the SRP in effect 6 months before the docket date of the ESP application. In accordance with 10 CFR 52.39, COL applicants that reference an ESP are not required to re-address conformance with the applicable SRP sections included in the referenced ESP. COL applicants that include variances from the ESP should evaluate those variances for conformance with the SRP revision in effect 6 months before the submittal of the COLA.~~

~~**Regulatory Guides**~~

~~DC, ESP and COL applicants should provide information on which RGs were used to develop the applications and which RGs were not used and an explanation as to why they were not used.~~

~~In accordance with the provisions of 10 CFR 52.63, COL applicants that reference a DC are not required to re-address conformance with RGs for the portions of the facility design included in the referenced DC. However, for the site-specific portions of the facility design that are not included in the referenced DC, a COL applicant should address conformance with RGs in effect 6 months before the submittal date of the COLA. In addition, the COL applicant should address conformance with RGs in effect 6 months before the submittal date of the COLA insofar as they pertain to operational aspects of the facility. COL applicants that include departures that require NRC approval from the referenced DC should evaluate these departures for conformance with the RGs in effect 6 months before the submittal date of the COLA. If an applicant wishes to evaluate a departure for conformance with the RG revision relevant to the DC review process, the staff recommends that the applicant inform the NRC in advance and provide a justification.~~

~~ESP applicants should provide information that addresses conformance with applicable RGs that were in effect 6 months before the submittal date of the ESP application. In accordance with the provisions of 10 CFR 52.39, COL applicants that reference an ESP are not required to re-address conformance with the applicable RGs included in the ESP. COL applicants that include variances from the ESP should evaluate these variances for conformance with the RGs in effect 6 months before the submittal of the COLAs.~~[GD34]

Combined License Application Timing

A COLA submittal date may differ considerably from the submittal date of the referenced DC or ESP (i.e., a DC is valid for 15 years, an ESP may be issued for up to 20 years, and COLAs that reference a DC or ESP may do so at any point during the valid life of the DC or ESP)[GD35]. COL applicants that reference a DC should provide information on [SRP or DSRS Sections and] RGs ~~used~~relied upon the development of the ~~for~~ site-specific portions of the facility design that are not included in the referenced DC and departures that require NRC approval from the referenced DC. ~~Therefore, t~~The revision to the [SRP or DSRSs and] RGs that a COL applicant ~~should address~~relied upon in the development of its application might also differ considerably from those considered in the referenced DC. ~~However, the COL applicant should address those SRP and RG revisions issued after the SRP and RGs that were evaluated for the referenced DC only insofar as they may impact site-specific portions of the facility design not included in the referenced DC.~~ [GD36]In addition, the COL applicant should address operational aspects of the facility and any departures and variances consistent with the aforementioned guidance.

Completeness and Accuracy of a Referenced Design Certification and Early Site Permit

A COL applicant referencing a DC or ESP, or both, is not required to revise the information included in the DC and ESP. However, 10 CFR 52.6, "Completeness and Accuracy of Information," states that a COL applicant "shall notify the Commission of information identified by the applicant or the licensee as having for the regulated activity a significant implication for public health and safety or common defense and security." An applicant referencing an ESP is required to submit the information specified in 10 CFR 51.50(c)(1).

Design Certification and Early Site Permits Applications under Review

The regulations in 10 CFR Part 52 allow a COL applicant, at its own risk, to submit a COLA that references an application for a DC or an ESP, or both, that has been docketed and is undergoing review by the NRC staff, as follows:

a. Under 10 CFR 52.26(c), an applicant for a COL may, at its own risk, reference in its application a site for which an ESP application has been docketed but not granted. The COLA applicant that plans to reference an ESP that has not yet been issued should discuss with the staff the practical considerations associated with developing and submitting a COLA ER prior to the completion of the ESP proceeding because of the potential effects on the scope and schedule of the environmental review.
b. Under 10 CFR 52.55(c), an applicant for a COL may, at its own risk, reference in its application a design for which a DC application has been docketed but not granted.

This RG does not include guidance specific to the "concurrent review" approach allowed by 10 CFR 52.26(c) and 10 CFR 52.55(c) because of the numerous "what if" scenarios involving regulatory issues and schedule interactions associated with concurrent application reviews. In general, the NRC staff recommends that the COL applicant that elects to reference an application for a DC or ESP, or both, that is undergoing staff review should ensure timely synchronization of information contained in the COLA with that in the DC/ESP application. Such a COL applicant should discuss and coordinate closely with NRC staff regarding the synchronization and planning.

C.2.7 Design Centered Review Approach

OVERVIEW

The NRC encourages 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 FR 34884; September 15, 1987) (Ref. 6870) laid the foundation for the later rulemaking related to ESPs, DCs, and COLs under 10 CFR Part 52. In 2006, the agency formalized the DCRA strategy in RIS 2006-06. The Commission endorsed the DCRA strategy in SRM-SECY-06-0187, "Semiannual Update of the Status of New Reactor Licensing Activities and Future Planning for New Reactors," dated November 16, 2006 (Ref. 6971). The DCRA subsequently continued to evolve through greater process definition and in response to changing projections of S-COL applications.

Under the DCRA, staff performs one technical review for each issue outside the scope of the DC and intends to make one consistent and justifiable decision to support COLA reviews. This approach is applicable to COLAs that reference a DC as discussed in Section C.2.6. RIS 2006-06 requested that for a given referenced DC, either under review or after certification, an industry-led design center working

group (DCWG) would voluntarily form and designate a lead COLA to serve as the R-COL application and use annotation of the FSAR, Part 2 of the COLA, and other portions of the application to clearly identify: (1) sections that incorporate by reference the generic DCD, (2) sections that are standard for all COL applicants that reference the same DCD, and (3) sections that are site-specific and, therefore, only apply to the specific location. Other subsequent applications in the design center are designated as S-COL applications and reference the "standard content" established in the R-COL.

This regulatory topic provides guidance relevant to the DCRA as it has evolved and to 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. The appendix to Section C.2.7 briefly discusses the evolution of the DCRA.

GUIDANCE

The development of the NRC staff's DCRA involved substantial input from vendors, applicants, the Advisory Committee on Reactor Safeguards, and the Commission. The initial plan to focus on a single R-COL application selected by a DCWG while other S-COL applicants delayed submittal was considered logical and beneficial at the time (See the U.S. Department of Energy's (DOE's) Nuclear Power 2010 Program, Combined Construction and Operating License & Design Certification Demonstration Projects Lessons Learned Report, dated August 30, 2012 (Ref. 7072). The tradeoffs associated with this approach became apparent later as the timing for new COLAs changed and some COLAs were suspended or withdrawn, thus changing the construction schedules of some S-COL applications. In addition to describing the DCRA, RIS 2006-006 indicated that, because of the projected applications, the NRC planned to prioritize COLAs based on the level of standardization.

Any COLA, including the FSAR, should 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 an appropriate precedent. This can be accomplished by using and/or refining current referencing practices that include 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-COL application, as demonstrated in the William States Lee III Nuclear Station (WLS) COLA (Ref. 7173), 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 applicants.

It is essential that S-COL applicants clearly reference any information related to previous NRC reviews whether such information is related to an R-COL application, another S-COL application, or post-licensing actions such as LARs and post-license departures and exemptions. Referencing such material should be an important part of preapplication meetings with NRC staff. Transparent communications with the NRC concerning 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 affect safety.

The use of the terms "reference COL" and "subsequent COL" does not imply that the S-COL applicant simply references the previous R-COL application as a whole. Instead, the S-COL applicant should 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 and

endorsement letters by S-COL applicants of RAI responses by the R-COL applicant and, in some cases, other S-COL applicants.

Left Margin Annotation in Combined License Applications

A key referencing approach associated with the DCRA used by COL applicants involves LMA of the FSAR and associated acronyms that have become standardized through practice. The specific choice of annotation is up to the DCWG and may vary from examples discussed in this guidance. Other DCWGs may have an equally effective, but different approach. The approach developed by a DCWG should be clear and consistent between R-COLA and S-COLAs.

COL applicants referencing the Advanced Passive 1000 (AP1000) and ESBWR DCs have used the following notations for departures or supplements, or both, in their site-specific DCDs:

a. STD is standard (STD) information that is identical in each COLA referencing the certified design.
b. Plant name or abbreviation represents plant-specific information that is specific to the application (e.g., LNP for Levy Nuclear Plant and WLS for William States Lee III Nuclear Station).
c. DEP represents a departure (DEP) from the DCD.
d. COL represents combined license information identified in the DCD.
e. VAR represents a variance (VAR) from an ESP.
f. SUP represents information that supplements (SUP) information in the DCD.
g. CDI represents design information that replaces conceptual design information (CDI) that is included in the generic DCD but that is not addressed within the scope of the DCD review.

For example, Section 1.1 of the Bellefonte Nuclear Plant (BNP) COLA FSAR (Ref. 72~~74~~) indicated that the section incorporated the AP1000 generic DCD by reference with specific departures or supplements, or both. A supplement to Subsection 1.1.6.3 was marked with an LMA that stated, "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 Levy Nuclear Plant COLA FSAR (Ref. 73~~75~~) used the same supplement with the same LMA. Similar notation was included in Revision 8 to the North Anna Power Station, Unit 3, COLA FSAR (Ref. 74~~76~~), 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 its notation and adopt a modification of the LMA to efficiently reference FSAR material from a later S-COL and even from post-licensing decisions, if appropriate. The primary importance is that the COL applicant provide clarity in its application so that the NRC, the applicant, and the public clearly understand the content of the application.

Endorsement Letters and Request for Additional Information Responses in the Reference Combined License Application

Endorsement letters from S-COL applicants indicate acceptance of R-COL responses to the NRC's RAIs associated with standard content. This approach involves identifying the R-COL application of RAI responses submitted as either "Expected to be Standard for the S-COL Applications" or "Plant Specific," which are then summarized in a table. An endorsement letter from an S-COL applicant confirms the applicability of standard content RAI responses by including an evaluation of the R-COL RAI responses. The evaluation may include the following:

a. a table listing R-COL RAIs, including RAI identification numbers;
b. a copy of the R-COL determination of the RAI as to whether the RAI was standard or site specific; and
c. a determination as to whether the RAIs designated as standard are endorsed by the S-COL applicant.

The S-COL application 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's changes. If an S-COL applicant's response differs from the R-COL applicant's standard response, the S-COL applicant typically notifies the NRC. Additional S-COL application endorsement letters may be submitted later as necessary.

Although this practice was initially limited to referencing R-COL standard content, the practice has now evolved to include referencing RAI responses of S-COL applications. For example, the WLS applicant referenced a series of RAI response letters from the LNP S-COL applicant in a letter titled "Voluntary Submittal of Exemption Request and Design Change Description for Departure from AP1000 DCD Revision 19 to Address Main Control Room Dose Analysis," February 12, 2016 (Ref. 75~~7~~), requesting an exemption associated with a departure for the WLS COLA. Enclosure 1 of that letter lists the NRC's number designation for the LNP RAI and the corresponding response to the LNP RAI. Enclosure 1 states that the NRC had reviewed the LNP RAI response letters and found them applicable to WLS. Although the WLS letter differs slightly from earlier letters that endorse R-COL responses to RAIs (e.g., the Progress Energy Carolinas, Inc., letter titled "Shearon Harris Nuclear Power Plant, Units 2 and 3, Docket Nos. 52-022 and 52-023, Levy Nuclear Power Plant, Units 1 and 2, Docket Nos. 52-029 and 52-030, Summary Identification of Concurrence with Standard Content in Response to Requests for Additional Information: Supplement 2," dated December 7, 2009 (Ref. 76~~8~~), both were initiated by the applicant and facilitated the NRC staff's review 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.

Reference Combined License and Subsequent Combined License 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. 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. Part 7 provides summary information on each departure supporting whether NRC approval or an exemption is required and making specific exemption requests. More detailed information on individual departures may be found in the FSAR or audit reports, or both. 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 should correlate with any revised LMA used in the FSAR to facilitate efficient review.

Post-licensing departures should not appear as modifications to Part 7 of the application. During the interval from the date of application for a license to the date on which the Commission makes its findings required by 10 CFR 52.103(g), COL applicants and licensees submit a report to the NRC semiannually, as required by Section X.B.3.b of the relevant appendix to 10 CFR Part 52. The semiannual report contains 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 of the relevant appendix to 10 CFR Part 52. These semiannual reports from previous COLs may be of value to S-COL applicants that want to reference a post-licensing departure. As discussed in Section C.2.16, a number of departures and license amendments may be deferred by a COL applicant that chooses to finalize licensing-basis information at a point during the licensing review through a "freeze point." This may result in additional post-licensing departures that a later S-COL application may want to reference. There are no regulatory requirements that would restrict such a practice although an efficient review would depend on clear and properly qualified referencing.

Combined License Applications Referencing Post-licensing Information

Consistent with the guidance in Section C.2.16, 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 issuance of the COL, the NRC may need to review a number of departures and LARs to support the eventual construction of the facility. In addition, resolving constructability issues encountered during construction or startup issues immediately after the 10 CFR 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 LARs. As discussed in regard to LMA in this regulatory topic, refined LMAs could be used for efficient referencing of post-licensing departures. The semiannual reporting of changes, tests, and experiments required by 10 CFR 50.59, "Changes, Test and Experiments," and departures under Section VIII of the relevant appendix in 10 CFR Part 52 (e.g., the Virgil C. Summer Nuclear Station letter dated August 1, 2016 (Ref. 7~~9~~) 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. LARs, such as the letter dated December 17, 2015, from South Carolina Electric & Gas Company requesting a license amendment and exemption (LAR 15-15, "Radiologically Controlled Area Ventilation System (VAS) Design Changes" (Ref. 78~~80~~), provide detailed information that could be used for a departure in future COLAs or in support of similar LARs if identified after an S-COL application's freeze point.

Supplement to C.2.7 —Background Information on the History of the Design Centered Review Approach

Constraints on applicants, the 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 DOE's Nuclear Power 2010 Program. Before issuing RIS 2006-06, the NRC presented the proposed DCRA at a public meeting with NEI in February 2006 (Ref. 79~~81~~). RIS 2006-06 also indicated that the 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 2017-08) and responses have been critical to resource planning for reviews.

The NuStart Energy Development, LLC (NuStart), consortium was formed in 2004 by six member companies focused on the AP1000 reactor and ESBWR. NuStart developed a cooperative agreement with DOE under its 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 COLA development phase. NuStart identified the Tennessee Valley Authority's BNP site and Entergy's Grand Gulf Nuclear Station site for initial COLAs for the AP1000 and ESBWR, respectively, through a letter dated November 17, 2005 (Ref. 8082). NuStart played a key role in the 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 through 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 industry and specifically the DCWGs proposed the original development of LMA. NuStart presented referencing approaches to the AP1000 Advisory Committee on Reactor Safeguards subcommittee which can be found in "AP1000 Advisory Committee on Reactor Safeguards subcommittee meeting transcript," October 2007 (Ref. 8183) and clarified that having a single R-COL was preferable for the AP1000 because of 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-COL application by a DCWG was primarily to avoid confusion and problems associated with multiple COLAs referencing each other.[5] Alternatively, NuStart, Dominion Virginia Power, and Entergy indicated initially that, for the ESBWR, standard content would be developed without identifying an R-COL application (Ref. 8284) and described planning for submitting the two first COLAs to reference the EWBWR simultaneously. NuStart proposed the use of endorsement letters from S-COL applicants in an AP1000 DCWG Category 1 public meeting on October 9, 2008 (Ref. 8485).

In addition to the evolving practices of COL applicants and DC vendors, the NRC staff has expanded the use of the DCRA to other areas with essentially identical information for regulatory purposes. FSERs on S-COLs have relied on and directly referenced earlier FSERs for COLAs incorporating by reference the same design. This practice has not been restricted to referencing standard content in the relevant R-COL application. The FSERs for S-COL applications have instead directly incorporated excerpts from the FSERs from previous COLA reviews that the staff relied on in its analysis of the application in question. The WLS FSER directly referred to LPN as the R-COL application for several design issues that were resolved after issuance of the COLs for VEGP and Virgil C. Summer Nuclear Station because of LPN's role as the default R-COL application that carried standard content related to more recently resolved issues in Section 21.0 of the WLS FSER (Ref. 856). 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.

[5] 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 BLN, Units 3 and 4, to VEGP, Units 3 and 4 (Ref. 837). 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, SE with open items. Standard content material from the SE for the R-COL (VEGP) application and referenced in a later SE includes evaluation material from the SE for the BLN COLA. Similar changes relevant to the ESWBR R-COL application designation have occurred.

The NRC's DCRA increased efficiencies associated with standardization of license applications under 10 CFR Part 52. The development of the DCRA was partially in response to an unprecedented increase in projected licensing and DC application reviews. The DCRA has relied historically on the use of LMA of the FSAR, identification of an R-COL application that would be a carrier of "standard content" that would be shared by S-COL applications, and use of endorsement letters related to R-COL applicant's 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 the industry and the NRC staff have effectively taken advantage of the efficiency associated with the standardization through the referencing practices. This process also lends itself positively to interested members of the public who can focus their scarce resources on important issues during the one issue, one review, and one position process of the DCRA.

The DCRA, in practice, has evolved and is expected to continue to evolve. Future COL applicants should clearly identify previous safety reviews that they want to reference regardless of whether an active DCWG chooses to support specific additional refinements of standard content or refinements in referencing procedures to take better advantage of S-COL applications and post-licensing actions of COLs.

C.2.8 Design Acceptance Criteria

OVERVIEW

The NRC expects DC applications to represent an "essentially complete" design, as described in 10 CFR 52.47. In the Statements of Consideration accompanying the original promulgation of 10 CFR Part 52 (Ref. 8~~6~~8), an "essentially complete nuclear power plant" is defined as a design that includes all SSCs that can affect safe operation of the plant except for site-specific features such as the service water intake structure and the ultimate heat sink. In addition, the Statements of Consideration specify that an essentially complete design is a design that has been finalized to the point that procurement specifications and construction and installation specifications can be completed and made available for audit if such information is necessary for the Commission to make its safety determination. The Statement of Consideration further states that how much detail is present in a DC will be an issue which will have to be resolved in each certification rulemaking but that a rule certifying a design is likely to encompass roughly the same design features that 10 CFR 50.59 prohibits changing without prior NRC approval.

The Commission established policy in its February 15, 1991, SRM for SECY-90-377 (Ref. 8~~7~~9). Section III, "Level of Detail," of SRM-SECY-90-377 addresses the expected level of detail in DC applications. Specifically, the design should be complete except for adjustment within established design envelopes during the procurement and installation process. The Commission, however, did not expect in all instances that design detail would be developed to the level found in actual procurement and construction specifications, thus affording some flexibility to accommodate as-procured characteristics. In SRM-SECY-90-377, the Commission approved the NRC staff's proposal for a graded approach to the level of needed design detail, reflecting the safety significance of the SSC. The Commission considered an appropriate level of detail to be that provided in the FSAR at the operating license stage for a recently licensed plant (except for site-specific, as-procured, and as-built information).

SECY-92-053, "Use of Design Acceptance Criteria during 10 CFR Part 52 Design Certification Reviews," dated February 19, 1992 (Ref. 88~~90~~), describes topics for which the design could not be completed to the level of detail originally envisioned in SECY-90-377 and its associated SRM. Instead, the NRC staff defined DAC as a set of prescribed limits, parameters, procedures, and attributes that it relies on in a limited number of technical areas to make a final safety determination to support a DC. For

these technical areas, the DC application could include DAC and associated methodologies, design processes, and acceptance criteria. Objective and measurable DAC would enable the NRC staff to make a final safety determination, subject only to satisfactory design implementation and verification by the COL applicant through appropriate ITAAC.

The NRC implemented the policy of approving DAC in a limited number of design areas. Some certified designs to date have used DAC in the areas of radiation protection, piping, instrumentation and controls, and human factors engineering. Recent designs have not used DAC for radiation protection. The NRC has allowed the use of DAC if applicants justified one of the following two conditions:

a. Providing detailed design information was not desirable because associated technologies could change so rapidly that the design could be rendered obsolete before it was built (cited for I&C and HFE).
b. Completing the final design was impractical because of the unavailability of sufficient as-built or as-procured information (cited for radiation protection (shielding) and piping).

GUIDANCE

Design Certification Applications

The DC applicant should initiate early engagement with the NRC staff concerning any design areas for which the use of DAC is being considered in the application. It is crucial that both the applicant and the NRC staff understand the proposed approach and the justification. The extent to which the DC applicant's justification will be accepted by the NRC staff, as well as the level of detail that will be needed in the application, depends on design-specific technical considerations.

If a DC applicant identifies portions of the design that meet one of the two conditions discussed above and intends to request the use of DAC, the applicant should provide a justification for the use of DAC that is specific to its design. The DC application itself should provide the justification, typically in Section 14.3 of the DCD where ITAAC are described.

The justification should include the following:

a. a description of the specific design area to be addressed by DAC;
b. a discussion of the condition (rapidly changing information or the need for as-built and as-procured information) being cited and its relationship to the design topic; and
c. references to all information associated with the DAC, including the following:

    (1) methodologies that may be described in DCD Tier 2 (e.g., Section 3.12, "ASME Code Class 1, 2, and 3 Piping Systems, Piping Components and their Associated Supports," of the SRP for piping);
    (2) a summary of information that should not be changed without prior NRC approval (e.g., through inclusion in Tier 1);
    (3) ITAAC presented in DCD Tier 1 and described in DCD Tier 2, Chapter 14;
    (4) any relevant topical or technical reports; and
    (5) a discussion of any possible system interactions that result from the use of DAC.

In addition, the technical portions of the DCD that relate to the DAC should include further technical information as referenced in the justification above, including the following:

a. sufficient information, through a combination of methodologies, design processes, and acceptance

criteria (including ITAAC associated with design analyses and as-built verification) for the NRC staff to make a safety determination using the relevant requirements and guidance;
b. related interface requirements; and
c. possible system interactions.

The following chapters and sections of the SRP present additional information on technical and regulatory acceptance criteria for the subjects identified above:

a. SRP Section 3.6.2, "Determination of Rupture Locations and Dynamic Effects Associated with the Postulated Rupture of Piping"; Section 3.6.3, "Leak-Before-Break Evaluation Procedures"; and Section 3.12 address piping.
b. SRP Chapter 7, "Instrumentation and Controls," addresses I&C.
c. SRP Chapter 12, "Radiation Protection," addresses radiation protection.
d. SRP Chapter 14, "Initial Test Program and ITAAC-Design Certification," includes ITAAC and Tier 1 information relevant to all DAC.
e. SRP Chapter 18, "Human Factors Engineering," addresses HFE.

