



# U.S. Nuclear Regulatory Commission

## Office of New Reactors

### Office Instruction

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Responsible Organization: **NRO/DARR/NRGB**

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# NRO Office Instruction

## NRO-REG-104

### Pre-application Readiness Assessment

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#### 1. **PURPOSE**

This guidance document provides the expectations for implementation of the safety pre-application readiness assessment<sup>1</sup> (hereinafter “readiness assessment”) of a draft application prior to being submitted for a formal U.S. Nuclear Regulatory Commission (NRC) licensing or certification review (i.e., design certification, combined license, or early site permit). The readiness assessment will allow the NRC staff to (1) identify information gaps between the draft application and the technical content expected to be included in the final application submitted to the NRC, (2) identify major technical or policy issues that may adversely impact the docketing or technical review of the application, and (3) become familiar with the application, particularly in areas where prospective applicants are proposing new concepts or novel design features. The results of the readiness assessment will inform prospective applicants in finalizing their application and assist the NRC staff in planning NRC resources in preparation for the review once the application is formally submitted.

#### 2. **GENERAL REQUIREMENTS**

Following the issuance of combined licenses for Vogtle Units 3 and 4, and V.C. Summer Units 2 and 3, the NRC initiated a lessons-learned review to identify potential enhancements to the licensing process under Title 10 of the *Code of Federal Regulations* (CFR), Part 52, “Licenses, Certifications, and Approvals for Nuclear Power Plants,” that could contribute to more effective and efficient reviews of future applications. After extensive outreach to external and internal stakeholders, in April 2013, the NRC issued the “New Reactor Licensing Process Lessons Learned Report” (hereinafter “Lessons Learned Report”) (Agencywide Documents Access and Management System [ADAMS] Accession No. ML13059A239). In the Lessons Learned Report, the NRC identified the quality of applications as a significant contributor to overall project performance. The report identified readiness assessments as one of the means of enhancing the quality of applications. In addition, this office instruction incorporates lessons learned from the pre-application audit that was performed for the design certification application of the Korea Hydro and Nuclear Power APR1400 standard plant design.

As stated in the Lessons Learned Report, the NRC staff plans to engage prospective applicants to schedule a pre-application readiness assessment. If the prospective applicant agrees to a readiness assessment, it should be conducted at least 6 months prior to the expected date of submittal. Also, the staff should encourage prospective

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<sup>1</sup>The readiness assessment is a voluntary pre-application activity, but as stated in the Lessons Learned Report, experience has shown that this pre-application interaction is a contributor in achieving high quality applications.

applicants to consider the results of the readiness assessment while finalizing their application and re-evaluate the application submission date based on their evaluation of the time to address the readiness assessment observations. If the prospective applicant chooses not to have a readiness assessment, the staff should acknowledge this decision via e-mail or letter to the prospective applicant. The readiness assessment does not conform to, nor is it part of, the NRCs official acceptance review process and does not predetermine whether the application will be docketed.

### **3. SPECIFIC REQUIREMENTS**

#### **3.1 Responsibilities**

##### **Safety Project Manager (PM)**

The Lead PM within the Office of New Reactors (NRO), as supported by other PMs.

- Through interactions with the prospective applicant determine the dates and scope of the readiness assessment and communicate these to the technical staff.
- With the support of the technical staff and considering the agreed scope of the readiness assessment, develop the readiness assessment plan which will be transmitted to the prospective applicant at least 30 days prior to the review activity. The plan will be publicly available (see Attachment A).
- Coordinate the logistics of the readiness assessment, including a list of documents that should be provided by the prospective applicant, agendas, interactions between NRC and prospective applicant personnel, etc.
- Ensure that an Enterprise Project Management task is created and a fee-billable Technical Activity Code (TAC) number is obtained before the technical staff conducts any fee-billable activity.
- Schedule a planning meeting with all the NRC staff involved in the readiness assessment to discuss individual responsibilities and logistics of the readiness assessment, including how to document the observations, issues, and concerns.
- Provide support to the technical staff during the readiness assessment.
- Compile technical staff observations.
- Lead the entrance, exit, and daily status meetings during the readiness assessment.
- Brief management on the results of the readiness assessment.
- Develop and issue a readiness assessment report within 45 calendar days of completion of the readiness assessment (see Attachment B). The readiness

report will be publicly available; however, parts of it could be withheld from public disclosure due to proprietary information. Coordinate with the technical divisions to determine the level of detail of the results to be shared with the prospective applicant in the report (i.e., general observations no RAIs).

