
INSPECTION PROCEDURE 69022

INSPECTIONS OF OPERATIONAL READINESS DURING CONSTRUCTION OF NON-POWER PRODUCTION AND UTILIZATION FACILITIES

PROGRAM APPLICABILITY: IMC 2550

69022-01 INSPECTION OBJECTIVES

01.01 Evaluate the status of the Nuclear Regulatory Commission's (NRC) Non-Power Production and Utilization Facilities (NPUF) construction inspection program.

01.02 Evaluate the status of construction and preoperational testing and identify incomplete system acceptance and testing by the licensee.

01.03 Evaluate the status of the construction of the facility and identify areas where construction is incomplete.

01.04 Evaluate the licensee's readiness to perform activities during operation of the facility.

01.05 Evaluate the status of open items and their significance.

69022-02 INSPECTION REQUIREMENTS AND GUIDANCE

02.01 Background. An operating license will not be issued until the Commission verifies through inspection that the facility has been constructed in accordance with the requirements of the license. An operational readiness inspection is a tool to provide input for NRC decisions regarding the issuance of an operating license. The resulting inspection report will serve as the vehicle for informing Office of Nuclear Reactor Regulation (NRR) management of the status of Construction Inspection Program (CIP) implementation and the readiness of the licensee to begin operating the facility.

02.02 Inspection Requirements.

a. Inspection Planning

1. The inspection planning process is especially important for operational readiness inspections because the scope of and schedule for the inspection will depend on the specifics of the facility being inspected.
2. The operational readiness inspection should be scheduled after construction is substantially complete, but prior to the issuance of the operating license.

3. Region II should coordinate with the Office of Nuclear Material Safety and Safeguards (NMSS), NRR, the Office of Nuclear Security and Incident Response (NSIR) and (if appropriate) the Office of Enforcement (OE) in the planning for the operational readiness inspection. The facility specific plan for development of an operational readiness inspection will be developed by the NPUF Facility Specific Assessment and Review Group (FSARG). Items to be considered for inclusion in the inspection include:
 - Status of significant findings identified either by the licensee (Title 10, of the *Code of Federal Regulations* (10 CFR) 50.55e, 10 CFR Part 21, etc.) or by the NRC during previous inspections.
 - Status of operational programs (e.g., operator training, radiation protection, security, etc.). If operational programs are to be included in the scope of the inspection, Region II Regional Project Inspection should coordinate with the relevant organizations to ensure that the inspection team includes personnel with the appropriate technical expertise.
 - Adverse trends or problem areas identified through the assessment process described in Inspection Manual Chapter 2550, "Non-Power Production Facilities (NPUFs) Licensed Under 10 CFR Part 50: Construction Inspection Program (CIP)."
 - Pre-operational testing activities.
 - Structures, Systems, and Components (SSC) turnover process from construction to operation.
 - Licensee use of contractors and turnover of SSCs from contractor to licensee control.

Additional guidance on inspecting the licensee's readiness for operation is included in Appendix A, "Readiness for Transition to Operations."

4. This Inspection Procedure (IP) addresses suggested topics for inclusion in the operational readiness inspection. Inspection planning may identify that not all of the topics are applicable/appropriate for the specific facility being inspected. Inspection planning may also identify additional topics that need to be covered, even though they are not directly addressed in this IP.

b. CIP Status.

1. Verify that all inspections required for completion of the NPUF CIP have been completed. If all required inspections have been completed, this should be noted in the inspection report. If additional inspections are needed, they may be incorporated into the overall operational readiness inspection (using the appropriate IP). If the remaining inspections cannot be completed during the operational readiness inspection, this should be noted in the inspection report, along with a listing of the inspections that still need to be completed.

c. Construction and Pre-Operational Testing.