Combined License Applications

A COL applicant referencing a DC with DAC should understand that the path to successfully resolving DAC issues and completing the associated ITAAC may include the NRC staff's inspection of information or procedures that are prepared early in the construction, fabrication, or development processes. These inspections require NRC inspectors to become involved early in such processes (e.g., safety system software development). For this reason, it is crucial that a COL applicant using DAC provide the NRC staff with timely access to detailed design information to resolve potential issues.

In addition, COL applicants whose applications reference a DC with DAC may find, when completing the analysis associated with the DAC, that changes are needed to the plant design or other licensing documents (e.g., generic and plant-specific technical specifications), some of which may require prior approval of the NRC. A COL applicant referencing a DC may include sufficiently detailed design information in the design areas where DAC are used in the certified design. In these circumstances, the COLA should include a notification that the ITAAC associated with the design aspects of these DAC have been completed in accordance with 10 CFR 52.80(a)(3). The NRC staff would review this information in the context of the COLA, and, if approved, the NRC staff would indicate completion of these ITAAC in the *Federal Register* notice required by 10 CFR 52.85, "Administrative Review of Applications; Hearings." During the construction stage, the NRC staff would verify the final as-built state through the remaining ITAAC. This approach may be used when detailed design has already been completed potentially as a result of the construction of another facility referencing the same DC (e.g., the R-COL) for which the DAC ITAAC have been closed.

A COL applicant that does not reference a DC (i.e., custom COL) should include the same level of design detail that would be appropriate for a DC application in such a manner that enables the NRC staff to make a final safety finding on the design. The COL applicant should initiate early engagement with the NRC staff to address any design areas for which DAC may be proposed.

C.2.9 Inspections, Tests, Analyses, and Acceptance Criteria

OVERVIEW

This section provides guidance on the ITAAC information to be submitted in a COLA for a nuclear power plant. Therefore, it addresses many, albeit not all, of the application options allowed by

10 CFR Part 52. Although a COL applicant is not required to conform to this guidance, its use will facilitate both the preparation of a COLA by the applicant and the timely review of the application by the NRC staff. Much of this guidance also applies to ITAAC for an ESP and DC.

The history of ITAAC is coupled with the history of nuclear power plant standardization, particularly with the standardization of the processes for issuing COLs. Many first-time nuclear plant applicants, designers, and consultants and many novel design concepts emerged in the early commercial nuclear power industry. Accordingly, the agency structured the 10 CFR Part 50 licensing process to allow it to make licensing decisions while design work was still in progress and focus reviews on individual plant-specific and site-specific considerations. The NRC commonly issued construction permits with the understanding that open safety issues would be addressed and resolved during construction and that issuance of a construction permit did not constitute the Commission's approval of any design feature. Consequently, the operating license application review became very broad in scope.

A fundamental premise of 10 CFR Part 52 is that, with a mature nuclear industry, it is possible to describe and evaluate nuclear power plant designs on a generic basis and to have designs that are essentially complete in scope and level of detail before construction.

An "essentially complete nuclear power plant design" is defined as a design that includes all the SSCs that can affect the safe operation of the plant, except for site-specific features such as the service water intake structure and ultimate heat sink. An essentially complete design is a design that has been finalized to the point that procurement specifications and construction and installation specifications can be completed and made available for audit if the NRC determines that they are required for the Commission's review in accordance with 10 CFR 52.47(a) (see SRM SECY-90-377 and the Statement of Considerations section published in 72 FR 49352).

The intent of 10 CFR Part 52 in providing for the review and approval or certification of standard designs is to resolve safety issues early and to enhance the safety and reliability of nuclear power plants through standardization. With an "essentially complete design" and the early resolution of safety issues, the attributes of a construction permit can possibly be combined with much of those of an operating license issued under 10 CFR Part 50. Operation can then be authorized under the COL following an opportunity for a hearing on a more limited set of issues related to whether the acceptance criteria in the COL for the inspections, tests, and analyses are met or will be met.

Applications for a COL under Subpart C of 10 CFR Part 52 may, but need not, incorporate by reference an ESP or DC, or both. The scope of ITAAC development for a COL applicant will differ depending on which of these, if any, it references in the application. The scope of ITAAC at the DC stage is limited to and should be consistent with the SSCs that are in the certified design, and ITAAC for the site-specific design features should be developed at the COL stage. The ITAAC are limited to those design features and requirements that can be verified before fuel load. Therefore, license conditions in the COL should cover items like power ascension testing that are also described in the application.

The COL applicant should propose a complete set of ITAAC that addresses the entire facility, including ITAAC on EP and physical security hardware. The type of information and the level of detail included in the ITAAC should be based on a graded approach that is commensurate with the risk- and safety-significance of the SSCs for the design.

The NRC will incorporate the complete set of ITAAC included in the COL application as required by 10 CFR 52.80(a) into the COL as a license condition that the facility must satisfy before fuel load. After the Commission has made an affirmative finding that the applicant has performed the inspections, tests, and analyses and has met the acceptance criteria in accordance with 10 CFR 52.103(g),

the ITAAC do not, by virtue of their inclusion in the COL, constitute regulatory requirements for the applicant.

Once the completion of ITAAC and the supporting design information demonstrate that the facility has been properly constructed, existing programs, such as the plant-specific technical specifications, the in-service inspection and in-service testing program, the quality assurance program, the maintenance program, and other operational programs, then demonstrates that the facility continues to operate in accordance with the certified design and the COL.

The guidance in this section focuses on the ITAAC requirements for a COLA, including those COLAs that incorporate by reference an ESP or DC, or both. Table 4 provides regulatory history relevant to ITAAC.

GUIDANCE

Requirements for Inspections, Tests, Analyses, and Acceptance Criteria

Early Site Permit

For an ESP that does not seek an LWA, detailed guidance related to ITAAC related to EP is provided in sections C.1.5 and C.1.8 of this RG. If an ESP applicant seeks an LWA, then ITAAC is required for work performed on safety-related structures (e.g., engineered backfill, soil compaction, foundation base mat, and other site-related conditions).

Design Certification

As required by 10 CFR 52.47(b)(1), an application for a DC includes the proposed ITAAC that are necessary and sufficient to provide reasonable assurance that, if the inspections, tests, and analyses are performed and the acceptance criteria met, a facility that incorporates the DC has been constructed and will be operated in conformity with the DC, the provisions of the AEA, and the Commission's rules and regulations.

Table 4. Regulatory History[6]

SECY OR SRM NUMBER	SECY TITLE/SECY CONTENT
SECY-90-016 & SRM-90-016	Title: Evolutionary Light Water Reactor (LWR) Certification Issues and Their Relationship to Current Regulatory Requirements Content: SECY-90-016 does not directly address ITAAC. However, it does provide policy decisions on 15 issues considered fundamental to agency decisions on the acceptability of evolutionary ALWR designs. The issues and policy contained in SECY-90-016 were summarized in Part I of the attachment to SECY-93-087.

[6] Excerpt from NEI 15-02, "Industry Guideline for the Development of Tier 1 and ITAAC under 10 CFR Part 52," Draft A of Revision 0, issued May 2015 (Ref. 8991), submitted to NRC for review and discussion on May 27, 2015 (Ref. 9092). Although cited by NEI, these documents are available in the NRC Library on the NRC Web site.

SECY OR SRM NUMBER	SECY TITLE/SECY CONTENT
SECY-90-241 & SRM-90-241	Title: Level of Detail Required for Design Certification under Part 52 Content: SECY-90-241 presents options for Commission consideration regarding the implementation of the provisions of 10 CFR Part 52 that address the level of design detail.
SECY-90-377 & SRM-90-377	Title: Requirements for Design Certification under 10 CFR Part 52 Content: SECY-90-377 provides recommendations to the Commission regarding (1) the level of detail required for an essentially complete nuclear power plant design for design certification, and for a combined license under 10 CFR Part 52, and (2) the use of the industry's proposed two-tier approach to design certification.
SECY-91-178 & SRM-91-178	Title: Inspections, Tests, Analyses, and Acceptance Criteria (ITAAC) for Design Certifications and Combined Licenses Content: SECY-91-178 describes how the ITAAC for design certification, the ITAAC associated with site-specific design information, and certain Tier 2 information could constitute a verification program to be implemented by the combined license holder. The form and content of the ITAAC document is proposed with an example. The SECY also describes how the successful completion of the ITAAC requirements and any other acceptance criteria in the combined license will constitute the basis for the NRC's determination to allow operation of the facility.
SECY-91-210 & SRM-91-210	Title: Inspections, Tests, Analyses, and Acceptance Criteria (ITAAC) Requirements for Design Review and Issuance of a Final Design Approval (FDA) Content: SECY-91-210 requests Commission guidance on a policy matter related to an industry proposal that would allow the NRC staff to issue standardized plant final design approvals (FDAs) prior to final staff approval of the proposed ITAAC.
SECY-92-053	Title: Use of Design Acceptance Criteria during 10 CFR Part 52 Design Certification Reviews Content: SECY-92-053 addresses design acceptance criteria (DAC) for pipe stress analyses, radiation shielding and airborne concentrations, instrumentation and control systems, and control room design details.
SECY-92-196	Title: Development of Design Acceptance Criteria (DAC) for the Advanced Boiling Water Reactor (ABWR) Content: SECY-92-196 addresses the proposed use of DAC as an approach to the design review and resulting design certification for the GE ABWR to resolve the difficulties being experienced in obtaining detailed design information for selected areas of the plant. Enclosure 1 is a draft of the staff's final Safety Evaluation Report on the radiation protection and airborne concentration DAC area. Enclosure 2 is a draft of the staff's final Safety Evaluation Report on the piping design DAC area.

SECY OR SRM NUMBER	SECY TITLE/SECY CONTENT
SECY-92-214	Title: Development of Inspections, Tests, Analyses, and Acceptance Criteria (ITAAC) for Design Certifications Content: SECY-92-214 addresses issues identified in SECY-91-178, "Inspections, Tests, Analyses, and Acceptance Criteria (ITAAC) for Design Certifications and Combined Licenses," and SECY-91-210, "Inspections, Tests, Analyses, and Acceptance Criteria (ITAAC) Requirements for Design Review and Issuance of a Final Design Approval (FDA)."
SECY-92-287, SECY-92-287A, & SRM-92-287/287A	Title: Form and Content for a Design Certification Rule Content: SECY-92-287 proposed a format for a design certification rule for standardized plant designs. The SECY proposed that Tier 1 is the portion of the design-related information contained in the DCD that constitutes the certified standard design. SECY-92-287A addresses apparent inconsistencies between the staff's proposed change process for Tier 2 design information in SECY-92-287 and the Commission's SRM on SECY-90-377, "Requirements for Design Certification under 10 CFR Part 52."
SECY-92-294	Title: Acceptance Review of the Westinghouse Electric Corporation's Application for Final Design Approval and Design Certification for the AP600 Design Content: SECY-92-294 addresses that in order for the NRC staff to complete its review of an application for an FDA/DC, a complete set of ITAAC must be submitted with the application.
SECY-92-299	Title: Development of Design Acceptance Criteria (DAC) for the Advanced Boiling Water Reactor (ABWR) in the Areas of Instrumentation and Controls (I&C) and Control Room Design Content: SECY-92-299 addresses Development of DAC for the ABWR in the areas of I&C and control room design.
SECY-92-327	Title: Reviews of Inspections, Tests, Analyses, and Acceptance Criteria (ITAAC) for the General Electric (GE) Advanced Boiling Water Reactor (ABWR) Content: SECY-92-327 presents the results of the "Greybeard" Committee Review of the 10 CFR Part 52 licensing process for the GE ABWR. This review also provided comments relating to sufficient and appropriate scope and level of detail for the Tier 1 design certification process (Design Description and ITAAC).

SECY OR SRM NUMBER	SECY TITLE/SECY CONTENT
SECY-93-087 & SRM-93-087	Title: Policy, Technical, and Licensing Issues Pertaining to Evolutionary and Advanced Light-Water Reactor (ALWR) Designs Content: SECY-93-087 contains the NRC staff position on 42 technical and policy issues pertaining to either evolutionary LWRs, passive LWRs, or both. The Commission's SRM response enabled the NRC staff to proceed with the final design approval and the design certification review of the GE Advanced Boiling Water Reactor (ABWR) and ABB-CE System 80+ LWR designs. A cross-reference between the 42 issues and associated commission papers is provided. Section II.L of the SECY-93-087 directly addresses ITAAC by identifying seven SECYs issued in 1991 and 1992 related to ITAAC for the GE ABWR. SECY-93-087 also directly addresses ITAAC for leak-before-break analysis (LBB), control room habitability, and the design reliability assurance program (D-RAP).
SECY-94-084 & SRM-94-084	Title: Policy and Technical Issues Associated with the Regulatory Treatment of Non-Safety Systems in Passive Plant Designs Content: SECY-94-084 provided the NRC staff recommendations for eight issues pertaining to the regulatory treatment of non-safety systems in passive advanced light water designs. The SECY also addressed ITAAC for control room habitability and the design reliability assurance program (D-RAP).
SECY-95-132 & SRM-95-132	Title: Policy and Technical Issues Associated with the Regulatory Treatment of Non-Safety Systems (RTNSS) in Passive Plant Designs (SECY-94-084) Content: SECY-95-132 is a response to the Commission's SRM on SECY-94-084. SECY-95-132 provides certain guidance and positions for ensuring consistent and complete treatment of those systems that might be classified as nonsafety-related by the designer or applicant but are important to safety or otherwise provide defense-in-depth functions. The SECY also addressed ITAAC for control room habitability and the design reliability assurance program (D-RAP).
N/A	Title: Consolidation of SECY-94-084 and SECY-95-132, Memo from Crutchfield to NRC Docket File, dated July 24, 1995 Content: This memorandum completes the action directed by SRM-95-132 and consolidates the approved RTNSS policy and technical positions into one, versus three, documents for convenience of reference.
SECY-02-0059	Title: Use of Design Acceptance Criteria for the AP1000 Standard Plant Design Content: SECY-02-0059 addressees design acceptance criteria (DAC) used in the AP1000 standard plant design.

SECY OR SRM NUMBER	SECY TITLE/SECY CONTENT
SECY-02-0067 & SRM-02-0067	Title: Inspections, Tests, Analyses, and Acceptance Criteria (ITAAC) for Operational Programs (Programmatic ITAAC) Content: SECY-02-0067 recommended ITAAC for operational programs required by regulations such as training. In its SRM, the Commission directed that (with the exception of ITAAC required on emergency planning), ITAAC for a program should not be necessary if the program and its implementation are fully described in the application and found to be acceptable by the NRC at the COL stage.
SECY-05-0197& SRM-05-0197	Title: Review of Operational Programs in a Combined License Application and Generic Emergency Planning Inspections, Tests, Analyses, and Acceptance Criteria Content: SECY-05-0197 allows the use of the generic emergency planning ITAAC as described in Attachment 2 of SECY-05-0197.

A DC is a process whereby standard designs are approved by rulemaking. The resulting DCR is included in 10 CFR Part 52 as an appendix. Appendices A through E have each incorporated by reference a generic DCD that contains the Tier 1 and Tier 2 information and generic technical specifications. If an inconsistency exists between information contained in Tier 1 and Tier 2, the Tier 1 certified information takes precedence. To date, all DC applications that ultimately resulted in a DC via rulemaking were originally submitted and docketed before a 2007 revision of 10 CFR Part 52 and have incorporated by reference a DCD. A DC applicant, however, is currently required to submit an FSAR with all the information required under 10 CFR 52.47(a). A DC applicant must additionally submit ITAAC required by 50.47(b)(1) and may additionally provide any information needed to distinguish certified design material (CDM) from approved material if desired.

The design descriptions contained in the Tier 1 document are derived exclusively from the Tier 2 document. In addition, the Tier 1 design descriptions include tables and figures that are referenced in the acceptance criteria of the ITAAC. The tables and figures identify the components, equipment, system piping, building walls, and so forth that are verified by ITAAC and provide a convenient method for managing the size of the ITAAC tables. For example, a single ITAAC that requires verification of the design functions of multiple motor-operated valves may refer to a specific table listing them.

Design descriptions and ITAAC for a DC are provided for the SSCs that are: (1) fully within scope of the DC and (2) the in-scope portions of those systems that are only partially within scope of the DC. Additionally, in accordance with 10 CFR 52.47(a)(26), the method used for verifying the significant interface requirements (10 CFR 52.47(a)(25)) is included as part of the proposed ITAAC required by 10 CFR 52.47(b)(1).

For a COL that incorporates by reference a DC, the Tier 1 design descriptions serve as binding requirements for the lifetime of a facility.

Combined License

As required by 10 CFR 52.80(a), the COLA shall include the proposed inspections, tests, and analyses (including those applicable to EP) that the applicant performs and the acceptance criteria that are necessary and sufficient to provide reasonable assurance that, if the inspections, tests, and analyses are

performed and the acceptance criteria met, the facility has been constructed and will be operated in conformity with the COL, the provisions of the AEA, and the Commission's rules and regulations:

a. If the COLA references an ESP with ITAAC, as required by 10 CFR 52.80(a)(1), the ESP ITAAC should apply to those aspects of the COL that are approved in the ESP.
b. If a COLA references a DC, as required by 10 CFR 52.80(a)(2), the ITAAC in the certified design should apply to those portions of the facility design that are approved in the DC.

A COL applicant that references a DC complies with both the rule certifying the design and the DCD. A COL applicant or licensee that wishes to make a change to the DCD Tier 1 or Tier 2 information should do so in accordance with Section VIII of the applicable DCR appendix to 10 CFR Part 52.

In accordance with 10 CFR 52.47(a), the COL applicant should submit a plant-specific FSAR. The FSAR is similar to the design-specific DCD required by a COL applicant that incorporates by reference a DC that includes the Tier 2 design information as modified by the addition of the site-specific information, approved Tier 2 changes, and the approved departures and/or exemptions from Tier 1.

Although not a requirement, COL applicants that do not incorporate by reference a DC may also develop detailed design descriptions that include design bases, tables, and figures specifically for use and reference by the COL ITAAC. In this case, the COL applicant should call its descriptions "ITAAC Design Descriptions" to distinguish these design descriptions from those included in the Tier 1 document for a certified design. These ITAAC design descriptions should be separate, but should be derived from the detailed design information in the FSAR portion of the COLA. The proposed COL ITAAC may reference the specific sections, tables, and figures in the ITAAC design descriptions for verification of the design requirements and commitments. However, the Tier 1 and Tier 2 designations do not apply to a COLA that does not reference a DC because certified design information is subject to a different change process than that of a COL (i.e., Section VIII of the applicable appendix to 10 CFR Part 52).

The COL applicant should include the proposed ITAAC in Part 8 of the COLA. Title 10 CFR 52.80 identifies ITAAC as additional technical information required in the application. Therefore, Part 8 of the COLA containing the ITAAC is not part of the facility's FSAR. If the COLA references an existing DC, however, the COL applicant ~~should follow Section IV.A.2.a of the applicable 10 CFR Part 52 appendix regarding the organization and numbering of the FSAR, but~~ may include applicable generic ITAAC from the DCD in Part 8 along with site-specific ITAAC.

Basis; Format and Content; and Inspections, Tests, Analyses, and Acceptance Criteria Design Descriptions

Inspections, Tests, Analyses, and Acceptance Criteria Basis

In FSAR Section 14.3, the COL applicant should provide its proposed methodology for developing ITAAC for the facility, as well as its proposed criteria for establishing the necessary and sufficient acceptance criteria in accordance with 10 CFR 52.80(a).

In a table provided in FSAR Section 14.3, applicants should provide cross-references to the important design information and parameters from key safety analyses, including the key insights and assumptions from facility-specific PRAs and severe accident analyses, to show their treatment (i.e., inclusion or exclusion) in the ITAAC. These cross-references should be sufficiently detailed to enable the COL applicant or licensee to consider whether a proposed design change impacts the treatment

of these parameters in the ITAAC.

ITAAC should be constructed with simple language and should avoid unnecessary detail to minimize ambiguity and ensure that the focus is on the top-level design feature or performance characteristic to be verified. To ensure a clear understanding of the intent of the ITAAC, FSAR Section 14.3 may include additional information about each ITAAC. To help individuals who implement ITAAC, the additional information related to ITAAC in Section 14.3 of Tier 2 should be presented along with the ITAAC itself.

The additional information provided may include, but is not limited to, the following:

a. a reference to the FSAR discussion of the top-level design feature or performance characteristic to be verified by the ITAAC;
b. a discussion of the verification method;
c. a clarifying discussion of the ITAAC acceptance criteria;
d. a reference to or discussion of associated NRC regulatory guidance, industry codes, or industry standards; and
e. a reference to the FSAR Section 14.2 test abstract that describes the preoperational test that will satisfy the ITAAC (if the ITAAC is a preoperational test).

Inspections, Tests, Analyses, and Acceptance Criteria Format and Content

The applicant should format the ITAAC in a three-column table, as shown below.

ITAAC TABLE X.X.X-X

DESIGN COMMITMENT	INSPECTIONS, TESTS, ANALYSES	ACCEPTANCE CRITERIA
Xxxxxxxxx	**Yyyyyyyyy**	***Zzzzzzzzzz***

The first column of the ITAAC table should identify the proposed design commitment (i.e., requirement) to be verified. This column should contain the specific text of the design information extracted from the detailed design descriptions in the COL FSAR. Applicants should minimize any differences in the text unless their intent, for example, is to better conform the commitments in the design description to the ITAAC format. Any differences in text, however, should retain the principal performance characteristics and safety functions of the design feature that should be verified.