### Technical Staff

Technical Staff - NRO and other offices as assigned.

- Participate in the planning meeting scheduled by the PM.
- Become familiar with guidance and regulations associated with scope of the readiness assessment (e.g., requirements for content of applications, applicable Design Specific Review Standard or Standard Review Plan sections, Regulatory Guides, etc.).
- Develop an assessment strategy for the area of expertise by considering lessons learned from previous application reviews, guidance, regulations, and requirements. For example, a reviewer can create a list of the information that should be part of the application (such as requirements, general design criteria, drawings, graphs, and analysis inputs/outputs values, among others) to be used in assessing the technical content of the draft application within the time constraints of the readiness assessment schedule.
- Review area of expertise sections and identify information gaps or other concerns that may pose challenges during the acceptance review process.
- During the readiness assessment, communicate issues and concerns to the prospective applicant and PMs.
- Document the results of the readiness assessment in a memo (see Attachment C) or e-mail (use the memo as the body of the e-mail) addressed to the Projects Branch Chief (BC). The memo or e-mail should identify (1) areas where the level of detail is not sufficient and/or (2) areas where significant information gaps or technical and policy issues might negatively impact the application review schedule. A “significant information gap” exists when missing information is needed to conduct the application review and the issue could not be addressed through a reasonable<sup>2</sup> round of requests for additional information (RAIs) during the technical review. In contrast, a “minor information gap” exists when missing information can be addressed through a reasonable round of RAIs.

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<sup>2</sup>The term “reasonable round of RAIs” could be interpreted as two to four rounds of RAIs while precluding any adverse impact on the review schedule. As stated in the Lessons Learned Report, for complex issues that can exceed the 30-day response time of RAIs, the staff should ensure a common understanding of the technical issue early in the process to obtain a timely resolution.

- Place the branch memo or e-mail in ADAMS as Non-Publicly Available (Sensitive Internal Info - No Periodic Review) documents and provide them to the projects BC within 2 weeks of the completion of the readiness assessment.

### Management

- Support the staff's briefing on the results of the readiness assessment and evaluate the significance of information gaps, issues, and concerns.
- Communicate the results of the readiness assessment to upper management.
- Support the briefing on results of the readiness assessment to the prospective applicant and approve transmittal of the public readiness assessment report.

### **3.2 Interface Guidance for the NRC Staff**

The readiness assessment will allow the NRC staff to identify major issues or information gaps between the draft application and the technical content expected to be included in the final application submitted to the NRC. Guidance below will aid the PMs and reviewers in keeping the readiness assessment on the appropriate topics.

### Do's

Prior to the readiness assessment

- The staff should review the latest documentation related to the design available in ADAMS under the project number.
- The staff should develop an assessment strategy for the area of expertise.

During the readiness assessment

- The staff should identify aspects of the draft application that may be inconsistent with applicable review guidance and regulations (other than where the application indicates it is proposing an alternative to an approach contemplated by review guidance).
- The staff should identify areas that appear to need clarification to support a complete technical review, such as where the level of detail appears to be different than what is described in regulatory guidance.
- The staff should identify documents referenced in the application that they would need to review to support the licensing review process if the application is docketed.
- The staff should identify regulations and current guidance that may be related to an identified issue or information gap.
- The staff should do a preliminary categorization of the identified issues based on the impact of the issue on docketing or technical review of the application

(e.g., Significant issue means that it could negatively impact the docketing or technical review of the application; Minor issue means that it could be addressed through RAI process). The categorization of observation provides an efficient method of communicating the identified issues to the prospective applicant.

### Don'ts

During the readiness assessment

- The staff shall not provide any guidance to the prospective applicant on what to write to make the information “acceptable” or provide written revision for the prospective applicant’s consideration.
- The staff shall not provide actual regulatory determinations (i.e., safety findings) on the draft application.
- The staff shall not return with any materials reviewed during the readiness assessment.

## **4. SCOPE OF THE READINESS ASSESSMENT**

The readiness assessment may focus on either the whole application or selected parts identified in early interactions between the staff and prospective applicant. If the prospective applicant requests a partial readiness assessment, the staff should encourage the assessment of the following review topics, which have been challenging areas during an application review.

- Seismic Analysis
- Long Term Cooling and Generic Safety Issue 191
- Instrumentation and Controls
- Radioactive Effluents, Radiation Protection, and radiation-related portions of Equipment Qualification
- Severe Accident Analysis and Probabilistic Risk Analysis
- Human Factors Engineering

A list of the sections/topics to be reviewed during the readiness assessment should be described in the readiness assessment plan (see Attachment A).

