



**Procedure Professionals
Association**

Procedure Process Description

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Forward

In March 2005, at the direction of the Nuclear Information Management Strategic Leadership (NIMSL) steering committee, an Institute of Nuclear Power Operations (INPO) Community of Practice (CoP), an industry task force was chartered to address the broader scope of the procedure process through the development of an industry process description. This task force was composed of representatives from the NIMSL CoP and industry subject matter experts.

In 2010, the Procedure Professionals Association (PPA) assumed ownership and maintenance responsibilities for AP-907-001 (Procedure Process) and AP-907-005 (Procedure Writers' Manual). PPA is an industry working group for procedure related interests and is composed of subject matter experts from the U.S. commercial nuclear field, the U.S. Department of Energy, and other similar business interests. PPA is an open forum for procedure related issues and accepts membership from a variety of business entities.

In November 2010, PPA formed a standards committee and commenced work on a revision to AP-907-001 and AP-907-005. These revisions were completed and published in August 2011.

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1.0 PURPOSE AND SCOPE

- 1.1 The purpose of this procedure process description is to provide a standard process for creating and altering procedures.
- 1.2 This document is intended to be used by nuclear facility owners and operators to assess their organization's management of the procedure process as defined in the EUCG Standard Nuclear Performance Model. This process description establishes a baseline for consistent procedure activities and discusses performance measures.
- 1.3 This document is also intended to be used as a tool for performing effective self-assessments and benchmarking. An effective process description enables standardized comparisons to be made and provides a basis for improvement suggestions.

2.0 REFERENCES

- 2.1 10 CFR 50 Appendix B, Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants
- 2.2 10 CFR 71.113, Document Control
- 2.3 10 CFR 73.55.B.3.1, Requirements for Physical Protection of Licensed Activities in Nuclear Power Reactors Against Radiological Sabotage
- 2.4 ANSI N18.7-1976/ANS-3.2, Administrative Controls and Quality Assurance for the Operational Phase of Nuclear Power Plants
- 2.5 IAEA TECDOC-1058, Good Practices with Respect to the Development and Use of Nuclear Plant Procedures
- 2.6 INPO 85-026, Writing Guideline for Maintenance, Test, and Calibration Procedures
- 2.7 INPO 01-002, Guidelines for the Conduct of Operations at Nuclear Power Stations
- 2.8 INPO 06-002, Human Performance Tools for Workers
- 2.9 INPO 11-003, Guideline for Excellence in Procedure and Work Instruction Use and Adherence
- 2.10 INPO SOER 91-1, Conduct of Infrequently Performed Tests or Evolutions
- 2.11 INPO SOER 92-1, Reducing the Occurrence of Plant Events Through Improved Human Performance
- 2.12 NEI AP-907, Information Management Process Description and Guideline
- 2.13 NEI/EUCG TASK Force Report, Standard Nuclear Performance Model – a Process Management Approach, Revision 4
- 2.14 NRC Generic Letter 83-28 and Supplement, Required Actions Based On Generic Implications of Salem Anticipated Transient Without Scram Events
- 2.15 NRC Regulatory Guide 1.33, Quality Assurance Program Requirements (Operations)

- 2.16 NSAC-105, Guidelines for Design and Procedure Changes in Nuclear Power Plants
- 2.17 NUREG-0737, Post TMI-Requirements
- 2.18 NUREG-1358, Lessons Learned from the Special Inspection Program for Emergency Operating Procedures
- 2.19 NUREG/CR-1369, Procedure Evaluation Checklist for Maintenance, Test, and Calibration Procedures
- 2.20 NUREG/CR-3817, Development, Use, and Control of Maintenance Procedures in Nuclear Power Plants: Problems and Recommendations
- 2.21 NUREG/CR-3968, Study of Operating Procedures in Nuclear Power Plants: Practices and Problems
- 2.22 NUREG/CR-4613, Evaluation of Nuclear Power Plant Operating Procedures Classifications and Interfaces

3.0 **DEFINITIONS**

Administrative Procedure. A document that specifies requirements and actions necessary to implement a program or process. See the definition of Procedure for additional details.

Alteration. A generic term used to describe types of activities that modify approved procedures.

Approval Authority. The individual, by organizational title, designated in writing to approve procedures.

Backlog. Total quantity of uniquely identified procedure actions within a single tracking system.