The second column of the ITAAC table should identify the proposed method (inspection, testing, or analysis or some combination of the three) by which the applicant will verify the design commitment described in column 1. In situ testing of the as-built SSCs is the preferred method of ITAAC verification, but is not required or expected in all cases. The detailed design information in the COL FSAR should include supporting information for each ITAAC, which describes at least one method that can and should be used to satisfy the ITAAC acceptance criteria. This information describes an acceptable means (albeit not the only means) of satisfying an ITAAC. The following describes the methods used to verify the design commitment:

a. “Inspect” or “inspections” include visual observations, physical examinations, or reviews of records based on visual observation or physical examination that compare the SSC condition to one or more design commitments. Examples include walk downs, configuration checks, measurements of dimensions, or nondestructive examinations.

b. "Test" means the actuation, operation, or establishment of specified conditions to evaluate the performance or integrity of the as-built SSCs, unless explicitly stated otherwise. In situ testing, where possible, of the as-built facility is the preferred means of ITAAC verification. Conversion or extrapolation of test results from the test conditions to the design conditions may be necessary to satisfy the ITAAC. The licensee or applicant should provide suitable justification for and applicability of any necessary conversions or extrapolations of test results necessary to satisfy the ITAAC.

c. "Type test" means a test on one or more sample components of the same type and manufacturer to qualify other components of that same type and manufacturer. A type test is not necessarily a test of the as-built components.

d. "Analysis" means a calculation, mathematical computation, or engineering or technical evaluation. Engineering or technical evaluations could include, but are not limited to, comparisons with operating experience or design of similar SSCs. The details of the required analysis should be specified in either the ITAAC or preferably the FSAR. The ITAAC should not reference the applicable section in the FSAR; however, the FSAR sections may reference the ITAAC. For example, FSAR Chapter 3 contains detailed analysis methods of seismic and environmental qualifications that support detailed design descriptions for SSCs and detailed piping design information that supports additional design material applicable to multiple sections of the design.

The third column of the ITAAC table should identify the proposed specific acceptance criteria for the inspections, tests, or analyses described in column 2 that, if met, demonstrate that the applicant has met the design commitments/requirements in column 1. In general, to prevent misinterpretation, the acceptance criteria should be unambiguous, objective, and inspectable. When possible, measurable numeric performance values should be specified in the ITAAC acceptance criteria when failure to meet the stated acceptance criteria would clearly indicate a failure to properly implement the design commitment. The numeric values selected should be those assumed in the safety analyses rather than the design values.

For Emergency Planning ITAAC, the applicant should format the ITAAC in a four-column table, as shown below and discussed in SRP 14.3.10.

ITAAC TABLE X.X.X-X

Planning Standard	EP Program Elements	Inspections, Tests, Analyses	Acceptance Criteria

Each numbered design commitment is entered into the "Design Commitment" column of the ITAAC table. Each design commitment occupies a single row of the ITAAC table. In the "Design Commitment" column, the first ITAAC is numbered "1" followed by a period. Subsequent ITAAC are numbered consecutively and occupy their own row in the ITAAC table. In the "Inspections, Tests, Analyses" and "Acceptance Criteria" columns, information is entered without numbering if a single entry in these columns is sufficient to address the design commitment. If multiple entries are required in these columns, each entry is numbered using the lower case Roman numeral numbering format "i, ii, iii, and so on." Entries in the "Acceptance Criteria" column should align with the entries in the "Inspections, Tests, and Analyses" column and should have corresponding numbering. For a specific DC; inspection, test, and analysis; or acceptance criteria entry, which has multiple parts, the individual parts should be listed using bullets.

The number of ITAAC tables provided will depend on the individual applicant or on whether a DC is incorporated by reference or the COL applicant has chosen to provide its own "ITAAC Design Descriptions." In either case, the ITAAC incorporated into Appendix C of the COL will be listed with a sequential ITAAC index number starting from 1 to XX.

DAC are a set of prescribed limits, parameters, procedures, and attributes that the NRC relies on in a limited number of technical areas to make a final safety determination to support a DC. DAC are designated as "{{DAC}}" in the "Inspections, Tests, and Analyses" column and "Acceptance Criteria" column of the ITAAC tables where appropriate. Section C.2.8 provides explanatory information and guidance on this topic.

The applicant should minimize the use of codes and standards in the ITAAC, with exceptions granted on a case-by-case basis. Instead, the applicant should state the applicable requirements from the regulations, codes, or standards instead of referencing them. It is more important to provide substantive ITAAC verification criteria (even if by reference) than to leave the ITAAC acceptance criteria open for interpretation. In general, the specific code edition, volume, version, date, and other such information should be specified in the FSAR rather than in the ITAAC or Tier 1 of the DCD.

Inspections, Tests, Analyses, and Acceptance Criteria Design Descriptions

The ITAAC design descriptions, if provided, are derived solely from the detailed design information in the COL FSAR and should address the essential top-level design information and performance characteristics that the NRC staff relies on as the bases for its safety review of the design.

The type of information and the level of detail included in the ITAAC and ITAAC design descriptions for each SSC are based on a graded approach (SECY-90-377) that is commensurate with the risk- and safety-significance of the facility's SSCs. Top-level design information selected for verification in the ITAAC should contain the principal performance characteristics and safety functions of the SSCs, their important features in various safety analyses, and their functions for defense-in-depth considerations.

The COL applicant should do the following in its development of proposed ITAAC and ITAAC design descriptions:

a. Carefully consider design-specific and unique features of the facility for inclusion in ITAAC.
b. Ensure that the ITAAC reflect the important insights and assumptions from the PRA with respect to the risk- and safety-significance of SSCs.
c. Ensure that the ITAAC reflect the resolutions of technically relevant unresolved safety issues and generic safety issues, NRC generic correspondence (such as bulletins and generic letters), and relevant industry operating experience.
d. Ensure that the ITAAC are consistent with the technical specifications, including their bases and LCOs.
e. Ensure that the ITAAC are consistent with the preoperational test program described in FSAR Section 14.2 because many of the preoperational tests for SSCs may be used to satisfy ITAAC. However, the applicant should not rely on preoperational tests for testing in lieu of ITAAC.
f. Ensure that the ITAAC emphasize testing of the as-built facility and use the definitions for testing provided in this guide.
g. Ensure that the ITAAC include SSCs for the top-level design features or functions necessary to satisfy the NRC's regulations in 10 CFR Part 20, "Standards for Protection against Radiation";

10 CFR Part 50; 10 CFR Part 73, "Physical Protection of Plants and Materials"; or 10 CFR Part 100, "Reactor Site Criteria."

h. Ensure that ITAAC include severe accident design features and plant features designed for protection against hazards.

i. Ensure that ITAAC include SSCs determined to be risk significant under SRP Section 19.3, "Regulatory Treatment of Nonsafety Systems for Passive Advanced Light Water Reactors."

The NRC staff is particularly interested in ensuring that the ITAAC adequately consider the assumptions and insights from key safety and integrated plant safety analyses in the FSAR under which plant performance depends on contributions from multiple systems of the facility design. Addressing these assumptions and insights in ITAAC ensures that the as-built facility preserves the integrity of the fundamental analyses for the facility design. These analyses include flooding, overpressure protection, containment, core cooling, fire protection, transients, anticipated transient without scram, steam generator tube rupture (pressurized-water reactors only), radiological concerns, unresolved safety issues, generic safety issues, Three Mile Island action plan items, or other key analyses specified by the NRC staff.

The applicant should consult RIS 2008-05, "Lessons Learned to Improve Inspections, Tests, Analyses, and Acceptance Criteria Submittal," Revision 1, dated September 23, 2010 (Ref. 9193) for lessons learned in regard to improving the ITAAC. Additionally, more specific and detailed ITAAC guidance may be found in the SRP. Section 14.3, "Inspections, Tests, Analyses, and Acceptance Criteria," of Chapter 14, "Initial Test Program and ITAAC-Design Certification," of the SRP provides introductory and general ITAAC guidance and should be used in conjunction with the following associated SRP sections that have been organized in accordance with the primary review responsibilities of the NRC's technical staff branches:

a. SRP Section 14.3.2, "Structural and Systems Engineering Inspections—Tests, Analyses and Acceptance Criteria";

b. SRP Section 14.3.3, "Piping Systems and Components Inspections—Tests, Analyses and Acceptance";

c. SRP Section 14.3.4, "Reactor Systems—Inspections, Tests, Analyses, and Acceptance Criteria";

d. SRP Section 14.3.5, "Instrumentation and Controls—Inspections, Tests, Analyses, and Acceptance Criteria";

e. SRP Section 14.3.6, "Electrical Systems—Inspections, Tests, Analyses, and Acceptance Criteria";

f. SRP Section 14.3.7, "Plant Systems—Inspections, Tests, Analyses, and Acceptance Criteria";

g. SRP Section 14.3.8, "Radiation Protection—Inspections, Tests, Analyses, and Acceptance Criteria";

h. SRP Section 14.3.9, "Human Factors Engineering—Inspections, Tests, Analyses, and Acceptance Criteria";

i. SRP Section 14.3.10, "Emergency Planning—Inspections, Tests, Analyses, and Acceptance Criteria";

j. SRP Section 14.3.11, "Containment Systems—Inspections, Tests, Analyses, and Acceptance Criteria";

k. SRP Section 14.3.12, "Physical Security Hardware—Inspections, Tests, Analyses, and Acceptance Criteria"; and

l. SRP Section 19.3, "Regulatory Treatment of Nonsafety Systems for Passive Advanced Light Water Reactors."

A set of draft standardized inspections, tests, analysis and acceptance criteria (ITAAC) that applicants may use in a future design certification application using the Title 10 of the *Code of Federal Regulations* (10 CFR) Part 52, "Licenses, Certifications, and Approvals for Nuclear Power Plants," process, is publically available (Ref. 9294, Ref. 9395). The majority of these draft standardized ITAAC were discussed in public meetings that included significant participation from industry representatives, NRC staff and management, and the NEI. The draft standardized ITAAC include basis discussions for each ITAAC that applicants may include in their discussion for the development of their ITAAC. Applicants are cautioned that the draft standardized ITAAC do not represent the complete set of ITAAC that would be required to be included in a design certification application.

C.2.10 Applicability of Consensus Standards

The National Technology Transfer and Advancement Act of 1995 (NTTAA) (Public Law 104-113) requires all Federal agencies to: (1) consult with voluntary consensus standards bodies, (2) participate with voluntary consensus bodies in the development of consensus standards when such participation is in the public interest and is compatible with agency missions, authorities, priorities, and budget resources, and (3) use consensus standards as a means to carry out an agency's policy objectives or activities unless such use is inconsistent with applicable law or is impractical. The Office of Management and Budget (OMB) issued Circular No. A-119, "Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities" (Ref. 9496), which provides guidance to Federal agencies on compliance with the NTTAA.

NRC Management Directive (MD) 6.5, "NRC Participation in the Development and Use of Consensus Standards," provides the NRC's position on OMB Circular No. A-119. MD 6.5 describes the NRC policy's to: (1) be involved with all interested stakeholders in the NRC's regulatory development processes, (2) participate in the development of consensus standards that support the NRC's mission, and (3) use consensus standards developed by voluntary consensus bodies consistent with the NTTAA provisions. The objectives of the NRC policy on its participation in the development and use of consensus standards include: (1) promoting the efficient and effective use of NRC resources by focusing staff participation on the development of standards that address a defined current or anticipated regulatory need, (2) implementing the NTTAA and OM Circular No. A-119, and (3) monitoring and assessing internal performance indicators to ensure efficient and effective staff involvement in the development and use of consensus standards needed in NRC program offices. The NRC reserves the right to apply conditions on the use of consensus standards that it uses in its regulatory process. The NRC staff follows this management directive in applying consensus standards in its regulatory activities.

The NRC applies the use of consensus standards in numerous aspects of its regulatory activities to promote their efficiency and effectiveness. The NRC incorporates by reference consensus standards in the Title 10, Chapter I, of the CFR such that those standards become equivalent to the NRC regulations. For example, the NRC incorporates by reference portions of the American Society of Mechanical Engineers (ASME) Boiler and Pressure Vessel Code and the ASME Code for Operation and Maintenance of Nuclear Power Plants in 10 CFR 50.55a, "Codes and Standards." In addition, the NRC accepts the use of consensus standards in various regulatory guidance documents, such as RGs, RISs, NUREGs, and standard review plans. For example, in RG 1.100, "Seismic Qualification of Electrical and Active Mechanical Equipment and Functional Qualification of Active Mechanical Equipment for Nuclear Power Plants" (Ref. 9597) the NRC accepts ASME Standard QME-1-2007, "Qualification of Active Mechanical Equipment Used in Nuclear Power Plants" (Ref. 9698) issued 2007, with regulatory positions. In RIS 2007-06, "Regulatory Guide 1.200 Implementation" (Ref. 979), dated March 22, 2007, the NRC staff discusses the use of PRA standards. RG 1.200, "An Approach for Determining the Technical Adequacy of Probabilistic Risk Assessment Results for Risk-Informed Activities" (Ref. 98100), provides more specific guidance on the use of consensus PRA standards.

If an applicant intends to apply a standard that has not received endorsement or acceptance in the NRC regulations or RG documents, the applicant is responsible for providing justification for the acceptability of the standard as part of its application. In Section C.2.6, the NRC staff describes the use of consensus standards in DC and COLAs as a general reference or by incorporation by reference.

C.2.11 COL Action Items and Post-License Commitments

OVERVIEW

In addition to complying with the requirements of 10 CFR 52.77; 10 CFR 52.79, and 10 CFR 52.80, a COL applicant that references a DC shall comply with provisions of the referenced DCR contained in the appendices to 10 CFR Part 52.

~~In~~[TO37] ~~each DCR of 10 CFR Part 52, Section IV.A.2.e~~The regulation in 10 CFR 52.79(d)(5)(v) requires the COLA to include information that addresses the COL action items[7] identified in the DCR. These COL action items are regulatory matters that the DC vendor deferred to the COL applicant to address in the COLA.

~~Similarly, a~~A COL applicant that references an ESP should address any COL action items included as part of the ESP that were deferred to be addressed in the COLA. In addition, a COL applicant may, at its discretion, address in the COLA commitments performing future regulatory actions (e.g., update information and programmatic schedules) that are related to site-specific design features or programs that were not identified in the referenced DC or ESP.

Although the COLA addresses all COL action items in the referenced DC or ESP, or both, the NRC staff recognizes that it may not be feasible for all COL action items to be completed before issuance of the COL. However, a COL application contains all information in the COLA that is necessary for the NRC staff to make the findings required to issue the license. The information necessary for the NRC staff to issue the license cannot be deferred until after COL issuance. This may necessitate, for example, partially closing COL action items and identifying the remaining portions of the items associated with information that is not necessary to issue the license as "post-license commitments."

COL applicants referencing a certified plant design must propose plant-specific technical specifications containing all site-specific information that is necessary to ensure plant operation within its design basis. The COL applicant must confirm all preliminary information and provide all missing information that is denoted in the generic technical specifications by bracketed values, reviewer's notes, or any other placeholder. The plant-specific technical specifications, which must be issued with the COL as required by the AEA, shall be complete and shall contain no COL action items for the COL holder to resolve. The COL shall contain no license condition on completing the plant-specific technical specifications.

To comply with 10 CFR 52.79(a)(30), COL applicants must resolve all generic technical specification COL action items before COL issuance. Chapter 16 of the SRP provides the COL applicant with the following three recommended options to resolve each such item for their consideration:

[7] ~~As defined in Section II.E.3 of each DCR, COL action items (COL license information) identify certain matters that are addressed in the site-specific portion of the FSAR by an applicant that references this appendix. These items constitute information requirements but are not the only acceptable set of information in the FSAR. An applicant may depart from or omit these items as long as the FSAR identifies and justifies the departure or omission. After issuance of a construction permit or COL, these items are not requirements for the licensee unless it restates such items in the FSAR.~~

a. provide a plant-specific value or plant-specific information;
b. provide a value or information that bounds the plant-specific value or information, but by which the plant may be safely operated (i.e., a useable bounding value or useable bounding information); or
c. establish a plant-specific TS Section 5.5 or 5.6 administrative controls program or report. Administrative controls technical specifications should require (i) use of an NRC-reviewed and -approved methodology for determining the plant-specific value, (ii) the establishment of an associated document, outside the plant-specific technical specifications, in which the relocated plant-specific value must be recorded and maintained, and (iii) any other information or restrictions the NRC staff deems necessary and appropriate to satisfy 10 CFR 50.36.

The NRC staff determined that it should provide additional guidance and clarification on COL action items that cannot be resolved before issuance of a COL to ensure consistency and facilitate common understanding by COL applicants. Further, the guidance should include options and illustrative examples to assist in determining the most appropriate post-license commitments for ensuring completion of COL action items following license issuance. The guidance herein identifies options available to the COL applicant for treatment of those COL action items that can only be completed after license issuance and those post-license information commitments identified by the COL applicant or by the NRC staff during the application review.

GUIDANCE

Combined License Action Items

The COL applicant that references a DC should address all COL action (information) items in its application. COL applicants should review the COL action items to identify those items that can be resolved as part of the COLA and those items that cannot be resolved as part of the COLA. Regardless of the disposition of these items, each COL applicant should provide a cross-reference identifying the section in the COLA that addresses each COL action item from the referenced certified design. The COL applicant should include this cross-reference information in the COLA's FSAR Chapter 1.

In addition, the COL applicant that references a DC should review the NRC staff's FSER for the referenced DC. The FSER contains a listing of COL action items, which are cross-referenced with COL action items in the related DCD. In addressing the COL action items in the DCD, the COL applicant should ensure that it has also addressed the issues described by the COL action items listed in the related FSER. The staff intends to review the FSER list of COL action items during its review of each COLA and may request additional information from the COL applicant to address issues described by the listed action items that the COLA did not adequately consider.

Similarly, the COL applicant that references an ESP should review each COL action item identified in the ESP and determine those items that can be resolved as part of the COLA and those items that cannot be resolved as part of the COLA. The COL applicant should provide a cross-reference identifying the section in the COLA that addresses each COL action item from the referenced ESP. The COL applicant should include this cross-reference information in the COLA's FSAR Chapter 1.

Combined License Action Items that Cannot Be Resolved before Issuance of a License

For each COL action item, whether its source is the referenced certified design or an ESP, the COL applicant should provide the requested information or justify why that item cannot be completed

before issuance of the license. For example, items that call for plant walkdowns cannot be completed because the plant has not been constructed at the time the applicant submits its application. The COL applicant should provide sufficient information to support the NRC licensing decision. Therefore, a COL action item cannot be deferred until after a COL is issued if resolution of that item is necessary for the NRC staff to make the findings required to issue the license. For example, if the COL action item addresses both information necessary for licensing action and information necessary to update the FSAR or other licensing-basis documents following issuance of the license, the COL applicant should provide the information necessary for licensing and should propose a method for ensuring the final closure of the remaining portion of the COL action item following the issuance of a COL. The COL applicant should identify the COL action items that cannot be completely resolved before the COL is issued, as well as any post-license information commitments made to the NRC as part of the license application review.

The COL applicant may select among the following options for proposing the completion, after license issuance, of those COL action items that are not necessary for the NRC staff to issue the license. These options are also applicable to post-licensing information commitments that were identified during COLA reviews that were not associated with COL action items.

a. Consider the COL action item unnecessary if it is found to be completely redundant to an ITAAC from the referenced certified design that will be included or incorporated by reference in the COLA.
b. Identify new site-specific ITAAC to resolve the COL action item. COL applicants may also propose, in accordance with the appropriate change process, new or revised ITAAC for items within the scope of a referenced certified design.
c. Identify a new condition to the license or an existing license condition (e.g., technical specifications) to govern the matter addressed by the COL action item. The license condition should include implementation schedules, where appropriate.
d. Ensure that the COLA describes the proposed approach for addressing a COL action item in sufficient detail to support the NRC licensing finding. The COL applicant should also describe how it intends to update any affected licensing-basis documents (e.g., the FSAR) or otherwise inform the NRC staff of the final disposition of the COL action item. The descriptions provided should include implementation schedules, where appropriate.

The COL applicant may propose the option considered appropriate, however, the NRC staff will make the final determination as to whether the proposed option is appropriate during the application review. In selecting an option, the COL applicant should consider the following discussion of: (1) ITAAC, (2) license conditions, and (3) FSAR commitments.

Inspections, Tests, Analyses, and Acceptance Criteria

The regulation at 10 CFR 52.80(a) establishes the requirement for inclusion of ITAAC in an application for a COL. The applicant is required to provide notification along with sufficient documentation to demonstrate that it has successfully completed the ITAAC in accordance with 10 CFR 52.99(c). The NRC is required to ensure that the applicant has performed the prescribed ITAAC and to publish notices in the *Federal Register* of its determination that the applicant has successfully completed the ITAAC in accordance with 10 CFR 52.99(e). The applicant may not operate the facility until the Commission finds that the acceptance criteria of the ITAAC are met.

The COL applicant should use the guidance in Section C.2.9 when considering whether a post-license information commitment or a COL action item that cannot be completed until after issuance of the license should be resolved using an ITAAC. ITAAC are post-license verification license conditions

that focus on ensuring that the as-built condition of the plant complies with the license for the facility and the Commission's regulations. Another consideration for ITAAC is that, in accordance with 10 CFR 52.103(g), "The licensee shall not operate the facility until the Commission makes a finding that the acceptance criteria in the combined license are met." The successful completion of all ITAAC enables the Commission to make the findings required before fuel load in accordance with 10 CFR 52.103(g).

License Conditions

The license for a nuclear facility contains terms and conditions for operation. For example, 10 CFR 50.54 identifies the standard conditions that, with some exceptions, apply to every COL issued. In addition to those standard conditions, the COL applicant may propose additional license conditions to address the completion of post-license information commitments or COL action items that it cannot complete until after issuance of the license. For example, a license condition may be necessary to govern those tests that can be performed only after fuel is loaded into the reactor, such as power ascension testing. However, a license condition is not necessary for those matters already covered by the license, including technical specifications or regulations. COL applicants should consider the following discussion when proposing license conditions in the application:

a. License conditions remain in effect for the applicant until it has satisfactorily completed them and until their removal is approved through the license amendment process in accordance with 10 CFR 52.98(f). Note that no regulation exists that requires an applicant to remove a condition from its license following satisfactory completion of the condition.
b. License conditions are enforceable in the same manner in which a regulation or order is enforceable. The terms of the FSAR are not similarly enforceable, but changes to the FSAR are made in accordance with the provisions of 10 CFR 50.71(e), which itself is an enforceable regulation.
c. The license may include some conditions that require the submission of information to verify compliance, to notify the NRC of the schedule of availability of information for inspection, or to provide an implementation schedule of programs or activities to be inspected. The NRC staff does not perform a safety review on submitted materials, but may review issues through the NRC's inspection program.
d. License conditions may be used to include operational restrictions for the facility, impose restrictions on operating power levels, require performance of special tests, and impose operational constraints associated with implementation of specific design features (e.g., containment sump screen sweepers).
e. License conditions may be used to include implementation schedules for operational programs.