## **5. INFORMATION AND OTHER MATERIAL NECESSARY FOR THE READINESS ASSESSMENT**

During the readiness assessment, the prospective applicant should make available full copies of the draft application, all supporting topical and technical reports, examples of important calculations, and personnel that can answer questions for the areas selected

for review. Supporting technical reports include those reports referenced in the application which will require the NRC's review as part of the application review.

**6. COMMUNICATING THE OBSERVATIONS OF THE READINESS ASSESSMENT**

- **Daily Briefs**  
A brief summary of the preliminary observations should take place at the end of each day. Also, confirm the topics that will be assessed the next day.
- **Exit Meeting with the Prospective Applicant**  
An exit meeting should take place on the last day of the readiness assessment to provide a summary of the most significant preliminary observations identified by the NRC staff.
- **NRC Staff**  
The PMs will discuss staff observations with the NRO management in order to gain alignment on the content of the readiness assessment report.
- **Letter to the Prospective Applicant**  
The readiness assessment report should be communicated to the prospective applicant by letter (Attachment B) within 45 calendar days of completion of the readiness assessment.



# **ATTACHMENT A**

Pre-application Readiness Assessment Plan

[Date]

[Name], [Title]  
 [Company]  
 [Address]

Dear Mr./Mrs. [Last Name]:

On [Day, Date], [Name of Prospective Applicant] submitted a letter notifying the U.S. Nuclear Regulatory Commission (NRC) that the application submittal date for the [Application Name] is [Date of Submittal]. The NRC, through discussions with [Name of Prospective Applicant], has determined that [Date] is an appropriate date to conduct the pre-application readiness assessment (hereinafter "readiness assessment") of the [Application Name] draft application.

The readiness assessment does not conform to, nor is it part of, the NRCs official acceptance review process. The readiness assessment of the [Application Name] draft application will allow the NRC staff to understand the level of detail and identify any major issues or information gaps between the draft application and the technical content expected to be included in the final application submitted to the NRC. Therefore, the observations from the readiness assessment do not predetermine whether the application will be docketed.

The attached readiness assessment plan provides the details and logistics of the readiness assessment activities.

If you have any questions concerns please contact [Name of Project Manager] at [Phone Number] or [E-mail].

Sincerely,

[Name], Division Director  
 [Division]  
 [Office]

Project No. [Project Number]  
 Attachment: Readiness Assessment Plan  
 cc: Distribution via listserv

**DISTRIBUTION:**

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 RidsNro/Division (Technical divisions)  
 RidsNrr/DE

**ADAMS Accession No. MLxxxxxxxx**

**[Template #]**

<b>OFFICE</b>	PM: Office/Division/Branch	BC: Office/Division/Branch	DD: Office/Division
<b>NAME</b>			
<b>DATE</b>			

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**PRE-APPLICATION READINESS ASSESSMENT PLAN OF THE [APPLICATION NAME]  
[TYPE OF APPLICATION] DRAFT APPLICATION**

**[Dates]**

**[Application Name]  
[Name of Prospective Applicant]  
Project No. PROJXXXX**

**LOCATION [Name of Location]  
[Street Address]**

**PURPOSE**

The pre-application readiness assessment (hereinafter “readiness assessment”) of the **[Application Name]** draft **[Type of Application]** application prior to being submitted for a formal U.S. Nuclear Regulatory Commission (NRC) review will allow the NRC staff to (1) identify information gaps between the draft application and the technical content expected to be included in the final application submitted to the NRC, (2) identify major technical or policy issues that may adversely impact the docketing or technical review of the application, and (3) become familiar with the application, particularly in areas where **[Name of Prospective Applicant]** is proposing new concepts or novel design features. The observations from the readiness assessment will inform prospective applicants in finalizing their application and also assist the NRC staff in the planning of NRC resources in preparation for the review once the application is formally submitted.

**BACKGROUND**

Following the issuance of combined licenses for Vogtle Units 3 and 4, and V.C. Summer Units 2 and 3, the NRC initiated a lessons-learned review to identify potential enhancements to the licensing process under Title 10 of the *Code of Federal Regulations* (CFR), Part 52, “Licenses, Certifications, and Approvals for Nuclear Power Plants,” that could contribute to more effective and efficient reviews of future applications. After extensive outreach to external and internal stakeholders, in April 2013, the NRC issued the “New Reactor Licensing Process Lessons Learned Report” (hereinafter “Lessons Learned Report”) (Agencywide Documents Access and Management System [ADAMS] Accession No. ML13059A239). In the Lessons Learned Report, the NRC identified the quality of applications as a significant contributor to overall project performance. The report identified readiness assessments as one of the means of enhancing the quality of applications.