1. Evaluate the status of construction and pre-operational testing activities required by the facility licensing documents. Verify that the testing is either complete, or that the schedule supports the issuance of an operating license.
2. If additional inspections of construction and/or pre-operational testing are needed (either to support the completion of the CIP, or to address findings, adverse trends, etc.) the inspections can be performed during the operational readiness inspection using the appropriate IP (e.g., Appendix K of IP 69021, "Inspection of Quality Assurance Program Implementation During Construction of Non-Power Production and Utilization Facilities"). If additional inspections of pre-operational testing need to be performed, this should be noted in the inspection report.

d. Construction Status

1. Evaluate the status of the construction of the facility. If construction of safety related items is complete, note this in the inspection report. If construction is not complete, verify that construction schedules support issuance of an operating license, and identify any construction activities that still need to be inspected.

e. Operational Program Inspections

1. Evaluate the adequacy of operational programs required by the facility licensing documents. Inspection planning should identify which, if any, operational programs need to be included in the operational readiness inspection. Operational programs are those programs required to be implemented by the licensee during operations, but which might not have been implemented during construction (e.g., criticality control, radiation protection, etc.).
2. Operational program inspections are not intended to take the place of licensing reviews. The focus of the inspection should be on the readiness of the licensee to implement operational programs described in licensing documents (e.g., the radiological protection program would be described in licensing documents, and it would be reviewed/approved by the NRC during licensing. The inspection should focus on whether the licensee will be ready to implement the approved program, such as having adequate implementing documents, personnel training, etc.).
3. Inspections of operational programs should be performed by personnel with the appropriate expertise (such as personnel from NRR's Research and Test Reactors oversight organization).
4. Inspectors should use existing operational IPs as guidance for performing the inspection (e.g., criticality control inspection procedures used for inspections of operating research and test reactors should be used to inform the operational readiness inspection).

f. Open Items from Previous Inspections or Other Activities

1. Evaluate the status of significant items requiring corrective action. Such items might include 10 CFR 50.55e, 10 CFR Part 21, significant NRC inspection findings, licensee identified deficiencies, license conditions related to operation, etc.
2. Identify any open items that need to be completed prior to operation of the facility, and then evaluate the plans for completing the required actions.
3. Evaluate whether planned actions support the issuance of an operating license and include the results of the evaluation in the inspection report.

g. Inspection Report

1. An inspection report and any findings will be prepared, approved, and released in accordance with Inspection Manual Chapter 2550.
2. The inspection report documenting the operational readiness inspection should be forwarded to NRR's Research and Test Reactors licensing organization.

69022-03 RESOURCE ESTIMATE

The resource estimate for conducting the operational readiness inspection is approximately 200 hours of direct inspection effort. However, the scope of the inspection needs to be based on the specific circumstances of the facility to be inspected, so the actual hours will vary. The operational readiness inspection may be spread out over multiple inspections, by technical area, if recommended by the NPUF FSARG.

69022-04 REFERENCES

10 CFR Part 21, "Reporting of Defects and Noncompliance."

10 CFR 50.55, "Conditions of construction permits, early site permits, combined licenses, and manufacturing licenses."

69022-05 PROCEDURE COMPLETION

Implementation of this IP is considered complete when the activities identified during the inspection planning process have been inspected.

END

Appendix:

A. Readiness for Transition to Operations

Attachment:

Revision History Sheet for IP 69022

Appendix A, Readiness for Transition to Operations

69022-A1.01 BACKGROUND

Under Title 10 of the *Code of Federal Regulations* (10 CFR) Part 50, “Domestic Licensing of Production and Utilization Facilities,” a construction permit is issued to allow construction of a facility and an operating license must be issued before operation can commence. The U.S. Nuclear Regulatory Commission (NRC) findings that must be made before a 10 CFR Part 50 operating license can be issued are identified in 10 CFR 50.57, “Issuance of operating license.” The findings include the following: “(a)(1) Construction of the facility has been substantially completed, in conformity with the construction permit and the application as amended...”; “(a)(2) the facility will operate in conformity with the application as amended...”; and (a)(3)(ii) there is reasonable assurance that the facility will be operated “in compliance with the regulations....”