Final Safety Analysis Report Commitments

COL applicants may address the completion of post-license information commitments or COL action items that cannot be completed until after issuance of the license through an FSAR commitment. In this context, an FSAR commitment is a commitment to provide updated information in the FSAR, which contains the design-basis portion of the licensing basis, or other licensing-basis documents that the NRC staff has considered appropriate to ensure that the licensing basis for the facility is up to date. This approach may also be used for other applicant-controlled documents such as quality assurance plans, emergency plans, and security plans.

The staff has identified two approaches for providing the information necessary to maintain the design basis for the facility: (1) include specific design-basis information items in a license condition and (2) include design-basis information in FSAR updates required by

10 CFR 50.71(e). The first approach focuses on ensuring that the FSAR update includes information that is identified during the COL review process and is included in the design basis. The second approach focuses on ensuring that routine FSAR updates that have traditionally occurred following issuance of an operating license are performed.

Final Safety Analysis Report Information Commitment Included in a License Condition

The regulations in 10 CFR 50.71(e) and the DCR appendices to 10 CFR Part 52 include requirements for COL holders to update their FSARs. Specifically, 10 CFR 50.71(e)(3)(iii) requires the COL holder to submit an updated FSAR to the NRC annually during the period from the docketing of a COLA until the Commission makes the finding under 10 CFR 52.103(g). In addition, 10 CFR 50.71(e)(4) requires subsequent FSAR revisions to be filed annually or 6 months after each refueling outage provided that the interval between successive updates does not exceed 24 months. These revisions reflect all changes made to the FSAR up to a maximum of 6 months before the date of the filing. Although these requirements for FSAR updates currently exist, requiring the inclusion of FSAR information commitment items in a license condition ensures that specific information identified during the initial licensing review is included in the design bases for the facility. This includes the information that should be reviewed as part of the design bases for the facility when reviews and evaluations, such as those performed in accordance with 10 CFR 50.54(f); 10 CFR 50.59; and 10 CFR 50.65, "Requirements for Monitoring the Effectiveness of Maintenance at Nuclear Power Plants," are required. The license condition should also include a milestone schedule for ensuring that the specific FSAR information identified is included in an FSAR update, as required by 10 CFR 50.71(e).

This license condition may include information such as the following:

a. FSAR-level design information from completed digital I&C DAC;
b. FSAR-level design information from as-built reconciliations of piping;
c. design features installed as a result of the completed pipe break hazards analyses;
d. an update to turbine missile generation analyses, as necessary, based on as-procured material data;
e. an update to reactor vessel materials data, as necessary, based on as-procured vessel material data; and
f. a specific subset of FSAR information that was identified during the original licensing review (e.g., the applicant could provide a commitment to include information associated with vendors in an FSAR update at least 60 days before the initiation of construction).

The NRC staff considers this information to be sufficiently relevant and distinct from the types of information typically included in routine FSAR updates to warrant its inclusion in a license condition. Along with the requirements of 10 CFR 50.71(e) and 10 CFR Part 52, this type of license condition furthers the NRC's goal of ensuring that the design basis for the facility (i.e., the FSAR) is up to date when operation of the facility begins.

For COLs referencing certified designs that include as-built reconciliation activities in COL action items rather than in ITAAC, a license condition containing specific FSAR information requirements could include the relevant as-built facility information from these activities in the FSAR (e.g., fire hazards analysis, pipe break hazards analysis, and site-specific seismic responses and the impact of these events on design features).

Final Safety Analysis Report Information Commitments Included in a Routine FSAR Update

The periodic FSAR updates required by 10 CFR 50.71(e) should include updated information that does not warrant inclusion in the above categories or that occurs after the milestone associated with the license condition. Guidance on FSAR updates appears in RG 1.181, "Content of the Update Final Safety Analysis Report in Accordance with 10 CFR 50.71(e)" (Ref. 99~~101~~) which endorses NEI 98-03, "Guidelines for Updating Final Safety Analysis Reports" (Ref. 100~~102~~).

The guidance for these routine FSAR updates appears in RG 1.181 and NEI 98-03 and is typically associated with the following changes and amendments:

a. changes to the facility in accordance with the requirements of 10 CFR 50.59,
b. changes to the facility resulting from approved exemptions and departures from a referenced certified design,
c. changes to the facility resulting from approved variances from a referenced ESP, and
d. amendments to the license in accordance with the requirements of 10 CFR 50.90.

C.2.12 Operational Programs for Combined Licenses

OVERVIEW

The "operational programs"[8] are a subset of the multiple programs supporting nuclear facility operation that are subject to NRC regulatory review. Operational programs have the following characteristics:

a. NRC regulations require operational programs.
b. The NRC staff reviews them as part of the COLA review process.
c. The NRC staff inspects these programs prior to operation to verify their implementation.

The NRC regulations require a COL applicant to address varied programs to support operation of the nuclear facility. For example, 10 CFR 52.79 requires the application to include both the description and the implementation of programs such as the in-service testing (IST) and inspection programs, primary containment leakage rate testing program, reactor vessel material surveillance program, operator training program, and a program for monitoring the effectiveness of maintenance.

The NRC staff will typically use applicable sections of the SRP in effect 6 months before the docket date of the COLA [GD38] to review the COL applicant's identification and descriptions of operational programs and make a reasonable assurance (high assurance for physical protection programs as described in 10 CFR 73.55 (b)) finding on each operational program and its implementation schedule. In addition, the staff will include a license condition on subsequent implementation milestones for each operational program description for which specific implementation requirements are not specified in the regulations.

[8] The NRC staff addressed operational programs in SECY-05-0197, "Review of Operational Programs in Combined License Applications and Generic Emergency Planning Inspections, Tests, Analyses, and Acceptance Criteria," dated October 28, 2005 (Ref. 101~~3~~). The Commission endorsed the staff recommendations on operational programs in SRM-SECY-05-0197, dated February 22, 2006 (Ref. 102~~4~~)

GUIDANCE

Program Description and Implementation

COL applicants should fully describe each operational program, including implementation and milestones, in the FSAR. If the applicant "fully describes" an operational program and its implementation and milestones, the applicant is not required to propose ITAAC in accordance with 10 CFR 52.80(a) for that operational program. The term "fully described" means that the operational program is clearly and sufficiently described in terms of scope and level of detail to allow the NRC staff to make a reasonable assurance or high assurance finding (as applicable) of the acceptability of that program. The applicant should describe each operational program at a functional level and at an increased level of detail where implementation choices could materially affect program effectiveness and acceptability.

For a COL applicant referencing a DC, the referenced DCD typically identifies COL action items that specify that the COL applicant provides a full description of each operational program. The COL applicant should satisfy these COL action items in the COL FSAR. If the DCD does not include such COL action items, the COL applicant remains obligated to provide a full description of each operational program to avoid the need for programmatic ITAAC.

SRP Section 13.4, "Operational Programs," identifies the operational programs that the FSAR should fully describe and provides guidance for the content and format of information to be included. Table 13.4-x in SRP Section 13.4 identifies the list of operational programs and the associated regulatory requirements and implementation milestones. This table illustrates an acceptable method of presenting the information in Section 13.4 of the COL FSAR.

Other SRP sections describe the technical information that the FSAR should include to fully describe each specific operational program. For example, SRP Section 3.9.6, "Functional Design, Qualification, and Inservice Testing Programs for Pumps, Valves, and Dynamic Restraints," specifies the information that the FSAR should include to fully describe the IST operational program for pumps, valves, and dynamic restraints. The COL applicant may incorporate by reference in its FSAR specific provisions provided in the DCD of the referenced DC that describe operational programs. In such instances, the staff will review the combination of the information in the COL FSAR and the provisions in the DCD to determine whether it fully describes the specific operational program.

The commitments for implementation of the operational programs should include specific implementation milestones (e.g., before fuel load or commercial service). Some operational programs have specific regulatory requirements for their implementation milestones (such as the IST programs in 10 CFR 50.55a), whereas other operational programs will have implementation milestones specified by a license condition. The number of implementation milestones depends on whether the program will be implemented on a phased basis. For example, the staff expects that the radiation protection program (RPP) will have four implementation milestones (sources on site, fuel on site, fuel load, and first shipment of waste), whereas the motor-operated valve testing program will be fully implemented at a specific milestone or before initial fuel load. Many fitness-for-duty program requirements under 10 CFR Part 26, "Fitness for Duty Programs," are implemented before construction activities.

License Conditions

The NRC will use license conditions to ensure the implementation of those operational programs for which the regulations do not specify an implementation milestone. Applicants shall implement the operational programs, or portions thereof, as specified in the regulations and the license conditions.

Applicants should expect license conditions to address implementation milestones for any operational programs for which the regulations do not address implementation milestones. Applicants should provide sufficient details on implementation milestones and later inspections to support the expected licensing conditions. The applicant may propose specific license conditions for NRC consideration and provide information that will support the determination of whether any license conditions are necessary to verify the implementation of specific aspects of an operational program. For example, the NRC imposed license conditions for the IST surveillance program for pyrotechnic-actuated valves (squib valves) at several nuclear power plants to verify that the provisions in the applicable FSARs for the IST program for squib valves were implemented.

The following provides a recommended format for license conditions:

[Name of licensee] shall implement the following programs or portions of programs identified below on or before the date [name of licensee] achieves the milestones listed:

a. the Environmental Qualification Program implemented before initial fuel load;
b. the Reactor Vessel Material Surveillance Program implemented before initial criticality; and
c. the Radiation Protection Program (RPP) or applicable portions as identified in Section 12.5 of the FSAR as follows:

    (1) RPP features applicable to receipt of byproduct, source, or special nuclear materials (excluding exempt quantities as described in Title 10 of the Code of Federal Regulations (10 CFR) 30.18, “Exempt Quantities”) implemented before initial receipt of such materials,

    (2) RPP features (including the as low as is reasonably achievable (ALARA) principle) applicable to new fuel implemented before receipt of initial fuel on site,

    (3) all other RPP features (including the ALARA principle) except for those applicable to control radioactive waste shipment implemented before initial fuel load, and

    (4) RPP features (including the ALARA principle) applicable to radioactive waste shipment implemented before the first shipment of radioactive waste.

[Name of licensee] shall, no later than 12 months after issuance of the COL, submit to the NRO Director (or Director of NRR after the merger of NRO and NRR), or the Director’s designee, a schedule for implementation of the operational programs listed in FSAR Table [13.4-x], including the associated estimated date for the initial loading of fuel. The schedule shall be updated every 6 months until 12 months before the scheduled fuel loading and every month thereafter until all the operational programs listed in FSAR Table [13.4-x] have been fully implemented.

Operational Program Options

COL applicants may incorporate by reference a generic operational program (e.g., authored by the NEI for which the NRC staff has previously prepared an SE report). In such cases, the expectation to “fully describe the program” would be considered to have been met by a COL applicant. The COL applicant should: (1) add the program to its list of operational programs in FSAR Section 13.4 adding plant-specific details as appropriate, (2) incorporate by reference the approved generic operational program description in the applicable FSAR section(s), and (3) propose an appropriate license condition for program implementation.

COL applicants may choose to use the operational program approach discussed above for other plant-specific programs that are not explicitly required by regulation. For example, a COL applicant might adopt a sump strainer cleanliness program to satisfy the emergency core cooling system requirements in the regulations. In such instances, the COL applicant should: (1) add the program to its list of operational programs in FSAR Section 13.4, (2) fully describe the program and its implementation in the respective section of the FSAR, and (3) propose an appropriate license condition for program implementation.

C.2.13 10 CFR Parts 30, 40, and 70 Materials Licenses for Combined Licenses

OVERVIEW

The regulations at 10 CFR Parts 30, 40, and 70 address the materials licensing requirements on the receipt, possession, and use of source material, byproduct material, and SNM. A COL applicant must have materials licenses to support facility construction and operation. For example, materials licenses are required to: (1) receive, possess, and use reactor fuel, (2) receive, possess, and use sealed neutron sources for reactor startup, and (3) receive, possess, and use material for sample analysis, instrumentation, and equipment calibration.

The NRC staff reviews a COLA for compliance with the requirements of 10 CFR Part 52, 10 CFR Part 50, and other regulations as needed. It is essential that a COL applicant provide sufficient information in its application to provide reasonable assurance that the applicable requirements of 10 CFR Parts 30, 40, and 70 will be met for the timeframe between the NRC's issuance of a COL and the NRC's finding under 10 CFR 52.103(g), as well as the timeframe for later operations.

In SECY-00-0092, "Combined License Review Process," dated April 20, 2000 (Ref. 103~~105~~), the Commission approved generic license conditions for 10 CFR Parts 30, 40, and 70. COL holders under 10 CFR Part 52 are authorized to receive, possess, and use source, byproduct, and SNM in accordance with 10 CFR Parts 30, 40, and 70, and applicants must address compliance with all applicable requirements in 10 CFR Parts 30, 40, and 70. To meet these requirements, the applicant should include in its application a request to receive, possess, and use source, byproduct, and SNM and provide sufficient information to support compliance with the applicable portions of 10 CFR Parts 30, 40, and 70.

The following guidance addresses the recommended approach for a COL applicant to request 10 CFR Parts 30, 40, and 70 materials licenses. The technical information that the applicant should include in its FSAR and other parts of the application to support the Commission's authorization of materials licenses appear in the SRP, as supplemented by NUREG-1520, and NUREG-1556. In addition, the NRC staff's SE reports documenting prior reviews of COLAs that requested 10 CFR Parts 30, 40, and 70 materials licenses are publicly available on the agency's Web site.

GUIDANCE

Materials Licenses Request

Under 10 CFR 52.8, "Combining Licenses; Elimination of Repetition," the COL applicant should request that 10 CFR Parts 30, 40, and 70 materials licenses be incorporated into the COL in order to receive, possess and use source, byproduct, and SNM. The applicant should identify and describe the request for materials licenses in Part 1, "General and Financial Information," of the COLA. Further, the COL applicant should provide the information sufficient to meet the applicable requirements of 10 CFR Parts 30, 40, and 70 in Part 2, "Safety Analysis Report," and other parts of the COLA.

COL applicants should request authority for activities regulated under 10 CFR Parts 30, 40, and 70 according to their needs. Historically, large LWR applicants have needed authority for the following:

a. to receive, possess, and use SNM as reactor fuel;
b. to receive, possess, and use any byproduct, source, and SNM as sealed neutron sources for reactor startup, sources for instrument and equipment calibration, sources associated with radioactive apparatus or components, sources for sample analysis, and sources for fission detectors in the required amounts; and
c. to possess, but not separate, such byproduct and SNM as may be produced by the operation of the facility.

License Conditions for a Combined License

The COL applicant should expect and may propose license conditions as needed for the COL in accordance with 10 CFR Parts 30, 40, and 70. The following are some examples taken from license conditions that have been successfully used in previous applications. These may follow a different license condition numbering system applicable to the chapter used by the applicant rather than the modeling example used below, and wording may need to be changed based on the application specifics of the site.

- License Condition (1-1)—Subject to the conditions and requirements incorporated herein, the Commission hereby licenses [applicant name]:

  (1) Pursuant to Sections 103 and 185b. of the Act and 10 CFR Part 52, to construct, possess, use, and operate the facility at the designated location in accordance with the procedures and limitations set forth in this license;

  (2)(a) Pursuant to the Act and 10 CFR Part 70, to receive and possess at any time, special nuclear material as reactor fuel, in accordance with the limitations for storage and in amounts necessary for reactor operation, described in the FSAR, as supplemented and amended;

  (b) Pursuant to the Act and 10 CFR Part 70, to use special nuclear material as reactor fuel, after a Commission finding under 10 CFR 52.103(g) has been made, in accordance with the limitations for storage and in amounts necessary for reactor operation, described in the FSAR, as supplemented and amended;

  (3) (a) Pursuant to the Act and 10 CFR Parts 30 and 70, to receive, possess, and use, at any time before a Commission finding under 10 CFR 52.103(g), such byproduct and special nuclear material (but not uranium hexafluoride) as sealed neutron sources for reactor startup, sealed sources for reactor instrumentation and radiation monitoring equipment calibration, and as fission detectors in amounts not exceeding those specified in 10 CFR 30.35(d) and 10 CFR 70.25(d) for establishing decommissioning financial assurance, and not exceeding those specified in 10 CFR 30.72 and 10 CFR 70.22(i)(1);

  (b) Pursuant to the Act and 10 CFR Parts 30, 40, and 70, to receive, possess, and use, after a Commission finding under 10 CFR 52.103(g), any byproduct, source, and special nuclear material (but not uranium hexafluoride) as sealed neutron sources for reactor startup, sealed sources for reactor instrumentation and radiation monitoring equipment calibration, and as fission detectors in amounts, as necessary;

(4) (a) Pursuant to the Act and 10 CFR Parts 30 and 70, to receive, possess, and use, before a Commission finding under 10 CFR 52.103(g), in amounts not exceeding those specified in 10 CFR 30.72, any byproduct or special nuclear material (but not uranium hexafluoride) that is: (1) in unsealed form; (2) on foils or plated surfaces, or (3) sealed in glass, for sample analysis or instrument calibration or other activity associated with radioactive apparatus or components, in amounts not exceeding those specified in 10 CFR 30.35(d) and 10 CFR 70.25(d) for establishing decommissioning financial assurance, and not exceeding those specified in 10 CFR 30.72 and 10 CFR 70.22(i)(1);

(b) Pursuant to the Act and 10 CFR Parts 30, 40, and 70, to receive, possess, and use, after a Commission finding under 10 CFR 52.103(g), in amounts as necessary, any byproduct, source, or special nuclear material (but not uranium hexafluoride) without restriction as to chemical or physical form, for sample analysis or instrument calibration or other activity associated with radioactive apparatus or components; and

(5) Pursuant to the Act and 10 CFR Parts 30 and 70, to possess, but not separate, such byproduct and special nuclear materials as may be produced by the operation of the facility.

- License Condition (1-2)—Before the initial receipt of SNM onsite, the licensee shall implement the SNM Material Control and Accounting Program. No later than 12 months after issuance of the COL, the licensee shall submit to the Director of NRO a schedule that supports planning for and conduct of NRC inspections of the SNM Material Control and Accounting program. The schedule shall be updated every 6 months until 12 months before scheduled fuel loading, and every month thereafter until the SNM Material Control and Accounting program has been fully implemented.

- License Condition (1-3)—The fire protection measures in accordance with RG 1.189 for designated storage building areas (including adjacent fire areas that could affect the storage area) shall be implemented before initial receipt of byproduct or special nuclear materials that are not fuel (excluding exempt quantities as described in 10 CFR 30.18).

- License Condition (1-4)—The fire protection measures in accordance with RG 1.189 for areas associated with new fuel (including all fuel handling, fuel storage, and adjacent fire areas that could affect the new fuel) shall be implemented before receipt of fuel onsite.

- License Condition (1-5)—All fire protection program features shall be implemented before initial fuel load.

Operational Programs Which Support 10 CFR Parts 20, 30, 40, and 70

Section C.2.12 addresses operational programs required by NRC regulations for COLs, and SRP Section 13.4 identifies the technical information that the COL applicant must include in its FSAR to support the operational programs. Several of these programs support the requirements in 10 CFR Parts 20, 30, 40, and 70 for materials licenses; the COL applicant should identify the milestones and commitments for the implementation of these programs. The milestones for the portions of operational programs applicable to radioactive materials that support the issuance of licenses and the requirements relative to 10 CFR Parts 30, 40, and 70 include the following:

a. RPP (including ALARA principles): before the initial receipt of byproduct, source, or SNM (excluding exempt quantities as described in 10 CFR 30.18;

b. fire protection program: before the initial receipt of byproduct, source, or SNM (excluding exempt quantities as described in 10 CFR 30.18);

c. security program, including physical security, safeguards contingency, training and qualification programs, and the cybersecurity program: before ~~receipt of fuel on site (protected area)~~ initial fuel load into the reactor. If the applicant plans to receive and store non-irradiated fuel or other SNM at or above the threshold for SNM of low strategic significance under the requested part 70 license before ~~the protected area is declared under the 10 CFR Part 52 license as required under~~ implementation of 10 CFR 73.55 requirements, then it should be protected in accordance with the requirements of 10 CFR 73.67. The security program should address all SNM the licensee is authorized to receive and possess;

d. fitness-for-duty program: occur before receipt of SNM;

e. non-licensed plant staff training program associated with receipt of the radioactive material: before initial receipt of byproduct, source, or SNM (excluding exempt quantities as described in 10 CFR 30.18); and

f. SNM physical protection program: before receipt of any SNM that is at or above the threshold for SNM of low strategic significance (e.g., nuclear fuel assemblies, external-to-the core detectors) and including the following elements:

(1) SNM physical protection program description, which describes the requirements in 10 CFR Part 70 for a protection program in effect for the period of time during which SNM is received and stored in a controlled access area in accordance with 10 CFR 73.67, "Licensee Fixed Site and In-Transit Requirements for the Physical Protection of Special Nuclear Material of Moderate and Low Strategic Significance";

(2) new fuel shipping plan, which addresses the applicable requirements in 10 CFR 73.67 for transport of SNM (including, for example: 1) shipment of reactor fuel and SNM that is at or above the threshold for SNM of low strategic significance, and 2) shipment that returns of to the manufacturer unirradiated fuel assemblies and/or components thereof, and/or external -to-the-reactor-core detectors); and

(3) SNM material control and accounting procedures. Note that a material control and accounting system consisting of SNM accounting procedures is used to delineate the requirements, responsibilities, and methods of SNM control from the time SNM is received until it is shipped from the plant. These procedures provide detailed steps for SNM shipping and receiving, inventory, accounting, and record and report preparation.

Clarification of 10 CFR Parts 30, 40, and 70 Materials and Use

The COL applicant should identify in the FSAR the specific types of sources, byproducts, and SNM requested to be licensed under 10 CFR Parts 30, 40, and 70. The information should include the name, amount, specifications (including the chemical or physical form and isotopic content where applicable), the use or purpose, and the maximum amount at any one time of such materials. Further, the COL applicant should provide: (1) a physical description and the amount of licensed material to be received, possessed, or used during the period between the issuance of the COL and before the 10 CFR 52.103(g) finding and provide (2) a physical description and the amount of licensed material to be received, possessed, or used after the 10 CFR 52.103(g) finding to verify that the amounts do not exceed those specified in the example license conditions provided above.