In a letter dated **[Date]** (ADAMS Accession No. **MLxxxxxxx**), **[Name of Prospective Applicant]** stated that the application submittal date is **[Date of Submittal]**. In agreement with **[Name of Prospective Applicant]**, the NRC has scheduled a readiness assessment of the **[Application Name]** draft application on **[Date]** at **[Location]**.

**SCOPE OF THE READINESS ASSESSMENT**

The readiness assessment of the **[Application Name]** draft application will focus on the following **[choose one of the following]**: ...major areas identified from past reviews of applications to be challenging review areas. or ...areas identified from past reviews of

applications to be challenging review areas and areas identified based on pre-application interactions with **[Name of Prospective Applicant].**

**[The following are the minimum topics to consider for a readiness assessment.]**

1. Seismic Analysis (Chapter 3).
2. Long-Term Cooling and Generic Safety Issue 191 (GSI-191) (Chapters 4 and 6).
3. Instrumentation and Controls (Chapter 7).
4. Radioactive Effluents (Chapter 11), Radiation Protection (Chapter 12 and radiation-related portions of Equipment Qualification [Section 3.11]).
5. Severe Accident Analysis and Probabilistic Risk Analysis (Chapters 15 and 19).
6. Human Factors Engineering (Chapter 18).
7. **[Add other review topics as desired.]**

**INFORMATION AND OTHER MATERIAL NECESSARY FOR THE READINESS ASSESSMENT**

As previously discussed with **[Name of Prospective Applicant]**, the following should be available to support the readiness assessment: full copies of the draft application, all supporting topical reports, all major supporting technical reports, examples of important calculations, and staff that can answer questions related to these documents.

**READINESS ASSESSMENT TEAM**

The following table shows the technical review area and the responsible technical staff.

Review Area	Reviewer(s)

**LOGISTICS**

The readiness assessment will take place at the **[Name of Location]** located in **[City, State]**. It is scheduled to begin with an entrance meeting upon the arrival of the team on **[Date]** and end with an exit meeting on **[Date]**. Daily debriefings will be performed as needed.

The NRC technical staff will charge time to the following fee-billable TAC number: **XXXXXX**.

**SPECIAL REQUESTS**

Appropriate handling and protection of proprietary and/or safeguard information shall be acknowledged and observed throughout the readiness assessment.

## READINESS ASSESSMENT OBSERVATIONS

The readiness assessment observations including any identified technical concerns or major information gaps will be sent to **[Name of Prospective Applicant]** in a publicly available report which will also summarize the scope of the readiness assessment. The staff's expectation is that **[Name of Prospective Applicant]** will consider the observations from the readiness assessment while finalizing the application and re-evaluate the application submission date based on their evaluation of the time to address the readiness assessment observations.

## REFERENCES

1. U.S. Nuclear Regulatory Commission, "**[Name of Design] Design-Specific Review Standard,**" **[Document Number]**, **[Date]**, Agencywide Documents Access and Management System Accession No. **MLxxxxxxx**. [present the accession number as a hyperlink if possible]
2. U.S. Nuclear Regulatory Commission, "Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants: LWR Edition," NUREG-0800. ([Link](#))
3. U.S. Nuclear Regulatory Commission, "Combined License Applications for Nuclear Power Plants (LWR Edition)," Regulatory Guide 1.206. ([Link](#))
4. Title 10 of the Code of Federal Regulations, Part 50, "Domestic Licensing of Production and Utilization Facilities." ([Link](#))
5. Title 10 of the Code of Federal Regulations, Part 52, "Licenses, Certifications, and Approvals for Nuclear Power Plants." ([Link](#))

## **ATTACHMENT B**

Template of Letter to the Prospective Applicant Documenting the  
Pre-application Readiness Assessment Observations

[Date]

[Name], [Title]  
[Company]  
[Address]

Dear Mr./Mrs. [Last Name]:

On [Day, Date], members of the staff of the U.S. Nuclear Regulatory Commission (NRC) completed a pre-application readiness assessment (hereinafter "readiness assessment") of the draft application and supporting documents that [Name of Prospective Applicant] intends to submit as part of the [Application Name] [Type of Application] application. The readiness assessment was conducted at [Name of Location] in [City, State]. The readiness assessment plan used for the [Application Name] [Type of Application] application can be found in the Agencywide Documents Access and Management System (ADAMS) under Accession Number **MLxxxxxxx**.