Region II supports the NRC’s program offices by implementing construction inspection programs. The results of construction inspections are used to support findings in 10 CFR 50.57(a)(1), 50.57(a)(2), and 50.57(a)(3)(ii). Specifically, completion of the inspections identified in Inspection Procedure (IP) 69020, “Inspections of Safety-Related Items (and Services) During Construction of Non-Power Production and Utilization Facilities,” and IP 69021 “Inspection of Quality Assurance Program Implementation During Construction of Non-Power Production and Utilization Facilities” support the finding required by 10 CFR 50.57(a)(1). Completion of certain inspections identified in IP 69021 (i.e., Appendix K, “Inspection of Requirement 2.11 – Test Control,” and related appendices) supports the finding required by 10 CFR 50.57(a)(2). Completion of the inspection identified in IP 69022, “Inspections of Operational Readiness During Construction of Non-Power Production and Utilization Facilities,” Section 02.02e, “Operational Program Inspections,” supports the finding required by 10 CFR 50.57(a)(3)(ii).

As described in Inspection Manual Chapter (IMC) 2550, “Non-Power Production and Utilization Facilities (NPUFs) Licensed under 10 CFR Part 50: Construction Inspection Program (CIP),” the NRC established a Facility Specific Assessment and Review Group (FSARG). The FSARG is an advisory group comprised of NRC staff from various offices including the Office of Nuclear Reactor Regulation (NRR), Office of Nuclear Material Safety and Safeguards (NMSS), and Region II. The FSARG has the responsibility for overseeing the implementation of the NRC’s NPUF construction inspection program and providing the basis for verifying that the construction of the NPUF was completed in accordance with applicable regulatory requirements and described in the operating license application as amended. The FSARG will serve as the focal point for coordination between Region II and Headquarters. The NRR representative will be responsible for coordinating group activities.

The FSARG will also assist Region II in developing the performance-based master construction inspection plan consistent with the construction inspection program guidance in IMC 2550 and associated inspection procedures.

69022-A1.01 INSPECTION OBJECTIVES

A1.01.01 Inform the Director, NRR, of when Region II has completed the inspections necessary to support the findings required by 10 CFR 50.57(a)(1), 50.57(a)(2), and 50.57(a)(3)(ii).

A1.01.02 Inform the Director, NRR, of any incomplete inspections or open items, including their significance, when Region II communicates its conclusions for Item 01.01.

A1.01.03 Inform the Director, NRR, of any significant issues identified during the inspection of construction or testing that could affect the conclusions associated with Item 01.01. Provide an updated list of any incomplete inspections or open items and their significance at that time.

69022-A1.02 INSPECTION REQUIREMENTS AND GUIDANCE

Licenses are expected to notify the NRC in writing when construction of the facility is substantially complete. Additionally, licenses are expected to provide a complete list of remaining construction and preoperational test activities that must be addressed prior to operation.

At the time a licensee notifies the NRC that construction is substantially complete, the NRC expects that the safety-related Structures, Systems, and Components (SSCs) required for initial startup; handling and storage of special nuclear material; shutdown of the facility; and prevention of accidents and the mitigation of consequences of accidents of the NPUF will have been installed at the site. The NRC also expects that the construction and pre-operational tests necessary to ensure the functionality of safety-related SSCs will have been performed and documented by the licensee in accordance with a formal plan. The licensee should have developed the operational test programs necessary to demonstrate that safety-related SSCs will remain functional during normal conditions and during and following design basis events.

Note: Notification by the licensee does not serve as the formal 10 CFR 50.57(a)(1) finding that construction is substantially complete; the NRC makes this finding based on the results of inspection activities described in this IP. Notification by the licensee only serves to inform the NRC that the licensee believes that construction has progressed to the point that Region II personnel can implement the provisions of this IP and determine that the facility is substantially complete.

After receipt of the “substantially complete” notification by the licensee, the FSARG will assess the status of the facility as described in the notification by reviewing the results of baseline inspections and the status of any planned inspections that have not been completed. The review will include the results of the operational readiness inspection described in this IP. If the FSARG concludes that the findings in 10 CFR 50.57(a)(1), 50.57(a)(2), and 50.57(a)(3)(ii) are supported by the results of inspections and any necessary licensee actions, it will provide its conclusion with the appropriate basis in the form of a recommendation to the Regional Administrator (RA) for Region II. If the RA for Region II agrees with the FSARG’s recommendation, the RA for RII will notify the Director, NRR, that it is reasonable to make the findings required by 10 CFR 50.57(a)(1), 50.57(a)(2), and 50.57(a)(3)(ii).