The applicant should ensure that all relevant requirements of 10 CFR Parts 30, 40, and 70 are met for all materials that it possesses, including, as needed, before the 10 CFR 52.103(g) finding. Therefore, the application should specify if, during the period before the 10 CFR 52.103(g) finding, the total quantities of such material to be possessed will exceed the quantities and forms referenced in 10 CFR 30.32(i)(1), 10 CFR 70.22(i)(1), 10 CFR 30.35(d), and 10 CFR 70.25(d). If the total quantities

referenced in any of these regulations are to be exceeded, the applicant should address how it will meet the specific requirements of those regulations in the application. In addition, the applicant should ensure that it provides any necessary information related to special nuclear material control and accountability and physical security of Part 70 material that is not addressed elsewhere in the application.

Application Information for a 10 CFR Part 70 License

The COL applicant should include the detailed information identified in NUREG-1520, 10 CFR 70.22(i)(1), 10 CFR 70.25(d), and the SRP to address the following areas for a 10 CFR Part 70 license:

a. general information—applicant identifications, location, licenses sought, financial qualifications, exemption requests, site layout, population, geography, nearby facilities, meteorology, hydrology, geology, and seismicity;
b. organization and administration—structure, management, functions, qualifications, experience, communications, and turnover of the construction to operation;
c. radiation protection;
d. criticality safety;
e. fire safety;
f. emergency preparedness;
g. environmental protection;
h. SNM material control and accountability (MC&A)—exemptions, MC&A, and fixed site security review; and
i. physical security.

Application Information for 10 CFR Parts 30 and 40 Licenses

The COL applicant should include the detailed information identified in NUREG-1556, 10 CFR 30.32(i)(1), 10 CFR 30.35(d), 10 CFR 40.36, and the SRP to address the following areas for 10 CFR Parts 30 and 40 licenses:

a. general information—license action type, legal identities, address, and points of contact;
b. radioactive materials to be possessed and used, including the element and mass number, chemical and/or physical form, and maximum amount that the applicant will possess at any one time;
c. the purpose(s) for which licensed material will be used;
d. financial assurance and recordkeeping;
e. individuals responsible for the radiation safety program and their training and experience;
f. training for workers in or frequenting restricted areas;
g. facilities and equipment;
h. radiation safety program;
i. waste management;
j. physical security; and
k. emergency preparedness.

Exemption Associated with the Material Control and Accounting Program for Special Nuclear Material

The COL applicant may find it appropriate to request an exemption from the requirements in 10 CFR 70.22(b); 10 CFR 70.32(c); 10 CFR 74.31, "Nuclear Material Control and Accounting for Special Nuclear Material of Low Strategic Significance"; 10 CFR 74.41, "Nuclear Material Control and Accounting for Special Nuclear Material of Moderate Strategic Significance"; and 10 CFR 74.51,

"Nuclear Material Control and Accounting for Strategic Special Nuclear Material," concerning an SNM MC&A program. Such an exemption allows the same regulations that apply to nuclear reactors licensed under 10 CFR Part 50 in regard to MC&A for SNM to be applied to COLs under 10 CFR Part 52. Prior COL applicants have requested and have been granted this type of exemption.

The provisions of 10 CFR 70.22(b) require an applicant to fully describe its program for MC&A of SNM under 10 CFR 74.31; 10 CFR 74.33, "Nuclear Material Control and Accounting for Uranium Enrichment Facilities Authorized To Produce Special Nuclear Material of Low Strategic Significance"; 10 CFR 74.41; and 10 CFR 74.51. The provisions of 10 CFR 70.32(c) require a license authorizing the use of SNM to include and be subject to a condition requiring the applicant to maintain and follow an SNM MC&A program, a measurement control program, and other material control procedures that include corresponding record management requirements. The regulations in 10 CFR 70.22(b), 10 CFR 70.32(c), 10 CFR 74.31, 10 CFR 74.41, and 10 CFR 74.51 contain exceptions for nuclear reactors licensed under 10 CFR Part 50, and the regulations that apply to the MC&A of SNM for nuclear reactors licensed under 10 CFR Part 50 are in Subpart B, "General Reporting and Recordkeeping Requirements," of 10 CFR Part 74, "Material Control and Accounting of Special Nuclear Material," and in 10 CFR 74.11, "Reports of Loss or Theft or Attempted Theft or Unauthorized Production of Special Nuclear Material," through 10 CFR 74.19, "Recordkeeping," except for 10 CFR 74.17, "Special Nuclear Material Physical Inventory Summary Report." However, the regulations contain no exception for nuclear reactors licensed under 10 CFR Part 52. Accordingly, a COL applicant that seeks applicability of the same regulations in regard to MC&A of SNM that apply to nuclear reactors licensed under 10 CFR Part 50 should request an exemption from 10 CFR 70.22(b), 10 CFR 70.32(c), 10 CFR 74.31, 10 CFR 74.41, and 10 CFR 74.51.

C.2.14 Information Change Processes for Combined License Applicants

OVERVIEW

Under 10 CFR Part 52, a COLA may reference an ESP or DC, or both. A COL applicant that intends to deviate from portions of the information contained in the referenced ESP or DC, or both, should comply with the 10 CFR Part 52 provisions that address the unique information change processes. A referenced ESP has regulatory finality in regard to the site as provided by 10 CFR 52.39, which describes processes for a COL applicant to request or to make a variance from ESP information. A referenced DC has regulatory finality associated with the design as provided by 10 CFR 52.63(b) and the applicable Appendix to 10 CFR Part 52. 10 CFR 52.63(b) describes the process for a COL applicant to request or to make a departure from DC information.

It is essential that the COL applicant referencing an ESP or DC, or both, maintain a clear distinction between the information contained in the COLA itself and that information formally incorporated by reference from the ESP or DC, or both. Such distinction is necessary because of the different information change control and reporting requirements. The COL applicant is responsible for ensuring that the information presented in the application is complete through a combination of formal incorporation by reference and COLA-specific material. The COL applicant is also responsible for ensuring that the application is current and accurate. If information (e.g., site characteristics) has changed since the issuance of a referenced ESP or DC, a deviation from that referenced information may be necessary (e.g., an ESP variance).

The guidance provided herein addresses the processes that a COL applicant follows when it intends to deviate from portions of the information contained in the referenced ESP or DC, or both. This guidance does not apply to a COLA that references neither a DC nor an ESP, and the guidance does not apply to an ESP or DC application. This guidance does not address generic changes to DC nor changes

directly to an ESP via amendment. Thus the terms "change" and "change processes" refer to information in a COLA that reflects a change from the information provided in the referenced ESP or DC.

GUIDANCE

Combined License Application Referencing an Early Site Permit

As required by 10 CFR 52.39, a COL applicant referencing an ESP should demonstrate that the proposed facility falls within the site characteristics and design parameters specified in the ESP and should provide information to resolve any significant environmental issues not resolved in the ESP proceeding. In addition, the COL applicant should update the emergency preparedness information that was provided under 10 CFR 52.17(b) and discuss whether the updated information materially changes the bases for compliance with applicable NRC requirements. In addition, the information change process provisions in 10 CFR 52.39 state that a COL applicant referencing ESP may include in its application a request for a variance (i.e., a change) in one or more site characteristics, design parameters, or terms and conditions of the ESP or the SSAR associated with the ESP.

The COL applicant requesting a variance should clearly identify, evaluate, and justify each variance and include such explanatory documentation in Part 7 of the COLA (see Section C.1.7).

Combined License Application Referencing a Design Certification

A COL applicant referencing a DC shall comply with the 10 CFR Part 52 change process applicable to the type of information requested to be departed from (i.e. changed). The regulation at 10 CFR 52.63(b) describes processes for a COL applicant to request an exemption and/or make a departure from DC information. In addition, the DCR appendices to 10 CFR Part 52 are similarly structured, and Section VIII of the appendices addresses the information change processes. Although the DCRs are similarly structured, each DCR requires different technical information, under the same overall process, to be subject to review and approval by the NRC staff before departures are made.

~~The DCRs of 10 CFR Part 52, Appendix A, B, C, D and E establish a two-tier hierarchy of design-related information referred to as Tier 1 and Tier 2 information which includes certain information that is further designated as Tier 2*.~~ The COL applicant intending to depart from design information should either request an exemption or follow the appropriate departure process depending on whether the information is defined as Tier 1, Tier 2, or Tier 2* or, alternatively, pertains to operational requirements. Further, as required by Section IV of the DCRs, the COL applicant should include, as part of the application, a plant-specific DCD consisting of the information in the generic DCD as modified and supplemented by the plant-specific departures and exemptions made under Section-VIII of the DCRs. Table 5 summarizes the process for COL applicants proposing a change from information contained in the DC.

Table 5. COL Applicant Change Process for DC Information

TYPE OF INFORMATION	TYPE OF CHANGE	REQUIREMENTS FOR CHANGE
Tier 1	Exemption	DCR Section VIII.A.4 10 CFR 52.63(b)(1) 10 CFR 52.7 10 CFR 50.12(a)
All Tier 2 including 2*	Exemption†	DCR Section VIII.B.4 10 CFR 50.12(a)

TYPE OF INFORMATION	TYPE OF CHANGE	REQUIREMENTS FOR CHANGE
Operational Requirements	Exemption	DCR Section VIII.C.4 10 CFR 52.7 10 CFR 50.12(a)
Tier 2*	Departure (prior NRC approval required)	DCR Section VIII.B.6.a
Tier 2	Departure (prior NRC approval required)	DCR Section VIII.B.5
Tier 2	Departure (prior NRC approval not required)	DCR Section VIII.B.5 (Note that the departure does not involve a change to or departure from Tier 1, Tier 2*, or the generic technical specifications or otherwise require prior NRC approval.)

† An exemption is not automatically required for changes to Tier 2 information.

The COL applicant should identify, evaluate, and justify each exemption request and proposed departure. The applicant should include such explanatory documentation in Part 7 of the COLA (see Section C.1.7).

Changes to Tier 1 Information

As defined in ~~Section II, "Definitions," of the DCRs~~§52.1, Tier 1 is the portion of the generic DCD that is approved and certified by the DCR. It includes definitions and general provisions, design descriptions, ITAAC, significant site parameters, and significant interface requirements. It is derived from the more detailed information in Tier 2 (described below).

Because the information in Tier 1 represents the certified portion of the design, strict requirements for changes to this information are in place. A COL applicant requesting an exemption should describe the basis for the change (grouped by topic where appropriate) and justify the regulatory acceptability, as well as provide the appropriate revisions to the generic DCD in the plant-specific DCD. When the exemption involves an underlying substantive requirement (e.g., a regulation in 10 CFR Part 50), the COL applicant should also show, as appropriate under 10 CFR 52.7, that the exemption from the underlying applicable requirement meets the criteria in 10 CFR 50.12.

Information that departs from Tier 1 of the generic DCD, if approved by the NRC staff using the exemption process, becomes part of Tier 1 in the plant-specific DCD ~~(as defined in Section II of the DCR)~~ that is maintained by the applicant or licensee. For this reason, this information remains subject to the Tier 1 change process.

Changes to Tier 2 Information

As defined in ~~Section II of the DCRs~~§52.1, Tier 2 is the portion of the generic DCD that is approved but not certified by the DCR. It includes the following:

a. the information required by 10 CFR 52.47(a) and (c) except for generic technical specifications and conceptual design information,
b. supporting information on ITAAC,

c. COL action items, and
d. other items listed in the DCR as included in Tier 2.

Section VIII.B of the DCRs describes the process for making changes, some of which may be made without prior NRC approval. Sections VIII.B.5.b (for most Tier 2 information), VIII.B.5.c (for severe accident features), and VIII.B.5.d (for aircraft impact assessment) of the DCRs provide the criteria for determining whether prior approval is required. The criteria in Section VIII.B.5.b of the DCRs are similar to those in 10 CFR 50.59 and relate to accident analyses, SSC functions, design-basis limits, and methods of evaluation. An exemption is not automatically required because the material is approved but not certified; however, an applicant may determine that requesting an exemption from Tier 2 material in certain cases is appropriate.

A COL applicant departing from Tier 2 of the generic DCD should describe the basis for the change (grouped by topic where appropriate), justify the regulatory acceptability, and provide the appropriate revisions to the generic DCD in the plant-specific DCD. It should provide this information regardless of whether the individual change requires prior NRC approval. In determining that a change does not require prior NRC approval, the applicant should verify that the Tier 2 change does not affect Tier 1, Tier 2*, or the generic technical specifications. Departures from Tier 2 made in compliance with Section VIII.B.5 of the DCRs that do not require prior NRC approval will be considered resolved. The NRC staff will not re-review these departures in the COL proceeding, as described in Section VI.B of the DCRs. The applicant's compliance with the Tier 2 change controls in the DCR is subject to the NRC staff's inspection.

The basis for this position, as described in NUREG-1503, Final Safety Evaluation Report Related to the Certification of the Advanced Boiling Water Reactor Design, Supplement 1, May 1997 (Ref. 104~~106~~) is that the departure process, if it is properly implemented by a COL applicant, "must logically result in departures which are both 'within the envelope' of the Commission's safety finding for the DCR and for which the Commission has no safety concern. Therefore, it follows that properly implemented departures from Tier 2 should continue to be accorded the same extent of issue resolution as that of the original Tier 2 information from which it was 'derived.'"

Departures from Tier 2 of the generic DCD, executed according to the change control process described above and approved by the NRC staff where necessary, become part of Tier 2 in the plant-specific DCD ~~(as defined in Section II of the DCR)~~ that is maintained by the applicant or licensee. As such, this information remains subject to the Tier 2 change process.

Changes to Tier 2* Information

Tier 2* is different from the remainder of Tier 2 because NRC approval is required for any change, as described in Section VIII.B.6 of 10 CFR Part 52, Appendices A-E. The category of Tier 2* information was established during the NRC's initial DC reviews. During this development process, these applicants requested that the agency minimize the amount of information in Tier 1 to allow additional flexibility for a COL applicant or licensee who references a DCR. Tier 2 also specified many codes, standards, and design processes that Tier 1 does not specify but that the staff found acceptable for meeting ITAAC. As a result, Tier 2 contains certain significant information that cannot be changed without prior NRC approval. This information is designated Tier 2* and is generally marked with italics or brackets and an asterisk in the generic DCD.

SECY-17-0075, "Planned Improvements in Design Certification Tiered Information Designations," (Ref. ~~1~~10507), summarizes background information and provides information on planned changes related to Tier 2* information. The SECY noted that the 2007 update of 10 CFR Part 52

specifically described Tier 2* information as having the same safety significance as Tier 1 information and clarified that Tier 2* would have received Tier 1 designation had NRC not decided to provide more flexibility (72 FR 49352, Licenses, Certifications and Approvals for Nuclear Power Plants, p.49365, August 28, 2007). SECY-17-0075 describes staff plans to retain the use of Tier 2* information going forward with improved guidance. Regarding interpretation and implementation of SECY-17-0075, staff clarified at a public meeting via discussion of a handout entitled "Designation of Tier 2* Information, APR1400 Design Certification," August 16, 2017 (Ref. ~~1~~10~~608~~), that going forward, Tier 2* information must be demonstrated to have the same safety significance as Tier 1 and that Tier 2* information should be applied only when an applicant determines the additional flexibility for making changes could be beneficial.

A portion of this information retains its Tier 2* designation throughout the duration of a COL license, including any license renewal, because of the need for NRC review of any changes. The remainder is associated primarily with construction detail and, therefore, reverts to the standard process for Tier 2 information after the Commission makes its finding in accordance with 10 CFR 52.103(g) that the acceptance criteria in the COL are met. Examples of these two groups of information for the AP1000 DCR can be found in Section VIII.B.6.b (e.g., fuel information) and Section VIII.B.6.c (e.g., structural dimensions of the nuclear island) of Appendix D, "Design Certification Rule for the AP1000 Design," to 10 CFR Part 52.

A COL applicant proposing to depart from Tier 2* information in the generic DCD should describe the basis for the change (grouped by topic as appropriate), justify the regulatory acceptability, and provide appropriate revisions to the plant-specific DCD. Requests for departures from Tier 2* information that affect Tier 1 should also follow the Tier 1 change procedures described above.

Information that departs from Tier 2* of the generic DCD, if approved by the NRC staff using the license amendment process, generally becomes part of Tier 2* in the plant-specific DCD (as defined in Section II of the DCR) that is maintained by the applicant or licensee. For this reason, this information generally remains subject to the Tier 2* change process. Alternatively, SECY-17-0075 also states that COL applicants and licensees may request to change the designation of certain Tier 2* in their plant-specific FSAR and that such requests would be reviewed on a case-by-case basis.

Changes to Operational Requirements

In some cases, an operational requirement may be completely reviewed and approved as part of the DC rulemaking such that it is not reviewed by the NRC staff in the COL proceeding. Generic technical specifications (except for the COL action items - bracketed values and bracketed site-specific information) are an example of these operational requirements. For this category of information, a COL applicant intending to change this information should request an exemption, as described in Section VIII.C of the DCRs. The Commission may grant such a request only if it determines that the exemption will comply with the requirements of 10 CFR 52.7. It is advantageous for the generic DCD, COLA, and associated SE reports to clarify which information is considered an operational requirement within this category of information.

COL applicants should also be aware that, in a COL proceeding, the Commission may change operational program elements that were completely reviewed and approved in a DCR. If this change also involves a change to a design feature in the generic DCD, then the requirements of 10 CFR 52.63 apply. If a change to a design feature in the generic DCD is not involved, the Commission will not make generic changes to such operational requirements unless the standards of 10 CFR 50.109, "Backfitting," are met and will not make plant-specific changes to such requirements unless the standards of 10 CFR 2.335, "Consideration of Commission Rules and Regulations in Adjudicatory Proceedings," are met.

For those elements of an operational program that are outside the DC scope and were not completely reviewed and approved in the generic DCD, the Commission will need additional information to support the findings necessary for COL issuance. In particular, COL applicants should address COL action items related to operational programs and provide plant-specific values for the generic technical specifications. Sections C.2.11 and C.1.4 provide guidance on COL action items and technical specifications, respectively.

C.2.15 Environmental Issue Finality for Combined License Applicants

OVERVIEW

The provisions of 10 CFR Part 52 state that a COLA may reference an ESP or DC, or both. A referenced ESP has regulatory finality concerning the site as provided by 10 CFR 52.39, and a referenced DC has regulatory finality associated with the design as provided by 10 CFR 52.63. The regulations in 10 CFR 51.50 require the COLA to include an ER entitled, "Applicant's Environmental Report—Combined License Stage," and state that the ER may incorporate by reference the EIS previously prepared by the NRC for the referenced ESP and/or may incorporate by reference the EA previously prepared by the NRC for the referenced DC.

The guidance herein addresses the finality of environmental issues for a COLA referencing an ESP or DC, or both, and the processes that the COL applicant should follow for identifying and evaluating environmental information and preparing the ER.

GUIDANCE

Finality of Environmental Issues Associated with an Early Site Permit

The NRC staff's review of an ESP application results, in part, in the staff's preparation of an EIS to: (1) inform the Commission's decision, (2) determine whether an obviously superior alternative site exists, and (3) disclose, to the extent addressed by the applicant, the environmental impacts associated with constructing and operating one or more nuclear facilities. For a COLA referencing an ESP, the EIS prepared for the ESP is an important starting point for the COL applicant when preparing the COL ER. The ESP EIS resolves environmental issues within certain bounding conditions; therefore, such issues are considered resolved at the COL stage as long as no "new and significant" information has become available. For issues resolved at the ESP stage, if no new and significant information is identified at the COL stage, the NRC staff may rely on or "tier off" the ESP EIS and will state in the COL EIS its conclusion as set forth in the ESP EIS. For the ESP stage, 10 CFR 51.50 (b)(1) states that the ER "must address all environmental effects of construction and operation necessary to determine whether there is any obviously superior alternative to the site proposed. The ER need not include an assessment of the economic, technical, or other benefits (for example, need for power) and costs of the proposed action or an evaluation of alternative energy sources." Conversely, if a given environmental issue was not resolved at the ESP stage for rare instances in which sufficient information outside the control of the applicant was not available to permit resolution (e.g. pending a biological assessment by U.S. Fish and Wildlife Service) or because the ESP applicant was permitted to defer the issue (e.g., benefits assessment), the COL applicant should address the issue in the COL ER.

The COL applicant referencing an ESP should provide information sufficient to resolve any significant environmental issue that was not resolved in the ESP proceeding. The information in the COLA should be sufficient to aid the NRC staff in developing its independent analysis (see

10 CFR 51.45, "Environmental Report"). In addition, 10 CFR 51.50(c)(1)(i) requires the COL applicant to provide information "to demonstrate that the design of the facility falls within the site characteristics and design parameters specified in the early site permit." In the absence of new and significant information or other influencing factors, site characterization information in an ESP can be considered valid to a COLA submitted prior to the expiration of the ESP. The demonstration that a facility will fall within the ESP's site characteristics and design parameters is part of the information that the COL applicant should provide in its ER to enable the NRC staff to perform the analyses that is included in the COL EIS under 10 CFR 51.92(e). This demonstration involves providing actual design or site characteristics and showing that the actual values are bounded by the values set forth in the ESP. For example, if the ESP specified a system flow rate of less than or equal to 5,000 gallons per minute (gpm), it would not be sufficient for the COL ER to include a statement that the actual flow rate is less than or equal to 5,000 gpm; instead, the ER should provide the actual system flow and show that it is bounded in a conservative direction by the flow value assumed in the ESP. In addition, the COL ER should demonstrate that all environmental terms and conditions of the ESP will be satisfied by the date of issuance of the COL. In some instances, however, terms or conditions of the ESP that cannot be satisfied before issuance of the COL may be addressed by including terms or conditions in the COL.

The regulations in10 CFR 51.50(c)(1)(iii) require the COL applicant to identify whether "new and significant" information has become available for environmental issues. The COL applicant should have a reasonable process for identifying "new and significant" information with respect to an NRC conclusion documented in the ESP EIS and should document the results of this process in an auditable form for issues for which the COL applicant does not identify "new and significant" information. The COL ER should address issues for which the COL applicant does identify "new and significant" information. Under 10 CFR 51.70(b), the NRC is required to independently evaluate and be responsible for the reliability of all information used in the EIS, including an EIS prepared for a COLA. Toward that end, the NRC staff may: (1) inquire into changes to information disclosed in an ESP EIS that is referenced in a COLA and (2) identify new information that may affect the assumptions, analyses, or conclusions in the ESP EIS. If the staff determines that new information that was not submitted is significant, it may send a request to the applicant to submit the information.