The readiness assessment does not conform to, nor is it part-of, the NRC's official acceptance review process. The readiness assessment was performed to understand the level of detail of the [Application Name] draft application and identify any major issues or information gaps between the draft application and the technical content expected to be included in the final application submitted to the NRC. Therefore, the observations from the readiness assessment do not predetermine whether the application will be docketed.

The attached document provides the NRC staff observations of the [Application Name] [Type of Application] draft application.

The staff's expectation is that you will consider the observations from the readiness assessment while finalizing your application and re-evaluate the application submission date based on their evaluation of the time to address the readiness assessment observations.

If you have any questions, please contact **[Name of Project Manager]** at **[Phone Number]** or **[E-mail]**.

Sincerely,

**[Name]**, Division Director  
**[Division]**  
**[Office]**

Project No. **[Project Number]**  
 Attachment: NRC Staff Observations

cc: Distribution via listserv

**DISTRIBUTION:**

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**ADAMS Accession: MLxxxxxxxxx**

**[Template #]**

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<b>NAME</b>			
<b>DATE</b>			
<b>OFFICE</b>	DD: Office/Division*	OGC	DD: Office/Division
<b>NAME</b>			
<b>DATE</b>			

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\*Technical Division Director

Pre-application Readiness Assessment of the **[Application Name]** **[Type of Application]** Draft Application

NRC Staff Observations

[The following examples illustrate how the issue or information gap could be described.]

Chapter X

- Does not identify the results of the assessment of the standard design for the effects of seismic interaction, or Category II/I.
- Does not describe sensitivity studies for addressing uncertainties in seismic analysis.
- Etc.

Chapter X

- Does not provide a functional description of the Plant Protection System (PPS) and the Engineered Safety Feature-Component Control System (ESF-CCS).
- Etc.

## **ATTACHMENT C**

Template of Branch Memo Documenting Pre-application  
Readiness Assessment Observations

Date

MEMORANDUM TO: **[Name]**, Chief  
**[Branch]**  
**[Division]**  
**[Office]**

FROM: **[Name]**, Chief  
**[Branch]**  
**[Division]**  
**[Office]**

SUBJECT: PRE-APPLICATION READINESS ASSESMENT OBSERVATIONS FOR **[SECTION NUMBER(S)]** OF THE **[FACILITY NAME]** **[TYPE OF APPLICATION]** APPLICATION FOR THE **[APPLICATION NAME]**

During **[Date]**, the **[Branch Name(s)]** conducted a pre-application readiness assessment of the draft application and supporting documents that **[Name of Prospective Applicant]** intends to submit as part of the **[Application Name]** **[Type of Application]** application. The pre-application readiness assessment plan can be found in ADAMS under Accession Number **MLxxxxxxxx**.

The attached document identify the significant issues or information gaps between the draft application and the technical content expected to be included in the final application that the staff recognized on the pre-application readiness assessment related to **[topic(s)/section(s) reviewed]**. This report is designed to serve as input to an overall pre-application readiness assessment report to be prepared by the Project Manager. As such, this report's content is limited to a description of the sections reviewed and the insights and observations that will support development of the overall pre-application readiness assessment report.

Enclosure: See attached

CONTACT: **[Name]**, **[Office/Division/Branch]**  
**[Phone Number]**

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<b>OFFICE</b>	TR: Office/Division/Branch	BC: Office/Division/Branch
<b>NAME</b>		
<b>DATE</b>		

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Purpose:

The purpose of the readiness assessment is to understand the level of detail of the **[Application Name]** draft application and identify any major issues or information gaps between the draft application and the technical content expected to be included in the final application submitted to the NRC.

Scope:

This pre-application readiness assessment input provides the staff's observations on the portion of the review scope related to **[topic(s) reviewed]**.

Observations:

The staff identified the following significant issues or information gaps between the draft application and the technical content expected to be included in the final application submitted to the NRC.

[The following examples illustrate how the issue or information gap could be described.]

- Section XX, does not describe sensitivity studies for addressing uncertainties in seismic analysis. Sensitivity studies are typically performed to address modeling assumptions pertaining to water table effects, foundation uplift, location of model boundaries, element discretization, etc.
- Section XX, does not provide a detailed functional descriptions of the Plant Protection System (PPS) and the Engineered Safety Feature-Component Control System (ESF-CCS).
- Section XX, does not identify the results of the assessment of the standard design for the effects of seismic interaction, or Category II/I.
- Etc.