The FSARG recommendation will be in the form of a draft memorandum from the RA for Region II to the Director, NRR. The draft memorandum will include, as appropriate, appendices that address; (1) a description of any incomplete operational readiness inspections. Inspection items remaining to be completed should be discussed in sufficient detail to understand their impact on the proposed issuance of the operating license, (2) pending or open enforcement actions, and

(3) an assessment of whether any open allegations can potentially affect the outcome of any of the three findings¹.

The basis for supporting the conclusion that 10 CFR 50.57(a)(1) has been satisfied will be that the applicable inspections identified in IP 69020 and 69021 have been completed and there are no outstanding issues for which the licensee has not developed adequate corrective actions.

The basis for supporting the conclusion that 10 CFR 50.57(a)(2) has been satisfied will be that the inspections identified in IP 69020 and IP 69021 (i.e., Appendix K, "Inspection of Requirement 2.11 – Test Control" and related appendices), have been completed and there are no outstanding issues for which the licensee has not developed adequate corrective actions.

The basis for supporting the conclusion that 10 CFR 50.57(a)(3)(ii) has been satisfied will be that the operational programs inspections addressed in IP 69022, Section 02.02e, have been completed and there are no outstanding issues for which the licensee has not developed adequate corrective actions.

Region II may consider an inspection completed without completing all the inspection activities identified in the inspection procedures. For example, some of the appendices to IP 69020 may not be applicable to a specific NPUF. Consequently, the FSARG recommendation to the Region II Regional Administrator should be based on the completion of those inspection activities identified by the FSARG that constitute the construction inspection program for the facility. The completion of the construction inspection program for the facility provides reasonable assurance that the systems, structures, components, and operational programs will perform as described in the application or applicable regulation.

The Region II RA will issue the Readiness Memorandum after determining, based on the contents of the FSARG draft memorandum, the status of the construction inspection program for the facility, and the results of the most recent periodic performance assessment described in IMC 2550, that there is reasonable assurance that the findings of 10 CFR 50.57(a)(1), 50.57(a)(2), and 50.57(a)(3)(ii) have been met.

If the applicant experiences significant delays in completion of construction of the facility following the notification of substantial completion of construction, including: 1) the development of operational programs, 2) performance of construction and pre-operational testing, 3) closure of remaining open items, or 4) the discovery of significant technical errors in the design of the facility after the Readiness Memorandum is issued, then the FSARG should discuss whether additional inspection activities should be conducted and a follow-up Readiness Memorandum should be issued. Region II will promptly notify the Director, NRR, of any significant performance deficiencies or test failures that occur after the Readiness Memorandum is issued, but prior to issuance of the operating license. Any issues identified after issuance of the operating license will be addressed through the NRC's operational inspection, assessment, and enforcement processes.

¹ Allegations received after the Readiness Memorandum is issued, will be handled in accordance with Management Directive MD 8.8, "Management of Allegations," and Allegation Guidance Memorandum 2011-001, "Late-Filed Allegations." (Agencywide Documents and Access Management System (ADAMS) Accession No. ML11227A241).

Attachment 1 - Revision History for IP 69022

Commitment Tracking Number	Accession Number Issue Date Change Notice	Description of Change	Description of Training Required and Completion Date	Comment Resolution and Closed Feedback Form Accession Number (Pre-Decisional, Non-Public Information)
N/A	ML15083A165 12/14/15 CN 15-029	Initial Issue to provide guidance for the Operational Readiness inspections of Radionuclide Production Facilities licensed under 10 CFR Part 50.	Briefing for inspectors – prior to performing inspections covered by this IP	N/A
N/A	ML19193A110 10/09/19 CN 19-033	<p>This purpose of this update is to provide additional guidance on inspecting Moly-99 licensee readiness to transition to operations.</p> <p>Staff from the technical lead branch for this procedure has evaluated the document for continued applicability and have addressed previously identified change requests in the IMCIP update database.</p>	N/A	N/A