In the context of a COLA that references an ESP, the NRC staff defines "new" (as in "new and significant" information) as information that was: (1) not generally known or publicly available during the preparation of the EIS and thus was not considered in preparing the ESP ER or EIS and (2) has become known and available since the issuance of the ESP. New information may include, but is not limited to, specific design information that was not available during the review of the ESP application (especially where the design interacts with the environment) or information that was in the ESP application but has changed by the time of the COLA submittal (e.g., a change in the regional socioeconomic profile resulting from a natural event like Hurricane Katrina). New information may or may not also be "significant." For example, if a draft supplement to a referenced ESP's EIS prepared by NRC staff for a COLA under 10 CFR 51.75 (c)(1) identifies a new threatened or endangered species located within the identified area of potential effect, the staff will treat this as "new" information and will perform all necessary consultations and assessments to determine the significance of the new information.

For new information to be "significant," it should be material to the issue being considered (i.e., it has the potential to affect the finding or conclusions of the NRC staff's evaluation of the issue.) The COL applicant only needs to provide information about a previously resolved environmental issue if it is both new and significant.

The COL applicant should have a reasonable and auditable process to identify "new and significant" information, as required by 10 CFR 51.50(c)(1)(iv), and should describe the process in the ER. This process description should include: (1) the methods that the COL applicant uses to ensure that

it identifies new information if it exists and (2) the process used for evaluating the significance of such new information. Methods used to ensure identification of new information include the following:

a. reviewing environmental monitoring results;
b. reviewing related scientific literature;
c. conferring with environmental professionals familiar with the site environs (e.g., environmental and operations staff of a nearby nuclear or industrial facility);
d. exchanging information within the industry through peer groups and industry organizations;
e. consulting with subject matter experts knowledgeable of the local environment;
f. consulting with Federal, State, Tribal, and local environmental, natural resource,
g. permitting, and land use agencies;
h. verifying that the assumptions and representations made in the ESP ER are still valid;
i. verifying that the NRC staff's assumptions documented in the ESP EIS are still valid; and
j. reviewing information needed to perform the review described in the Environmental Standard Review Plan (NUREG-1555) and RG 4.2.

The COL applicant's process for evaluating the significance of new information should also include the organizational procedures for handling reports of new information and the criteria used to determine the applicability of such information. The ER does not need to include detailed supporting information, but such information should be available in auditable form for review by the NRC staff. Such supporting information may include the following:

- qualifications of participants involved in the process, their organizational affiliations, how they interact among themselves, and the role they serve in the process;

- communications with subject matter experts and Federal, State, Tribal, and local environmental, natural resource, permitting, and land use agencies; and

- new information identified and the assessment of its significance (with information that the applicant determines to be both new and significant submitted in the ER) (10 CFR 51.50(c)(1)(iii)).

Finality of Environmental Issues Associated with a Design Certification

The NRC staff's review of a DC application results, in part, in its preparation of an EA. For a COLA referencing a DC, the COL ER may incorporate by reference the EA prepared for the referenced DC, thereby resolving for the COL applicant those environmental issues that were previously resolved in the DC EA. The COL applicant should provide sufficient information in the COL ER to demonstrate that the site characteristics for the COL fall within the site parameters in the DC EA (10 CFR 51.50(c)(2)).

For matters resolved at the DC stage, if the site characteristics for the COL fall within the site parameters in the DC EA, the NRC staff may rely on or "tier off" the DC EA and will state in the COL EIS its conclusion set forth in the EA for the DC.

C.2.16 Finalizing Licensing-Basis Information

OVERVIEW

In 2008, the NRC staff recognized that activities such as engineering, procurement, and program development generally continue throughout and following licensing and certification reviews and that applicants for DCs, COLs, or other licenses or permits issued under 10 CFR Part 52 may need to define a point during the review process at which the licensing-basis information is considered final. This issue was discussed during public meetings held in September and November 2008 for which a discussion paper entitled "Controlling Design and Plant-Specific Changes During The Review of Licensing Applications Related to New Reactors" (Ref. ~~1~~107~~09~~) was provided. The NRC staff received preliminary comments from the NEI in an e-mail dated November 25, 2008 (Ref. 108~~10~~). The NRC staff subsequently issued a proposed ISG on May 28, 2009 (Ref. 10~~1~~9~~1~~) and final guidance (DC/COL-ISG-011, "Finalizing Licensing-Basis Information") on November 2, 2009. This regulatory topic provides updated guidance for current and future applicants and allows the retirement of DC/COL-ISG-011.

An applicant for a COL or DC may choose to finalize licensing-basis information at a point during the licensing review and then defer any subsequent licensing-basis information changes or additions until after the licensing or certification process is complete. The licensing-basis specified for final review before licensing and certification has been referred to as a "freeze point," and the process has been used by both COL and DC applicants. When a licensing-basis freeze point is defined, the licensing or certification decision will be based on the information that has been provided to the NRC on or before the applicant established freeze point. NRC reviews can take many months to complete. Having the applicant define a licensing-basis freeze point has supported the staff's ability to establish a predictable schedule for completion of the later phases of the reviews, thereby increasing the efficiency and reliability of the review process.

An applicant for a DC or COL is not required to define a freeze point, and the rationale for defining a freeze point may not be sufficient in future reviews to support this choice. Although this guidance is also applies to ESPs, the concept of a freeze point has primarily been associated with COL and DC applications. For DCs, using a freeze point in the generic design review results in significant challenges because any revisions after the DC involve either additional rulemakings or departures on multiple COLs that reference the DC. This regulatory topic preserves key guidance from the retired DC/COL-ISG-011 and focuses on criteria that would identify changes that are inappropriate to defer beyond licensing or certification and, therefore, would require a change to the licensing basis. Although a freeze point does not directly relate to COLAs that reference a DC with errors identified after certification, the guidance provided on safety significance applies and is discussed.

GUIDANCE

General Guidance

The concept of the freeze point reflects an applicant's ability to defer the submission of additional design changes and information for review until after licensing or certification. A requirement for a formal declaration or correspondence on such a decision does not exist, and the most recent submission of an application represents a de facto "freeze point" if the applicant does not formally identify a licensing-basis freeze point. In all cases, sufficient information is provided to support findings that are necessary in a FSER for a COL or DC application.

If an applicant chooses to defer submission of planned design changes, it may only do so if it

does not affect information that the staff relies on for its safety determination. The NRC staff may require an applicant to supply additional information to support its review under 10 CFR 2.102, and the NRC may deny an application, under 10 CFR 2.108, if the applicant fails to respond to an RAI within 30 days of the date of the request or within such other time as may be agreed upon between the NRC staff and the applicant. Under no circumstances will the NRC grant an application that does not satisfy the requirements of the AEA and the Commission's regulations.

Certain changes should not be considered for deferral because of their relevance to the staff's conclusions with respect to the requested certification or licensing decision. Categories of those changes that should not be deferred include, but are not limited to, the following:

a. the correction of significant errors in an application,
b. changes needed to ensure compliance with NRC regulations,
c. changes needed to support other licensing-basis documents (e.g., conforming changes to information in the FSAR supporting generic or plant-specific technical specifications),
d. the correction of significant technical errors associated with the design or program described in the licensing document (i.e., not making such corrections would preclude operation within the bounds of the licensing basis as opposed to proposed alternatives to the described design or program), and
e. changes needed to address a significant vulnerability identified by PRAs or other studies (e.g., a change in a PRA insight).

A COL or DC applicant that plans a change that falls under the above list should inform the NRC immediately. The NRC staff recommends that the applicant provide information, when available and appropriate, to support its determinations on whether addressing the design error can be deferred based on the level of its impact on the NRC's SE.

The applicant that defines a freeze point will need to rely on its programs to evaluate, track, and report (as appropriate) those changes identified after the licensing-basis freeze point. The applicant's processes will need to support its determinations on whether immediate notification of the NRC is warranted based on its potential impact on the NRC's SE so that the information may be considered in the pending licensing or certification decision. If immediate notification is not warranted, inclusion of the information in the application for the applicant's convenience may significantly delay the NRC's ultimate decision on the application. If the NRC grants the requested certification or license, the NRC staff anticipates that the applicant and DC vendor would use established change control processes to manage changes identified after the licensing-basis freeze point. For potential changes to a DC, ESP, or COL that are identified following the licensing-basis information freeze point, the applicant will need to ensure that it has met the reporting requirements for those specific changes for which submittals are deferred until after the issuance of the DCR or license.

The NRC staff and DC and COL applicants will need to closely coordinate their activities related to the reviews of each proposed design and COLA, including COLAs that reference a design certification that is still under review. Discussion of creating or changing a freeze point will facilitate this coordination and is strongly recommended. Although a formal notification referencing a freeze point is not required, the applicant should be clear on the design version that should be reviewed. The requirements in 10 CFR 50.30(a)(1) state that amendments to applications are submitted in accordance with 10 CFR 52.3 or 10 CFR 50.4, "Written Communications." Communicating clearly about the design version to be reviewed is also critical to the identification of appropriate review activities by the NRC staff to be covered by licensing fees stipulated under 10 CFR 52.45, "Filing of Applications," for DCs and 10 CFR 52.75, "Filing of Applications," for COLs.

Finalizing Licensing-Basis Information for Combined License Applications

For COL applicants, proposed changes to licensing-basis information provided in the FSAR or other documents that are identified following the freeze point would usually be controlled by the applicant and not submitted to the NRC for review in connection with the COLA (other than those of a type described in the general guidance section of this regulatory topic). Instead, the COL applicant would track the potential changes and, if the COL is granted, would later request the change under the appropriate control process and submit an LAR if such a submittal is required by NRC regulations. If no amendment is necessary, the applicant would submit updates to the FSAR or other documents in accordance with established reporting requirements. Changes to the licensing basis which should not be deferred because of their role in supporting staff's findings that are necessary in an FSER for a COL or DC application must be submitted to the NRC for review during the licensing process.

A COL applicant that indicates an intent to reference a DC that is still under review and not yet certified or approved bears the schedule risk associated with the DC review in addition to those schedule risks that are relevant to a COLA. Such a COL applicant should ensure that it synchronizes the information in the COLA with the information in the DC application as it is revised and supplemented during the review process and should submit a revision to its COLA, including the FSAR and other affected documents, upon the completion of the NRC's review of the referenced DC application.

Finalizing Licensing-Basis Information for Design Certifications

For DC applicants, proposed changes (other than those of a type described in the general guidance section of this regulatory topic) that are identified following the freeze point will not be included in the documents supporting the certification and, therefore, will not be part of the approved or certified design. Once the DCR is finalized, assuming that there are no subsequent DC amendments, changes that affect the DC FSAR that are identified after the freeze point would not be implemented unless they are proposed by a license applicant or licensee as departures from the certified design. The DC applicant would identify such potential departures to COL applicants or COL licensees that could, if they so choose, identify them as requested departures or exemptions in a COLA, an update to a COLA, or in a periodic report submitted by a COL applicant as applicable. The treatment of these proposed changes by the COL applicant could depend on the status of the DC application relative to the freeze point for the COLA. Until such changes are incorporated into an amendment to a DC, they would need to be handled as departures or exemptions, assuming that they meet the threshold in the applicable change control process. COL applicants may identify such departures or exemptions as standard content associated with an R-COL under the design-centered review approach described in RIS-2006-06 and discussed in Section C.2.7. To facilitate the NRC's review for S-COL applications, changes to the licensing basis which should not be deferred because of their role in staff's review of reasonable assurance of adequate safety are submitted to the NRC for review during the review and certification process.

For DCs, defining a freeze point has more significant and longer term impacts than that of a COLA. Under 10 CFR 52.63(a), later revisions that reflect additional design changes require rulemaking under a lengthier and more complex process than that of licensing departures associated with COLs under 10 CFR 52.98(e) and 10 CFR 50.91, "Notice for Public Comment; State Consultation." Any revisions to the DC would ultimately affect all COLs that reference the DC, those COLAs that reference the DC, as well as potential COL applicants that are still in the preapplication phase. Under 10 CFR 52.57, an application for DC renewal could alternatively include design changes after the freeze point; however, the time between certification of the DC and the expected renewal request could be significant. Unlike a DC

amendment, however, a DC renewal does not impact existing applicants or licensees that incorporate by reference a prior revision of the DC.

An example of information that may change frequently during a review relates to the fuel assembly design described in a particular DC application. In this example, a DC application or an amendment to a DC application is being reviewed by the NRC staff, and the reactor vendor identifies a proposed enhancement to its fuel assembly design. Supporting documents for the revised fuel assembly design may even have been submitted to the NRC for review and, in some cases, may already have been reviewed and approved by the NRC. The change in the fuel assembly design then becomes a departure recommended by the vendor for future COLAs or COL applicants that incorporate by reference the certified design. The COL applicant may propose to use the changed fuel design in its COLA or may continue to reference the certified design, including the original fuel assembly design, and submit the appropriate LAR and FSAR updates following the issuance of the COL. In either case, the fuel assembly design ultimately used in the reactor will have satisfied all applicable NRC requirements.

Errors in Design Certifications Referenced by Combined License Applications

Once one or more COLAs have been submitted that reference a specific DC, additional design work is required to address COL action items (as discussed in Section C.2.11), demonstrate compliance with interfacing system requirements in the DC, include proposed ITAAC, describe site-specific design features, and demonstrate that actual site characteristics fall within the site parameters specified in the DC. Similarly, initial COL licensees may need to resolve constructability issues encountered during the construction process. In the course of this work, the DC vendor or the COL applicant or licensee may identify errors in the certified design that are of a generic nature.

Regardless of whether an error in the DC is identified before or after a selected freeze point for the COLA, or in the case that no freeze point was specifically declared by the applicant, the general guidance of this regulatory topic applies. Notwithstanding the requirements in 10 CFR 52.63, the AEA requires the NRC to make the final safety finding for both construction and operation when it issues a COL. In making this finding for a COL applicant referencing a DC, the NRC relies on the safety findings made during the DC review. This reliance, however, must be reasonable. However, if the NRC knows of a significant error in the DC that undermines the statutorily required COL safety findings, the NRC may issue the COL only after the error is adequately addressed to enable the Commission to make the required findings. The resolution of a DC design error cannot be deferred until after a COL license is issued if it affects the information that the staff relies on in making its determination. Under no circumstances will the NRC grant an authorization or license that does not satisfy the requirements of the AEA and the Commission's regulations.

The regulations in 10 CFR Part 21 require any individual director or responsible officer of a firm constructing, owning, operating, or supplying the components of any facility or activity, which is licensed or otherwise regulated under the AEA or the Energy Reorganization Act of 1974, who obtains information reasonably indicating that: (1) the facility, activity, or basic component supplied to such facility or activity fails to comply with the AEA or any applicable rule, regulation, order, or license of the Commission relating to substantial safety hazards or (2) the facility, activity, or basic component supplied to such facility or activity contains defects that could create a substantial safety hazard to immediately notify the Commission of such failure to comply or such defect unless he or she has actual knowledge that the Commission has been adequately informed of such defect or failure to comply.

Under 10 CFR 52.6, information provided to the Commission by an applicant for a license and information required by statute or by the Commission's regulations to be maintained by an applicant for a

license should be complete and accurate in all material respects. A COL applicant that becomes aware of a potential design error, as described in "General Guidance" of this section of the RG, should inform the NRC immediately. The staff recommends that the applicant provide information, when available and appropriate, to support its determination on whether addressing the design error can be deferred based on its level of impact on the NRC's safety finding reported in its SE.

A COLA that references a DC bears schedule risk associated with any safety-significant design errors in the referenced DC that are identified after certification. Such design errors that affect the NRC staff's ability to reach conclusions necessary to support findings in the FSER, as described in "General Guidance" of this section of the RG, will require a change in the licensing-basis information. Although a freeze point does not directly relate to post-certification errors, similar considerations concerning safety significance apply.

For each DC, the NRC may choose to document safety-significant design errors and their resolution in a RIS and include additional errors, if any are found, in a supplement to the RIS. If the vendor decides to file a timely renewal of the certification, the NRC would expect these errors to be included in the scope of the review. Industry organizations or design-specific DCWGs, as described in RIS 2006-06, could additionally document such design errors and their resolution.

C.2.17 Small Modular Reactors and Design-Specific Review Standards

Prospective applicants have notified the NRC of their intent to submit applications under 10 CFR Part 52 for light-water SMR designs. The characteristics of SMRs present several potential policy, technical, and licensing issues for the NRC. However, the NRC staff has identified these issues and developed plans to address them and is prepared to review applications for all types of light-water SMRs as discussed in SECY-14-0095, "Status of the Office of New Reactors Readiness to Review Small Modular Reactor Applications," dated August 28, 2014 (Ref. 1[10~~12~~]).

A DSRS provides a means to enhance the effectiveness and efficiency of the NRC staff's review of light-water SMR applications that incorporate new and/or innovative design features. Each DSRS is specific to a particular SMR design. The NRC staff develops the DSRS based on plant design and other information provided by the prospective applicant during the preapplication timeframe. The development of a DSRS covering all chapters of the SRP requires approximately 2 years, however, the timeline for a DSRS could be less if staff determines that review of only select portions of the SRP is warranted. The completed DSRS serves the same purpose and has the same objectives as the SRP for non-SMR application reviews. The development and use of a DSRS is not a requirement and is voluntary at the discretion of the prospective SMR applicant.

OVERVIEW

Commission Policy

In response to the Commission's direction, the staff prepared SECY-11-0024, "Use of Risk Insights to Enhance the Safety Focus of Small Modular Reactor Reviews," dated February 18, 2011 (Ref. 1[11~~13~~]). In SRM-SECY-11-0024, "Use of Risk Insights to Enhance the Safety Focus of Small Modular Reactor Reviews, dated May 11, 2011 (Ref. 1[12~~14~~]), the Commission approved, and directed the staff to implement, the staff's recommendations in SECY-11-0024 for the development of a design-specific, risk-informed review plan for each SMR design.

NRC Staff Implementation

Consistent with the Commission's direction in SRM-SECY-11-0024 and the staff's recommendations in SECY-11-0024, the staff developed a review framework for light-water SMRs and documented the approach and provisions for implementation in a revision to NUREG-0800, "Introduction—Part 2, 'Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants: Light-Water Small Modular Reactor Edition,'" Revision 0, issued January 2014 (Ref. 1131~~5~~). The light-water SMR review framework documented in this SRP revision is distinct from that used by the staff for non-SMR applications; however, it satisfies the same objectives and purposes and does not change any NRC requirements for either applications or applicants. The key element of the light-water SMR review framework is the development and use of a DSRS, however, the conceptual approach has relevance to large LWR and non-LWR and has informed the development of the ESFRA discussed in Section C.2.1 of this guidance.

The NRC staff intends the SMR review framework to enhance the effectiveness and efficiency of the application review process by aligning the staff review focus and resources with risk-significant SSCs and other aspects of an SMR design that contribute most to safety. The SMR review framework builds upon the review process used for non-SMR applications. The staff implements the review framework for a specific SMR design during preapplication interactions and the application review process. The success of the implementation depends on both the willingness of the prospective applicant to engage with the NRC staff and the availability and timeliness of detailed safety and risk information from the prospective applicant. The staff documents the results of applying the review framework for the specific design in the DSRS.

Standard Review Plan and Design-Specific Review Standards

The SRP is the comprehensive and integrated document that provides the NRC staff reviewer with guidance describing methods or approaches that the staff has found acceptable for meeting NRC requirements. The staff's implementation of the guidelines and the review criteria in the SRP during the review of applications provides assurance that a given design will comply with NRC regulations and provide adequate protection of the public health and safety. The SRP is maintained current through an ongoing update and revision process and is publicly available. For SMR applicants that choose not to engage the NRC staff in development of a DSRS, the staff reviews a submitted application using current SRP guidance and methods.

Each DSRS serves the same purpose and has the same objectives as the SRP. For a prospective applicant that agrees to participate in the DSRS preapplication activities described below, the staff develops a DSRS for the prospective applicant's specific SMR design. The DSRS aligns with the SRP, and each DSRS includes a "safety review matrix" that provides a detailed cross-reference to the SRP.

GUIDANCE

A prospective applicant that wishes to engage with the NRC staff in preapplication activities for DSRS development should: (1) be familiar with the scope and extent of requisite preapplication activities, (2) be cognizant of the schedule duration (approximately 2 years), (3) be prepared to commit the necessary budget and resources, and (4) be prepared to actively interact with the NRC management, regulatory, and technical staff throughout the DSRS development.

The potential benefits of a DSRS are dependent on a number of factors including the number

of areas identified for new or revised guidance to staff and the timelines related to the availability of detailed design information. In order to further enhance the efficiency of reviews beyond development of a DSRS, staff developed the ESFRA which includes the ESFRA SSC review tool as well as internal guidance to staff and associated tools regarding reviews that do not specifically include SSC such as operational programs, as discussed in Section C.2.1 of this guidance. SRP Introduction - Part 2 laid the initial foundation for categorization of SSC into four review levels. Development of a DSRS is not a requirement for staff's initiation of ESFRA activities and the limitations and constraints related to the timeline of the DSRS development process need not affect implementation of ESFRA by staff for an individual review.

The sections below summarize the process and activities necessary for a prospective applicant to engage with the NRC staff to facilitate successful DSRS development.

Standard Review Plan Introduction - Part 2

To prepare for interactions with the NRC staff, the prospective applicant should be familiar with SRP Introduction - Part 2. The prospective applicant's management should have general familiarity to support planning, scheduling, and resource allocation, and the regulatory and technical staff should have a comprehensive understanding of the light-water SMR design to support engagement with the NRC staff and to facilitate the development of the DSRS. Although SRP Introduction - Part 2 was prepared to provide detailed guidance to the staff for implementation of the SMR review framework, it contains a comprehensive and detailed description of regulatory and technical considerations that can be used to enhance the effectiveness and efficiency of the application review process for large LWR and non-LWR technologies.