Bases. The source of information for or the rationale behind procedure step(s) or sequence of steps.

Change of Intent. A procedure alteration that modifies what is accomplished by the procedure or changes the method by which processes are performed in a manner that may have safety significance.

Change Management. The application of tools and techniques that promote the successful initiation, planning, communication, implementation, and evaluation of change.

Comments. Feedback provided to the procedure writer during the procedure review process.

Commitment. Requirements that are uniquely identified to ensure future alterations do not inadvertently remove the requirement.

Continuous Improvement. The ongoing betterment of a process based on constant measurement and analysis of results produced by the process and use of that analysis to modify the process. Continuous improvement includes the act of monitoring and measuring processes and products against policies, objectives, and requirements for the product and reporting the results as well as taking the appropriate actions to make the necessary adjustments to improve the processes and products.

Cross Discipline Review. A review conducted by knowledgeable personnel in organizations affected by the procedure to verify functional and technical adequacy of those portions of the procedure that describe the process directly controlled by the affected organizations. This review also includes the potential impact on any other applicable controlled documents under the ownership of the affected organization.

Diagnostic Measure. Useful indicators or analytical tools for assessing a process or components of a process for trending purposes.

Editorial Correction. Alteration of the procedure which maintains the original intent and does not change the technical content of the procedure.

Effective Date. The date that an approved procedure can be used to perform a task.

EUCG. The Electric Utility Cost Group (EUCG) is a global association of energy and electric utility professionals that meets semiannually to discuss current and emerging industry issues, share best practices, and exchange data for benchmarking purposes.

Error Trap. Procedure format or content that challenges the users' ability to successfully perform a task.

Human Performance. The system of processes, values, behaviors, and their ultimate results that determine performance.

IDEF0. Integrated Definition for Functional Modeling (IDEF0) is a method designed to model the decisions, actions, and activities of an organization or system.

Immediate Change. A procedure alteration which typically involves a stop work situation or business need of the facility that requires an immediate change to the procedure.

Information Management. The activities and costs that comprise the formal process by which information important to the business is generated, revised, received, stored, retrieved, distributed, and destroyed.

INPO. The Institute of Nuclear Power Operations (INPO) is an organization created by the U.S. nuclear electric industry in 1979 to promote the highest levels of safety, reliability, and excellence in the operation of nuclear electric generating plants. All U.S. organizations that operate commercial nuclear power plants are INPO members. Nuclear operating organizations in other countries and nuclear steam supply system, architect/engineering, and construction firms are INPO participants.

Issuance Date. The date that an approved procedure can be used to perform a task.

Level of Detail. The technical detail necessary within a procedure step to successfully interface the individual user's knowledge to the technology being manipulated or task being performed.

Level of Use. A procedure classification that designates the minimum requirements for procedure use during an activity. The following levels of use are described in INPO 11-003:

- **Continuous Use.** Required for complex or infrequent work activities for which the consequences of an improper action could have an immediate, possibly irreversible adverse impact on safety, production, or reliability. Each step is read before that step is performed.
- **Reference Use.** Allowed for activities for which the consequences of an improper action are not immediate and are not irreversible. The procedure is referred to at least once and as often as required to complete the task per the requirements.
- **Information Use.** Allowed for activities, usually administrative in nature, that do not involve direct contact with plant equipment, are performed frequently, have no immediate consequences if performed improperly, and are within the knowledge and skills of experienced individuals. The user may complete the task from memory; however, the user is responsible for performing the activity per the procedure.

Limited Use. An alteration of a procedure that is valid only for the job package being worked or a specified period of time.

Major Revision. An alteration, based on the scope and complexity, that requires full and rigorous reviews.

Minor Revision. An alteration, based on the scope and complexity, for which limited reviews are appropriate.

NEI. The Nuclear Energy Institute (NEI) is the policy organization of the U.S. nuclear energy and technologies industry and participates in both the national and global policy-making process. NEI's objective is to ensure the formation of policies that promote the beneficial uses of nuclear energy and technologies in the United States and around the world.

New Procedure. A task that is not currently addressed in any existing procedure and is assigned a unique identifier.

NRC. The U.S. Nuclear Regulatory Commission (NRC) is an independent agency created by Congress in 1974 to enable the nation to safely use radioactive materials for beneficial civilian purposes while ensuring that people and the environment are protected. The NRC regulates commercial nuclear power plants and other uses of nuclear materials, such as in nuclear medicine, through licensing, inspection, and enforcement of its requirements.