Design-Specific Review Standard Development

The prospective applicant should initiate the DSRS development process by formally notifying the NRC staff of its intent to engage the staff in the development of a DSRS for its SMR design. Following notification, the NRC staff will consider whether: (1) the prospective applicant has sufficient commercial intent, organizational capacity, and design maturity to support meaningful interactions with the NRC staff on regulatory requirements, (2) there is a reasonable expectation that the prospective applicant will submit an application, and (3) a DSRS will enhance the effectiveness and efficiency of the application review process. The staff then initiates interactions with the prospective applicant to develop the DSRS.

The prospective applicant should engage the NRC staff in a manner to support parallel development of both the DSRS and the SMR design. Typically, the design evolves from a concept through preliminary stages to a final design. Correspondingly, the DSRS development is iterative and evolves from a partial to complete draft to a final version over a period of approximately 2 years. The overall DSRS schedule incorporates both the NRC staff's development of DSRS content and the mandatory publication of the draft DSRS in the *Federal Register* for public review and comment. The staff's intent is to complete and publish the publicly available draft DSRS 1 year before submittal of the application and to issue the final DSRS for use not later than the date of the docketing of the application.

Consistent with the NRC's principles of good regulation and the purpose and objectives of a DSRS, the NRC staff engages stakeholders, including the public, throughout the development of the DSRS. In general, the staff makes the information authored by either the prospective applicant or the staff publicly available for review and comment. The prospective applicant shall comply with the provisions of 10 CFR 2.390, including specific identification and marking of documentation and any

applicable affidavit requirements, concerning information that it requests to be withheld from public disclosure.

Development of the DSRS provides a mechanism for ongoing communications and interactions among the staff, applicant, and other stakeholders to support the early identification and resolution of both technical and regulatory issues. In support of the DSRS development, the prospective applicant may elect to address regulatory and/or technical issues in separate documentation. For example, the prospective applicant may submit white papers, topical reports, and/or technical reports to the NRC for review. Such documents would be prepared and submitted to assist the NRC staff in understanding the SMR design and/or the prospective applicant's proposed approach to address specific regulatory or technical issues.

The prospective applicant should understand that certain factors within its purview impact the schedule and efficiency of the NRC staff's activities during DSRS development. For example, the prospective applicant's willingness to share preliminary information on the design and the associated PRA with the NRC staff is fundamental to its timely development of a quality DSRS. In contrast, numerous design changes during the development of the DSRS can negatively impact the schedule. The ability of the staff to formulate its review strategy and create useful draft DSRS content depends on the quality and timeliness of critical inputs from the prospective applicant. For example, early submittal of finalized or near final design information for use by the staff minimizes revisions to the DSRS sections. Preliminary PRA results and reliability assurance program list categorizations facilitate the staff's understanding of the applicant's safety/risk categorization strategy for the SSCs. If the design incorporates innovative features such as passive systems or simplified controls, early identification of these features to the staff facilitates timely identification of any unique regulatory issues.

The prospective applicant should perform a detailed review and comparison of the SMR design against each section of the current SRP and should identify those SRP sections that are applicable or not applicable to the design. NRC staff further recommends that the prospective applicant documents the results of the comparison in the form of a gap analysis. To support timely interactions with the NRC staff, the prospective applicant may perform the gap analysis with preliminary design information and, subsequently, refine and revise the gap analysis as the design is finalized.

To develop the DSRS, the NRC staff performs an in-depth review and comparison of the SMR design against each section of the SRP, similar to that performed by the prospective applicant, and reviews the prospective applicant's gap analysis. For each section of the SRP, the staff determines whether the respective SRP section should be: (1) referenced in the DSRS for "use as is" (i.e., the section is wholly applicable to the design), (2) included in the DSRS with minor "editorial" modifications (e.g., the SRP acceptance criteria is applicable but nomenclature changes are needed for design applicability), (3) replaced in the DSRS with an entirely new section (e.g., the design meets a regulatory requirement or accomplishes a safety function in a manner that is different from that described in the SRP section), or (4) deleted from the DSRS because the SRP section is not applicable to the design (e.g., innovative design features obviate the need for SSCs addressed in the SRP section). The staff documents this determination for each SRP section in a "safety review matrix" that illustrates the section-specific correlation between the SRP and the DSRS. The "safety review matrix" serves as both an overview and a table of contents for the DSRS.

The NRC staff prepares the DSRS in a format and with a numbering scheme that corresponds to the SRP. Similar to the SRP, each section/subsection describes the scope of review, identifies applicable requirements, identifies the acceptance criteria to be satisfied, and identifies relevant references for the reviewer's use in making a reasonable assurance finding that the applicant has adequately addressed the applicable NRC regulations and requirements.

Use of Design-Specific Review Standards

The prospective applicant should use the DSRS in the same manner that the prospective applicant would use the SRP absent the DSRS because, for the specific SMR design, the DSRS serves the same purpose and achieves the same objectives as the SRP.

The prospective applicant should prepare its application consistent with the content and criteria identified in the DSRS ~~and, further, may evaluate the completed application against the DSRS.~~ .[GD39]

Documentation of Standard Review Plan Sections and Design-Specific Review Standards Used to Develop the Application
~~**Evaluation against Design-Specific Review Standards**~~

In NRC MD 8.4, in Section I.B.2(e) of the Directive Handbook, the Commission has stated that for LWR facilities, applicants should be anticipated to reasonably rely upon in the development of their applications the version of the SRP or a DSRS, as applicable, in effect 6 months before the docket date of the application. The Commission further directed the NRC staff that any change in requirements or regulatory staff positions from that version of the SRP or DSRS, as applicable, interpreting the Commission's requirements should follow the same reasoned decisionmaking process as a forward fit. If a final version of the DSRS Section is not available, the applicable version would be the latest public draft version of the document

COL, DC, and ESP applicants should provide information on which SRP or DSRS Sections, as applicable, ~~and RGs~~ were ~~used~~relied upon to develop the applications and which SRP or DSRS Sections were not used and an explanation as to why they were not used. ~~Under 10 CFR 52.17(a)(1)(xii), 10 CFR 52.47(a)(9), and 10 CFR 52.79(a)(41), the applicant for an ESP, DC, or COL, respectively, should include in its application an evaluation of the facility against the SRP revision in effect 6 months before the docketed date of the application.~~

~~Alternatively, the SMR applicant may evaluate the facility against the~~identify a DSRS ~~section revision in effect 6 months before the docketed date of the application.~~or ~~I~~If a final version of the DSRS ~~is not available, the applicant may refer to the latest public draft version of the document to meet the intent of the regulations.~~[GD40]]

Deviations from Design-Specific Review Standards

The prospective applicant, as necessary, may deviate from the DSRS. Both the SRP and the DSRS describe an acceptable means, but not necessarily the only means, of meeting the regulations. Accordingly, the application content may deviate from the acceptance criteria in the SRP or the DSRS. The SRP and DSRS are not substitutes for the NRC regulations and compliance with them is not required. ~~However, applicants are required to identify differences from the SRP or DSRS acceptance criteria and evaluate how the proposed alternatives to the acceptance criteria provide an acceptable method for complying with the NRC regulations.~~[GD41]

The NRC staff intends to use the DSRS in the same manner that it would use the SRP absent the DSRS for the aforementioned reason. For example, the staff reviews and evaluates applications incorporating the specific SMR design against the methodology and criteria identified in the DSRS.

C.2.18 Limited Work Authorization

OVERVIEW

The LWA process allows COL applicants and applicants for and holders of ESPs to request approval to perform certain limited construction activities before the issuance of a COL. The regulations in 10 CFR 50.10, "License Required; Limited Work Authorization," govern the issuance of LWAs and specify the information to be included in an LWA application. The regulations clarify that activities defined as "construction" are those that fall within the NRC's regulatory authority and require an LWA because they have a reasonable nexus to radiological health and safety or common defense and security. Those activities that are not considered "construction" are referred to as "preconstruction" and do not require an NRC licensing action.

A COL applicant may submit an application for an LWA as part of its application for a COL. An ESP applicant may submit an application for an LWA as part of its application for an ESP, and a holder of an ESP may submit a request for an LWA as an amendment to the ESP.

As required by 10 CFR 50.10, the LWA application should include an SAR that describes the activities requested to be performed along with the information otherwise required for a COLA by 10 CFR 52.79 or an ESP application by 10 CFR 52.17. The LWA application should also include an ER in accordance with the applicable section(s) of 10 CFR 51.49, "Environmental Report—Limited Work Authorization." Further, the LWA applicant should include a redress plan that describes the scope of the actions to be taken following suspension of construction activities and addresses the mitigation of impacts incurred resulting from the performance of construction activities.

As an example, the NRC issued an LWA as the VEGP ESP and LWA (ESP-004) in August 2009. The NRC staff's safety and environmental reviews supporting issuance of the ESP and LWA are publicly available as NUREG-1923, "Safety Evaluation Report for an Early Site Permit (ESP) at the Vogtle Electric Generating Plant (VEGP) ESP Site," issued July 2009 (Ref. 1~~14~~16), and NUREG-1872, "Final Environmental Impact Statement for an Early Site Permit (ESP) at the Vogtle ESP Electric Generating Plant Site," issued August 2008 (Ref. 1~~15~~17).

The guidance herein updates that contained in COL/ESP-ISG-04, "Definition of Construction and on Limited Work Authorizations," issued February 2009, and upon issuance of revised RG 1.206, COL/ESP-ISG-04 is retired. However, COL/ESP-ISG-04 includes an explanatory discussion of "construction" and "preconstruction" activities that remains valid and may be useful to prospective applicants. Accordingly, the Appendix to Section C.2.18 in this document retains the explanatory discussion portion of COL/ESP-ISG-04.

GUIDANCE

Limited Work Authorizations and Combined License

The issuance of an LWA has no bearing on the issuance of the related COL. As set forth in 10 CFR 50.10(f), any activities that the applicant undertakes under an LWA are entirely at the risk of the applicant.

Applications

A COL applicant may submit a request for an LWA either as part of a complete application under 10 CFR 2.101(a)(1)–(4) or as a partial application under 10 CFR 2.101(a)(9) (i.e., "phased

COLA"). An ESP applicant may include a request for an LWA as part of a complete ESP application in accordance with 10 CFR 2.101(a)(1)–(a)(4). A holder of an ESP may submit a request for an LWA as an application for an amendment to the ESP in accordance with 10 CFR 52.39(e).

As required by 10 CFR 50.10, if the LWA request is submitted as part of a complete COLA or as part of an ESP or ESP amendment application, the application should include the following:

a. an SSAR required by 10 CFR 52.17 or an FSAR required by 10 CFR 52.79, as applicable;
b. a description of the LWA activities that the applicant seeks to perform;
c. proposed inspections, tests, and analyses (for the LWA activities that the applicant seeks to perform) that the applicant will perform and the acceptance criteria that are necessary and sufficient to provide reasonable assurance that, if the inspections, tests, and analyses are performed and the acceptance criteria met, the portion of the facility covered by the LWA has been constructed and will be operated in conformity with the LWA, the provisions of the AEA, and the Commission's rules and regulations;
d. an ER that meets the requirements in 10 CFR 51.49;
e. a plan for redress of activities performed under the LWA if: (1) LWAs are terminated by the holder of the LWAs, (2) the LWA is revoked by the NRC, or (3) the Commission denies the associated COLA; and
f. the technical qualifications of the applicant to engage in the proposed activities.

Safety Analysis Report

The SSAR or FSAR should demonstrate that the LWA activities will be conducted in accordance with applicable Commission requirements as follows:

a. If the LWA application is submitted as part of a complete COLA, the application should clearly identify which portions of the COL FSAR are applicable to the LWA request.

b. If the LWA application is submitted as part of a phased COLA or as part of an ESP or ESP amendment application, the SSAR or FSAR should include:

    (1) the final design for any foundation or other work being requested under the LWA,
    (2) the final design for any structures that would be supported by the foundation or other work being requested under the LWA,
    (3) a safety analysis for any foundation or other work being requested under the LWA, and
    (4) a safety analysis for structures that would be supported by the foundation or other work being requested under the LWA (e.g., stability (static and dynamic) analyses).

Environmental Report

In accordance with 10 CFR 51.49, the ER for an LWA should include:

a. a description of the activities to be conducted under the LWA,
b. a statement of the need for the activities,
c. a description of the environmental impacts that may reasonably be expected to result from the activities,

d. a description of the mitigation measures the applicant proposes to implement,
e. a discussion of the reasons why the applicant rejected additional mitigation measures under consideration, and
f. a description of the process used to identify new and significant information for an ESP holder or for a site where an EIS has been prepared, but the facility construction was not completed.

Guidance regarding the organization and content of the ER is available in RG 4.2, NUREG-1555, and COL/ESP-ISG-026.

Site Redress Plan

The primary purpose of the redress plan is to address activities that were authorized under the LWA, such as the placement of piles and installation of foundations, should the LWA activities be discontinued. Redress of site impacts resulting from preconstruction activities are not required under the redress plan. In addition, although redress of LWA impacts may have the practical effect of mitigating some environmental impacts, the redress plan is not a substitute for a thorough evaluation of environmental impacts or the development of mitigation measures that may be necessary to provide relief from environmental impacts associated with the proposed LWA activities.

In general, the site redress plan should describe the scope of actions to be taken following the suspension of construction. COL applicants and applicants for and holders of ESPs should consider the requirements in 10 CFR 52.25, "Extent of Activities Permitted," which allow the applicant to redress the site for alternative uses that were not considered at the time it prepared the original site redress plan.

As required by 10 CFR 50.10(g), if construction is terminated by the LWA holder, the underlying application is withdrawn by the applicant or denied by the NRC, or the LWA is revoked by the NRC, the holder must begin implementation of the redress plan in a reasonable time. The holder must complete the redress of the site no later than 18 months after termination of construction or revocation of the LWA or upon effectiveness of the Commission's final decision denying the associated construction permit application or the underlying COLA, as applicable.

Supplement to C.2.18 - Excerpt from COL/ESP-ISG-04, "Interim Staff Guidance on the Definition of Construction and on Limited Work Authorizations"

The text in this supplement is an excerpt from COL/ESP-ISG-04, "Definition of Construction and on Limited Work Authorizations."

General Discussion

As stated in 10 CFR 50.10(c), no person may begin the construction of a production or utilization facility on a site on which the facility is to be operated until that person has been issued either a COL, an ESP authorizing the activities under 10 CFR 50.10(d), or an LWA. As defined in 10 CFR 50.10(a), "construction" means the activities in paragraph (1) below and does not mean the activities in paragraph (2) below.

(1) Activities constituting construction are the driving of piles, subsurface preparation, placement of backfill, concrete, or permanent retaining walls within an excavation, installation of foundations, or in-place assembly, erection, fabrication, or testing, which are for:

(i) Safety-related structures, systems, or components (SSCs) of a facility, as defined in

10 CFR 50.2;

(ii) SSCs relied upon to mitigate accidents or transients or used in plant emergency operating procedures;

(iii) SSCs whose failure could prevent safety-related SSCs from fulfilling their safety-related function;

(iv) SSCs whose failure could cause a reactor scram or actuation of a safety-related system;

(v) SSCs necessary to comply with 10 CFR Part 73;

(vi) SSCs necessary to comply with 10 CFR 50.48 and Criterion 3 of 10 CFR Part 50, Appendix A; and

(vii) Onsite emergency facilities, that is, technical support and operations support centers, necessary to comply with 10 CFR 50.47 and 10 CFR Part 50, Appendix E.

(2) Construction does not include:

(i) Changes for temporary use of the land for public recreational purposes;

(ii) Site exploration, including necessary borings to determine foundation conditions or other preconstruction monitoring to establish background information related to the suitability of the site, the environmental impacts of construction or operation, or the protection of environmental values;

(iii) Preparation of a site for construction of a facility, including clearing of the site, grading, installation of drainage, erosion and other environmental mitigation measures, and construction of temporary roads and borrow areas;

(iv) Erection of fences and other access control measures;

(v) Excavation;

(vi) Erection of support buildings (such as, construction equipment storage sheds, warehouse and shop facilities, utilities, concrete mixing plants, docking and unloading facilities, and office buildings) for use in connection with the construction of the facility;

(vii) Building of service facilities, such as paved roads, parking lots, railroad spurs, exterior utility and lighting systems, potable water systems, sanitary sewerage treatment facilities, and transmission lines;

(viii) Procurement or fabrication of components or portions of the proposed facility occurring at other than the final, in-place location at the facility;

(ix) Manufacture of a nuclear power reactor under a manufacturing license under Subpart F of Part 52 to be installed at the proposed site and to be part of the proposed facility.

In accordance with 10 CFR 50.10(a)(2)(ii), the NRC does not consider site investigations that are required by 10 CFR 100.23(c) to be construction. Also, the above definition of construction excludes excavation. Excavation includes the removal of any soil, rock, gravel, or other material below the final ground elevation to the final parent material. Thus, all these excavation activities may be conducted without a COL, LWA, or ESP authorizing LWA activities. However, placing permanent, nonstructural dewatering materials, mud, or engineered backfill in advance of the placing the foundation and associated permanent retaining walls for SSCs within the scope of the definition of construction is not an excavation activity and is considered to fall within the scope of construction. Any person or entity that excavates should be aware that the NRC expects any subsequent application requesting construction authorization to accurately document and address the excavation process and the conditions exposed by excavation, to ensure that the NRC will have an adequate basis for evaluating the relevant portions of the application. The NRC staff may also discuss with applicants and prospective applicants the possibility of voluntarily allowing it access to the site during excavation activities to assist in its evaluation of the relevant portions of the application.

Construction includes installation of the foundation, including soil compaction; the installation of

permanent drainage systems and geofabric; the placement of backfill, concrete (e.g., mudmats), or other materials that will not be removed before placement of the foundation of a structure; the placement and compaction of a subbase; the installation of reinforcing bars to be incorporated into the foundation of the structure; the erection of concrete forms for the foundations that will remain in place permanently (even if nonstructural); and the placement of concrete or other material constituting the foundation of any SSC within the scope of the definition of construction. The term "permanent" in this context includes anything that will exist in its final, in-place plant location after fuel load.

Construction also includes the "onsite, in-place" fabrication, erection, integration, or testing activities for any in-scope SSC. The terms "onsite, in place, fabrication, erection, integration, or testing" are intended to describe the historical process of constructing a nuclear power plant in its final, onsite plant location, where components or modules are integrated into the final, in-plant location. The definition is intended to prevent persons from having to obtain a COL, LWA, or ESP authorizing LWA activities to fabricate, assemble, and test components and modules in a shop building, warehouse, or laydown area, even if located onsite. However, the installation or integration of that SSC into its final plant location would require a COL, LWA, or ESP authorizing LWA activities. Finally, construction does not include manufacturing a nuclear power reactor under Subpart F, "Manufacturing Licenses," of 10 CFR Part 52, even if the manufacturing is accomplished onsite, so long as the manufacturing is not done in place, at the final (permanent) plant location on the site.

Construction includes driving piles for SSCs that are described in the definition. Hence, an applicant must obtain permission from the NRC in the form of a COL, LWA, or ESP authorizing LWA activities to drive piles for such SSCs. However, driving piles that do not ensure the structural stability or integrity of an SSC within the scope of the definition of "construction" (e.g., piles driven to support the erection of a bridge for a temporary or permanent access road) would not be considered "construction" under this section; therefore, those piles may be driven without a COL, LWA, or ESP authorizing LWA activities.

In the LWA rule, the scope of SSCs falling within the definition of construction was derived from the scope of SSCs that are included in the program for monitoring the effectiveness of maintenance at nuclear power plants, as defined in 10 CFR 50.65(b), and supplemented with additional criteria (10 CFR 50.10(a)(1)(v–vii)). The supplementary information published with the 2007 final LWA rule contained a discussion of the definition of construction and guidance on the delineation of preconstruction and construction activities. As discussed in the supplementary information, the NRC selected the criteria used in the definition of construction to take advantage of the work done during the development and implementation of the maintenance rule (10 CFR 50.65, "Requirements for Monitoring the Effectiveness of Maintenance at Nuclear Power Plants"). Like the LWA rule, the maintenance rule defines a scope of SSCs that have some nexus to radiological health and safety (safety significance).

The NRC selected the maintenance rule criteria for use in the definition of construction, in part because the criteria are well understood and there is good agreement on their implementation. In addition, the NRC has prepared guidance for implementing the maintenance rule in RG 1.160, "Monitoring the Effectiveness of Maintenance at Nuclear Power Plants," issued March 1997, and that guidance has been tested. This RG endorses industry guidance provided in Revision 2 of NUMARC 93-01, "Industry Guideline for Monitoring the Effectiveness of Maintenance at Nuclear Power Plants," issued April 1996. For these reasons, the NRC has decided that the maintenance rule guidance can also be applied to determinations of SSCs that are within the scope of the definition of construction. Also, the NRC recognizes that determinations of which SSCs fall within the definition of construction will depend on the design of the facility.

In determining whether SSCs fall within the criteria in 10 CFR 50.10(a)(1)(v–vii), the

maintenance rule guidance should not be used. For these criteria, SSCs are considered within the definition of "construction" if they are designed to comply with 10 CFR Part 73, "Physical Protection of Plants and Materials"; 10 CFR 50.48, "Fire Protection"; Criterion 3, "Fire Protection," of Appendix A, "General Design Criteria for Nuclear Power Plants," to 10 CFR Part 50, "Domestic Licensing of Production and Utilization Facilities"; 10 CFR 50.47, "Emergency Plans"; or Appendix E, "Emergency Planning and Preparedness of Production and Utilization Facilities," to 10 CFR Part 50.

In addition to the criteria in 10 CFR 50.10(a)(1)(i–vii) that are used to determine the scope of SSCs that fall within the definition of construction, the final LWA rule also specifies criteria in 10 CFR 50.10(a)(1) for construction activities that take place within the necessary excavation for SSCs that fall within the definition of construction. A necessary excavation is the portion of an excavation that provides sufficient construction access to the structures that are within the definition of construction. Applicants should ensure that these preconstruction activities are separate from, and do not result in adverse interactions with, construction-related SSCs, including influence on the stability (static and dynamic) analyses. The definition of construction includes any change made to the parent material in which the excavation occurs (e.g., soil compaction, rock grouting); the driving of piles; the installation of foundations; the installation of permanent drainage systems and geofabric; the placement of backfill, concrete (e.g., mudmats) or other materials that will not be removed before placement of the foundation of a structure; the placement and compaction of a subbase; and the installation of reinforcing bars to be incorporated into the foundation of any SSCs that fall within the definition of construction.

The definition of construction includes use of the "temporary" and "permanent" criteria that are discussed in the statement of considerations for the "Limited Work Authorization for Nuclear Power Plants –Final Rule" (72 FR 57429; October 9, 2007) (Ref. 1161~~8~~). The term "permanent," in this context, includes anything that will exist in its final, in-place plant location after fuel load. By contrast, the term "temporary" means anything that will be removed from the excavation before fuel load. Therefore, the installation of permanent retaining walls within an excavation and the erection of concrete forms for the foundations that will remain in place permanently (even if nonstructural) fall within the definition of construction. However, if erosion control measures are conducted outside the excavated hole and do not cover up the exposed soil conditions, those activities would be considered preconstruction. Also, the placement of temporary SSCs in the excavation, such as retaining walls, drainage systems, and erosion control barriers, all of which will be removed before fuel load, would be considered preconstruction.

Discussion of Examples

In addition to the background discussion provided above, the following examples clarify the delineation of preconstruction and construction activities. It is important to recognize that the NRC may have regulatory authority over some preconstruction activities, such as the requirement to verify such activities by ITAAC (e.g., procurement of components). It should also be noted that, while the preconstruction activities do not require prior NRC approval, various local, State, or other Federal permits may be required.

Circulating Water System

As a general matter, the NRC staff considers the circulating water system (CWS), on a system level, to be within the scope of construction because 10 CFR 50.10(a)(1)(iv) includes equipment that can cause a reactor trip. Although the system and active equipment such as pumps and valves can cause a plant trip, an applicant could exclude certain portions of the CWS from construction as discussed below.

Buried Circulating Water System Piping up to the Turbine Building

Depending on the plant design, it is possible for an applicant to demonstrate that plausible failures (leakage) associated with the CWS piping (intake and discharge) would not result in a reactor trip. It is reasonable to exclude the piping from the scope of construction for certain designs, given that the reactor trip or safety system actuation criterion is the only reason to consider it within scope. This finding remains consistent with the NRC's decision to use the maintenance rule and related guidance to define the scope of SSCs within the definition of construction. RG 1.160 provides the following guidance for systems to include under this criterion:

(1) SSCs whose failure has caused a reactor scram or actuation of a safety-related system at their site

(2) SSCs whose failure has caused a reactor scram or actuation of a safety-related system at a site with a similar configuration

(3) SSCs identified in the licensee's analysis (e.g., FSAR, individual plant evaluation) whose failure would cause a reactor scram or the actuation of a safety-related system

A review of the licensee event reports for currently operating reactors did not identify occurrences of piping failures in the CWS up to the turbine building that resulted in plant scrams or safety system actuations. The turbine building demarcation may be important, since the piping within the building could, depending on plant design, cause internal plant flooding or safety system actuations, or prevent other SSCs from fulfilling their safety-related functions. Applicants need to perform design-specific reviews to ensure that piping failures in the CWS up to the turbine building are not identified in other analyses (e.g., FSAR, probabilistic risk assessment) as being a plausible initiating event for a reactor scram or safety system actuation. Therefore, CWS piping could be considered preconstruction in certain circumstances.

Circulating Water Intake Structure

Depending on the plant design, it is possible for an applicant to demonstrate, similar to CWS piping up to the turbine building, that the plant intake structure does not have a safety function (e.g., some plant intakes only provide makeup to the CWS). This conclusion would not apply to related SSCs, such as pumps, travelling screens, or other active components associated with the CWS, because there are many examples of plant transients and safety system actuations that have loss of circulating water flow as an initiating event. To expand the preconstruction activities beyond the intake structure, applicants need to perform design-specific reviews to ensure that a loss of CWS flow caused by pump failures or screen blockage is not a plausible initiating event for a reactor scram or safety system actuation. Therefore, the facility design will determine whether intake structures and related components are within the scope of construction.

Cooling Towers

Depending on the plant design, it is possible for an applicant to demonstrate, similar to that for intake structures, that cooling tower structures do not have a safety function. This conclusion may not apply to related SSCs, such as pumps associated with the CWS, because there are examples of plant transients and safety system actuations that have loss of circulating water flow as an initiating event. To expand the preconstruction activities beyond the cooling tower structure, applicants need to perform design-specific reviews to ensure that a loss of circulating water system flow caused by loss of pumps or other components is not a plausible initiating event

for a reactor scram or safety system actuation. Therefore, the facility design will determine whether cooling towers and related components are within the scope of construction.

Turbine Building Structure or Foundation

The turbine/generator system is within the scope of construction because failure of the turbine/generator could cause a reactor scram. However, depending on the plant design, it is possible for an applicant to demonstrate that a plausible failure of the turbine building structure or foundation (settling) would not result in a reactor scram or safety system actuation. Depending on the facility design, the turbine building structure or foundation may not fall within the scope of construction, if the reactor scram or safety system actuation criterion is the only reason to consider it.

Temporary or Permanent Features

This section addresses the distinction between temporary and permanent construction features (e.g., retaining walls and dewatering systems). As discussed in the supplementary information for the final LWA rule, excavation and other site preparation activities, whether permanent or temporary, are outside the scope of construction and are considered preconstruction. For example, piles driven to support the erection of a bridge for a temporary or permanent access road would not be considered as construction and may be performed without an LWA or combined license.

The installation of a temporary feature within the excavation or area associated with construction that will be removed during construction is considered to be a preconstruction activity. Such features include some retaining walls, some types of dewatering systems, ramps, and other structures that have no physical presence following construction.

Regarding installation of temporary features within the necessary excavation during preconstruction, if the applicant proposes to abandon the subject feature in place, the NRC must approve that action (i.e., abandonment) as part of an LWA or COL application. Examples may include certain retaining walls and some types of dewatering systems. The applicant must show that the abandoned feature would not adversely affect the SSCs, introduce undesirable flow paths, or otherwise conflict with nuclear plant safety or regulatory compliance, and the NRC would have to approve.

Construction Crane Foundations and Support Pads

Construction includes placing permanent features (e.g., retaining walls and foundations) within the necessary excavations for SSCs within the definition of construction. Site preparation activities that are performed outside the necessary excavations are considered preconstruction. Therefore, installing foundations and support pads outside the necessary excavations for SSCs that are within the definition of construction would be considered preconstruction. As stated previously, applicants should ensure that these preconstruction activities are separate from, and do not result in adverse interactions with, construction-related SSCs, including influence on the stability (static and dynamic) analyses.

C.2.19 Nuclear Insurance and Indemnity

An applicant may use one of the following processes to meet the financial protection requirements for obtaining a Part 52 license. For purposes of this RG, a “greenfield” reactor is defined as

a reactor that is to be built on a designated reactor station site where no operating reactor units currently exist. This classification of reactor must adhere to the regulations in a slightly different manner than an operating reactor because it must initiate financial protection policies, as opposed to simply amending existing policies, as is the case with a reactor that is being built on a reactor station site that already contains operating units. Thus, while the following process addresses requirements for both applicants who will build on a reactor station site with operating units, and greenfield reactors, the process will vary. These variations are annotated as "a" (for reactor additions) and "b" (for greenfield reactors) and should be adhered to accordingly.

The Part 52 Process

1) As required by 10 CFR 140.13, each holder of a combined license under 10 CFR Part 52, shall have and maintain financial protection in a specified amount, during the period when the Commission issues a license under 10 CFR Part 70, "Domestic Licensing of Special Nuclear Material," and before the date that the Commission makes a finding under 10 CFR 52.103(g) that the acceptance criteria in the COL have been met so that the licensees may load fuel and operate the reactor. Proof of financial protection shall be filed with the Commission before issuance of the license.

2) a) As required by 10 CFR Part 140.11(a)(4), each licensee must have and maintain financial protection in an amount equal to the specified amount for primary financial protection. Existing operating reactors on the reactor station site already have primary financial protection of a specified amount , the policy providing this insurance may simply be amended (by the applicant's insurer) to include the addition of the new reactor. The policy for the primary financial protection will satisfy both the 10 CFR 140.13 and the 10 CFR Part 140.11(a)(4) requirement. Proof of primary financial protection shall be filed with the Commission before issuance of the license.

   b) As required by 10 CFR Part 140.11(a)(4), each licensee must have and maintain financial protection in an amount available as secondary financial protection. Secondary financial protection must be provided in the form of private liability insurance available under an industry retrospective rating plan and is discussed in 10 CFR 140.11(a)(4).

3) Additionally, the requirement to obtain onsite financial protection (in the form of property insurance) is provided in 10 CFR 50.54(w).

4) Finally, as required by 10 CFR 140.21, applicants must use one of the guarantees in the regulation to demonstrate that they maintain the financial capacity to pay into the industry retrospective rating plan required for secondary financial protection. These requirements are only required for reactors once the 10 CFR 52.103(g) finding is made.

Proposed Financial Protection License Conditions

An applicant may propose license conditions to satisfy the requirements for offsite financial protection, onsite financial protection, and payment of deferred premiums before the issuance of the COL.

A commonly used license condition to satisfy the requirements for 10 CFR 140.11(a)(4) and 50.54(w) is:

> Before the scheduled date for initial fuel load, and within ninety (90) days after the NRC publishes the notice of intended operation in the Federal Register, [insert applicant(s)

name(s)] shall provide satisfactory documentary evidence to the Director of the Office of Nuclear Reactor Regulation, or the Director's designee, that it has obtained the appropriate amount of financial protection required of licensees pursuant to 10 CFR Part 140 and 10 CFR 50.54(w).

A commonly used license condition to satisfy the requirements for 10 CFR 140.21 (for reactor additions and greenfield reactors) is:

> Before the scheduled date of initial fuel load, and within ninety (90) days after the NRC publishes the notice of intended operation in the Federal Register, [insert applicant(s) name(s)] shall provide evidence to the Director of the Office of Nuclear Reactor Regulation, or the Director's designee, that it has the ability to pay into the nuclear industry retrospective rating plan in the event of a nuclear incident, and in the amount specified in 10 CFR Part 140.11(a)(4) for one calendar year using one of the following methods:
>
> a) Surety bond,
> b) Letter of credit,
> c) Revolving credit/term loan arrangement,
> d) Maintenance of escrow deposits of government securities, or
> e) Annual certified financial statement showing either that a cash flow (i.e., cash available to a company after all operating expenses, taxes, interest charges, and dividends have been paid) can be generated and would be available for payment of retrospective premiums within three (3) months after submission of the statement, or a cash reserve or a combination of cash flow and cash reserve.
>
> Thereafter, [insert applicant(s) name(s)] shall provide evidence of the guarantees of payment of deferred premiums in accordance with the timing provisions specified in 10 CFR 140.21.

Indemnification of a Part 52 Combined License Applicant

As required by 10 CFR Part 140.20 and 10 CFR 140.22, the Commission will enter into an indemnity agreement with the COL applicant(s).

a) If operating reactors on the reactor station site already have an active indemnity agreement, this agreement will simply be modified (via an Indemnity Amendment by the Commission) to include the addition of the new reactor.
b) A greenfield reactor will require the initiation of a new indemnity agreement. This agreement will address indemnity between the periods of construction and operations.

The COL applicants should provide information to update Item 1, Item 4, and Item 5 of the Attachment to the indemnity agreement provided in either 10 CFR 140.92, "140.92 Appendix B - Form of indemnity agreement with licensees furnishing insurance policies as proof of financial protection," or 10 CFR 140.93, "Appendix C - Form of indemnity agreement with licensees furnishing proof of financial protection in the form of licensee's resources." The Attachment can be found below Article VIII of each referenced regulation. The indemnity agreement will be signed and executed at the time of the license issuance.

C.2.20 Fukushima Recommendations

——Applicants should note that the NRC staff issued orders to operating plants to address issues that arose from the Fukushima event in February 2011. In addition, Part 52 applicants have submitted information to address these issues [see Appendix A]. For example, NuScale submitted an FSAR for a DC application in December 2016 (ADAMS Accession No. ML17013A291) that included an additional Chapter 20 titled "Mitigation for Beyond Design Basis Accidents." Consistent with the aforementioned orders, the NRC may request similar information from applicants to address post-Fukushima issues.

D. IMPLEMENTATION

The[EM42] NRC staff may use this RG as a reference in its regulatory processes, such as licensing, inspection, or enforcement. However, the NRC staff does not intend to use the guidance in this RG to support NRC staff actions in a manner that would constitute backfitting as that term is defined in 10 CFR 50.109, "Backfitting," and as described in NRC Management Directive (MD) 8.4, nor does the NRC staff intend to use the guidance to affect the issue finality of an approval under 10 CFR Part 52, "Licenses, Certifications, and Approvals for Nuclear Power Plants." The staff also does not intend to use the guidance to support NRC staff actions in a manner that constitutes forward fitting as that term is defined and described in MD 8.4. If a licensee believes that the NRC is using this RG in a manner inconsistent with the discussion in this Implementation section, then the licensee may file a backfitting or forward fitting appeal with the NRC in accordance with the process in MD 8.4.

~~The purpose of this section is to provide information on how applicants and licensees[9] may use this guide and information regarding the NRC's plans for using this regulatory guide. In addition, it describes how the NRC staff complies with 10 CFR 50.109, "Backfitting" and any applicable finality provisions in 10 CFR Part 52, "Licenses, Certifications, and Approvals for Nuclear Power Plants."~~

~~**Use by Applicants and Licensees**~~

~~Applicants and licensees may voluntarily[10] use the guidance in this document to demonstrate compliance with the underlying NRC regulations. Methods or solutions that differ from those described in this regulatory guide may be deemed acceptable if they provide sufficient basis and information for the NRC staff to verify that the proposed alternative demonstrates compliance with the appropriate NRC regulations. Current licensees may continue to use guidance the NRC found acceptable for complying with the identified regulations as long as their current licensing basis remains unchanged.~~

~~Licensees may use the information in this regulatory guide for actions which do not require NRC review and approval such as changes to a facility design under 10 CFR 50.59, "Changes, Tests, and Experiments." Licensees may use the information in this regulatory guide or applicable parts to resolve regulatory or inspection issues.~~

~~**Use by NRC Staff**~~

~~The NRC staff does not intend or approve any imposition or backfitting of the guidance in this regulatory guide. The NRC staff does not expect any existing licensee to use or commit to using the guidance in this regulatory guide, unless the licensee makes a change to its licensing basis. The NRC staff does not expect or plan to request licensees to voluntarily adopt this regulatory guide to resolve a generic regulatory issue. The NRC staff does not expect or plan to initiate NRC regulatory action which would require the use of this regulatory guide without further backfit consideration. Examples of such unplanned NRC regulatory actions include issuance of an order requiring the use of the regulatory guide, requests for~~

~~[9] In this section, "licensees" refers to licensees of nuclear power plants under 10 CFR Part 52; and the term "applicants," refers to applicants for licenses and permits for (or relating to) nuclear power plants under 10 CFR Part 52, and applicants for standard design certifications under 10 CFR Part 52.~~

~~[10] In this section, "voluntary" and "voluntarily" means that the licensee is seeking the action of its own accord, without the force of a legally binding requirement or an NRC representation of further licensing or enforcement action.~~

~~information under 10 CFR 50.54(f) as to whether a licensee intends to commit to use of this regulatory guide, or generic communication, or promulgation of a rule requiring the use of this regulatory guide.~~

~~During regulatory discussions on plant specific operational issues, the staff may discuss with licensees various actions consistent with staff positions in this regulatory guide, as one acceptable means of meeting the underlying NRC regulatory requirement. Such discussions would not ordinarily be considered backfitting even if prior versions of this regulatory guide are part of the licensing basis of the facility. However, unless this regulatory guide is part of the licensing basis for a facility, the staff may not represent to the licensee that the licensee's failure to comply with the positions in this regulatory guide constitutes a violation.~~

~~If an existing licensee voluntarily seeks a license amendment or change and: (1) the NRC staff's consideration of the request involves a regulatory issue directly relevant to this new or revised regulatory guide and (2) the specific subject matter of this regulatory guide is an essential consideration in the staff's determination of the acceptability of the licensee's request, then the staff may request that the licensee either follow the guidance in this regulatory guide or provide an equivalent alternative process that demonstrates compliance with the underlying NRC regulatory requirements. This is not considered backfitting as defined in 10 CFR 50.109(a)(1) or a violation of any of the issue finality provisions in 10 CFR Part 52.~~

~~Additionally, an existing applicant may be required to comply with new rules, orders, or guidance if 10 CFR 50.109(a)(3) applies.~~

~~If a licensee believes that the NRC is either using this regulatory guide or requesting or requiring the licensee to implement the methods or processes in this regulatory guide in a manner inconsistent with the discussion in this Implementation section, then the licensee may file a backfit appeal with the NRC in accordance with the guidance in NUREG-1409, "Backfitting Guidelines" (Ref. 119) and the NRC Management Directive 8.4, "Management of Backfitting, Forward Fitting, Issue Finality, and Information Requests~~Management of Facility-Specific Backfitting and Information Collection" (Ref. 120).
~~[GD43]~~

E. ACRONYMS

ABWR	Advanced Boiling Water Reactor
ADAMS	Agencywide Documents Access and Management System
AEA	Atomic Energy Act of 1954, as amended
ALWR	Advanced light water reactor
AP1000	Advanced Passive 1000
ARAI	Advance request for additional information
ASME	American Society of Mechanical Engineers
BNP	Bellefonte Nuclear Plant
CDI	Conceptual design information
CD-ROM	Compact disk/read-only memory
CFR	Code of Federal Regulations
COL	Combined licenses
COLA	Combined license application
CSP	Cybersecurity plan
DC	Design certification
DCD	Design control document
DCRA	Design-centered review approach
DCWG	Design center working group
DEP	Departure
D RAP	Design reliability assurance program
DSRS	Design-specific review standard
EIS	Environmental impact statement
ER	Environmental report
ESBWR	Economic Simplified Boiling-Water Reactor
ESP	Early site permit
FDA	Final design approval
FSAR	Final safety analysis report
GE	General Electric
HFE	Human factors engineering
I&Cs	Instrumentation and controls
ISG	Interim staff guidance
IST	In-service testing
ITAAC	Inspections, tests, analyses, and acceptance criteria
LAR	License amendment request
LBB	Leak before break analysis
LCO	Limiting Conditions for Operation
LMA	Left margin annotation
LNP	Levy Nuclear Plant
LWA	Limited work authorization

LWR	Light water reactor
MD	NRC Management Directive
NEI	Nuclear Energy Institute
NRC	Nuclear Regulatory Commission
NRO	Office of New Reactors
NRR	Office of Nuclear Reactor Regulation
NTTAA	National Technology Transfer and Advancement Act of 1995
NuStart	NuStart Energy Development, LLC
OMB	Office of Management and Budget
PPE	Plant parameter envelope
PRA	Probabilistic risk assessment
PSP	Physical security plan
PXS	Passive core cooling system
RCS	Reactor coolant system
RG	Regulatory guide
RIS	Regulatory issue summary
RPP	Radiation protection program
RTNSS	Regulatory treatment of non-safety systems
SAR	Safety analysis report
SCP	Safeguards contingency plan
SL	Safety limits
SMR	Small modular reactor
SPDS	Safety parameter display system
SR	Surveillance requirement
SRP	Standard review plan
SSAR	Site safety analysis report
SSC	Structures, systems, and components
STD	Standard
SUP	Supplements
TOC	Table of contents
T&QP	Training and qualification plan
USACE	U.S. Army Corps of Engineers
VAR	Variance
VAS	Ventilation System
VEGP	Vogtle Electric Generating Plant
WLS	William States Lee III Nuclear Station

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APPENDIX A

EXAMPLE TABLE OF CONTENTS FOR DESIGN CERTIFICATION APPLICATION FINAL SAFETY ANALYSIS REPORT

Appendix A provides an illustrative example of the table of contents (TOC) for an SAR for a DC. The example is derived from the DCD TOC for the AP1000 advanced passive pressurized-water reactor from the following documents: ADAMS Accession Nos. ML11171A303 (Introduction), ML11171A306 (Tier 1 which was both approved and certified via 10 CFR Appendix D), and ML11171A328 (Tier 2 which was approved via 10 CFR Appendix D). The example in Appendix A is not intended to be prescriptive but to illustrate how information that is submitted may be organized. For example, the FSAR submitted as part of the NuScale DC application in December 2016 (ADAMS Accession No. ML17013A291) included an additional Chapter 20 titled "Mitigation for Beyond Design Basis Accidents" to address post-Fukushima issues. Note, however, the example TOC does not reflect information from SRP Chapter 17.5 on quality assurance program description which was developed later and is relevant to newer DC applications.

DESIGN CONTROL DOCUMENT INTRODUCTION

TIER 1 MASTER TABLE OF CONTENTS

TIER 2 MASTER TABLE OF CONTENTS

CHAPTER 13 CONDUCT OF OPERATION

CHAPTER 14 INITIAL TEST PROGRAM

APPENDIX 14A DESIGN ACCEPTANCE CRITERIA/ITAAC CLOSURE PROCESS

CHAPTER 15 ACCIDENT ANALYSES

CHAPTER 17 QUALITY ASSURANCE

CHAPTER 18 HUMAN FACTORS ENGINEERING

CHAPTER 19 PROBABILISTIC RISK ASSESSMENT

APPENDIX B
EXAMPLE TABLE OF CONTENTS FOR COMBINED LICENSE APPLICATION FINAL SAFETY ANALYSIS REPORT

Appendix B provides an illustrative example of the table of contents for an FSAR for a COLA that incorporates both a DC and an ESP by reference. The example is derived from the TOC for the VEGP COLA (ADAMS Accession No. ML11180A100). The example in Appendix B is not intended to be prescriptive but serve as a sample of how the required information may be organized. For example, those sections in the COLA FSAR that reference an ESP SSAR may differ from those referenced below if the COLA is requesting a variance from the ESP or SSAR.

APPENDIX C
EXAMPLE TABLE OF CONTENTS FOR EARLY SITE PERMIT APPLICATION SITE SAFETY ANALYSIS REPORT

Appendix C provides an illustrative example of the table of contents for an SSAR for an application for an ESP. The example is derived from the TOC for the Vogtle ESP application (ADAMS Accession No. ML091540845). The example in Appendix C is not intended to be prescriptive but serve as a sample of how the required information may be organized. For example, the Vogtle ESP did not use a PPE, whereas Chapter 2 reflects PPE inforrmation in most other ESP applications.