Onsite Safety Review Committee. Standing committee for the review of items which may affect the safety of the facility (refer to NRC Regulatory Guide 1.33).

Operating Experience Review. Use of internal and industry operating experience and lessons learned to make organizational improvements.

Peer Check. Series of actions by two individuals working together at the same time and place, before and during a specific action, to prevent an error by the performer (refer to INPO 06-002).

Performance Measure. A management technique for evaluating the performance of a particular function, process, or person.

Procedure. A controlled document designed to improve human performance by clearly providing the purpose, specific intent, and sequenced direction for an activity or process.

Procedure Alteration Package. The information generated for obtaining required reviews and approval for a new or altered procedure. The alteration package includes the procedure alteration and relevant documents (e.g., copy of the procedures, procedure approval documentation, procedure review documentation, regulatory compliance documentation, incorporated procedure change requests, revised forms, bases documents, and commitment documents). Other items to include could be checklists or guides for performing required procedure reviews.

Procedure Change Request. A request to alter or develop a procedure (includes technical and administrative procedures).

Procedure Owner. The organizational position holder accountable for the integrity of the procedure throughout its life-cycle.

Procedure Reviewer. A knowledgeable individual to perform a specific type of procedure review.

Procedure Writer. The author or major contributor assigned to develop or alter a procedure. The procedure writer is responsible for the accuracy and usability of the revised portion of the procedure, its impact on the unrevised portion, and any other controlled documents. This individual is also responsible for developing a procedure alteration package, determining required reviews, and coordinating comment resolution for the alteration.

Process. A sequence of behaviors or series of steps designed to produce a product or service in a predictable, repeatable fashion.

Process Owner. The individual who coordinates the various functions and work activities at all levels of a process, regardless of the functional organizations involved. Process owners have the resource control and job skills to evaluate overall process operation and to evaluate potential process improvements. They design and manage the process end to end so as to ensure optimal overall performance. Process owners are responsible for ensuring the total process is both effective and efficient, and appropriate performance measures are in place to measure the process accordingly and ensure performance is continually improved.

References. Information used to develop the procedure content and support the requirements established within a procedure.

Regulatory Requirement. A federal, state, or local obligation that shall be met.

Requestor. Any person who identifies the need for a change to a procedure.

Review. A critical evaluation of a procedure alteration package.

SNPM. The Standard Nuclear Performance Model (SNPM) is an industry guiding document that is the result of a six year effort by the Nuclear Energy Institute, the Institute for Nuclear Power Operations, and the Electric Utility Cost Group. This model includes all INPO and NEI process descriptions, an aligned set of activity-based costing definitions for use in submission of cost data to the EUCG, and an aligned set of key performance indicators consistent with INPO guidance and supported by industry process owners known as Communities of Practice.

Stakeholder. An individual representing a business area that could be affected by the proposed change such that it may alter their behavior or processes as a result of a specified change. Stakeholders are in a position to provide the necessary input ensuring the final outcome meets required standards.

Subject Matter Expert. An individual that, by education, training and experience, is recognized as an expert on a particular system or subject.

Tacit Knowledge. Undocumented (tribal) knowledge.

Technical Procedure. A document that outlines a series of steps for the operation, maintenance, or testing of a structure, system, or component. See the definition of Procedure for additional details.

Technical Review. A review of the technical requirements and adequacy of a procedure.

Template. A writers' manual tool that determines the basic structure for a document and may contain document settings such as AutoText entries, fonts, key assignments, macros, menus, page layout, special formatting, and styles.

Validation. The process of exercising procedures to ensure that they are useable, the language and level of information is appropriate for the individuals for whom they are intended, and the procedures will function as intended.

Verification. The process of checking that procedures are technically correct, there is a correspondence between the procedures and the hardware, and the procedures accurately adhere to the guidance found in the writers' manual.

Writers' Manual. A controlled document that provides instructions for the format, human factoring, and content of procedures.

4.0 PROCEDURE PROCESS DESCRIPTION

4.1 Evaluate Request for New or Altered Procedure

Process Summary: A change request is received and placed into a single tracking system along with a minimal set of attributes which uniquely identify the request. A general review of the technical and administrative aspects of the request determines the validity and priority along with a review of impact on other procedures. Feedback on the request is provided to the submitter.

4.1.1 Receive Request

- a. When a procedure change request is received, it is placed into a single tracking system and assigned a unique number. This tracking system includes a minimal set of attributes for each procedure change request, including the following:
 - Procedure number
 - Clear description of the issue
 - Date issue identified
 - User or contact identification

4.1.2 Perform Initial Screening

- a. Once the procedure change request and associated attributes are entered into the single tracking system, the technical and administrative aspects of the request are reviewed to determine if the request is reasonable and appropriate.
 - If the procedure change request is determined to be reasonable and appropriate, it is evaluated further.
 - If the procedure change request is determined not to be reasonable or appropriate, it is rejected.
- b. Feedback on the status of the procedure change request is provided to the requester.

4.1.3 Evaluate Request

- a. The screened procedure change request is evaluated and either accepted or rejected.
 - If accepted, the procedure change request is statused as such in the single tracking system.
 - If rejected, the procedure change request is closed in the single tracking system or referred to another group for consideration and input.

- b. The following are potential reasons for rejecting a request:
 - Cost versus benefit
 - Risk versus benefit
 - Duplicate request
 - Technically incorrect
 - Format changes without human performance benefit
 - Personal preference alternations with insufficient management approval
 - Training issue
 - Individual accountability issue
 - Non-procedural issue (refer to Attachment 1, Procedure Decision Tree)
- c. The evaluation also addresses the impact of the proposed alternation on other procedures.
- d. Feedback on the status of the procedure change request is provided to the requestor.

4.1.4 Determine Priority

- a. Key attributes of the accepted procedure change request are evaluated to determine the risk and importance that the request presents to the facility. Some key attributes include the following:
 - Stop work issue
 - Reactivity issue
 - Safety issue
 - Potential for a direct impact on generation
 - Regulatory requirement
 - Next scheduled use of the procedure
 - Refueling outage activity
 - Engineering change request related activity
- b. Once risk and importance have been determined, scheduling is considered and the appropriate priority is assigned. Typical priorities include the following:
 - Technically incorrect such that the procedure must be revised to complete the task
 - Enhancement that provides additional level of detail to preclude a condition adverse to quality
 - Enhancement that is not adverse to quality
 - Editorial correction

4.2 Plan Procedure Development

Process Summary: The appropriate procedures to be revised are selected by reviewing the backlog and evaluating task priority, quantity, and other commitments. The type of change and appropriate work flow are based on the technical level of request. The task is then assigned to a procedure writer.

4.2.1 Evaluate Backlog and Select Next Priority Tasks

- a. Outstanding procedure change requests (backlog) are reviewed by priority, age, and the total number of procedure change requests per procedure.
- b. Outstanding procedure change requests are also reviewed for other considerations such as the following:
 - Outage goals
 - Management expectations
 - Cultural inputs
- c. The total number of procedure change requests against an individual procedure is also considered as it may be general indicator of overall procedure quality.
- d. Based on the review of outstanding procedure change requests, the appropriate procedures are selected for alteration.

4.2.2 Determine Workflow

- a. Based on the technical level of all planned alterations, time available to process the alteration, and duration of the alteration, the appropriate workflow is determined. Typical workflows include the following:
 - New procedure or major revision
 - Minor revision
 - Editorial correction
- b. Variations on these workflows may include but are not limited to the following:
 - An immediate change typically involves a stop work situation or business need that requires an immediate change to the procedure.
 - A limited use change is only valid for the job package being worked or a specified period of time.
- c. Use of the major revision process is considered for changes of intent, methodology, and a majority of steps. Also considered is the time since the last major revision.

4.2.3 Assign Work

- a. Once the workflow type is determined, the task is assigned to a procedure writer.

4.3 Research Request and Develop Procedure Draft

Process Summary: The assigned procedure writer (hereafter called procedure writer) assembles a procedure change package and validates the scope of the assigned work. The writer determines the change to the procedure by reviewing applicable operating experience, outstanding issues, references, human performance challenges, and technical content. The writer then develops the detailed draft of the procedure using the correct template and the writers' manual.

4.3.1 Validate Scope

- a. The procedure writer begins to assemble a procedure alteration package and performs the following actions, depending upon the workflow, to validate the assigned task. At this point, a questioning attitude is essential.
 1. Verify type of workflow to be followed.
 2. Determine appropriate level of use.
 3. Review plan with procedure owner and requestor to ensure issues are being addressed.
 4. Review material with the subject matter expert and appropriate stakeholders (e.g., licensing, engineering, safety analysis, training).
- b. The procedure writer identifies the following change management needs:
 - Impact on other documents (e.g., design basis documents, other procedures)
 - Impact to other processes (e.g., work management, design change)
 - Impact on training
 - Appropriate due date

4.3.2 Identify Applicable Internal and External Operating Experience

- a. The procedure writer reviews applicable operating experience that addresses issues related to the validated procedure alteration task. This includes the following actions:
 1. Search external databases for related issues (e.g., INPO, WANO, NRC).
 2. Search internal resources for related issues (e.g., Corrective Action Program, post-job critiques, tacit knowledge, self-assessments, benchmarking).
 3. Identify applicable operating experience.
- b. To be effective, the procedure writer's review considers not only the event but the error-likely situation and its precursors for applicability.
 - Carefully reviewed operating experience can be used to identify error precursors and their associated organizational weaknesses.
 - This review can take the form of a facilitated discussion of operating event precursors, flawed defenses, and the use of jobsite tools to prevent the event.
 - Any gaps indicate a need for modified or additional tools.

4.3.3 Evaluate Outstanding Issues

- a. The procedure writer evaluates outstanding issues related to this procedure and determines if they should be incorporated into this alteration. This includes the following actions:
 1. Review open procedure change requests.
 2. Review the procedure to determine compliance with the writers' manual and other administrative changes.
 3. Evaluate other work in process on this procedure (e.g., pending licensing amendments, modifications).

4.3.4 Verify References

- a. The procedure writer verifies existing references are current and the references for this alteration are correct.

4.3.5 Determine Technical Content

- a. The procedure writer determines the technical content to be incorporated into the procedure. Depending upon the extent of the alternation, the writer should identify the following when developing this content:
 - Performance objectives
 - Necessary activities
 - Level of detail
 - Need to define and refine processes
 - Interfaces with other processes and work groups
 - Impact of potential critical steps
 - Control points (e.g., quality, health physics, engineering, supervisory)
 - Expected plant responses, including effects on reactivity and nuclear safety
 - Configuration management and equipment status control requirements (e.g., independent verification of as-left positions)
 - Job hazards from radiological and industrial safety points of view, including consideration of any special precautions and personnel protective equipment
 - Special methods of communication
 - The environment and location where the work will be performed
 - Unique procedure use and adherence requirements (e.g., working out of sequence, wavier of placekeeping, use of not applicable)
 - Unique management controls (refer to INPO SOER 91-01)
- b. When addressing level of detail, the procedure writer takes into account the following:
 - Worker knowledge and skill, considering the procedure should be written for the least experienced qualified worker (The writer should recognize that worker knowledge and experience is expected to decline with the aging of the workforce. Tacit knowledge should be captured while the opportunity exists.)
 - Complexity and frequency of task
 - Consequence of error
 - Identification of instrumentation
 - Level of oversight
- c. If incorporating a new methodology or creating a new procedure, the procedure writer considers the need for a task analysis and process flow map.

4.3.6 Evaluate Human Performance Challenges

- a. The procedure writer identifies and develops defenses to human performance challenges, including the identification of latent weaknesses and potential error traps such as the following:
 - In-field decisions without clear guidance
 - Excessive in-field decisions
 - Vague steps or steps missing critical detail (consider if the job is knowledge-based and over-relying on the skill-of-the-craft)
 - Excessive physical challenges
 - Inappropriate use of verifications and peer checks
 - Inadequate defense-in-depth (termination criteria not specified)
 - Excessive branching
 - Inconsistent place-keeping methods
 - Information in prerequisites, notes, cautions, and warnings that does not add value
 - Un-related actions in the same step
 - Actions or acceptance criteria embedded in notes, cautions, or warnings
 - Complex calculations without peer check
 - Atypical steps or terms
 - Vague interpretive guidance (verbiage that could be perceived as giving tacit management acceptance of human behaviors such as shortcuts and non-compliance, or require the user to act based upon perceptions and background leading to knowledge-based errors)
 - Time constraints
- b. The procedure writer considers that administrative and technical procedures have different purposes and thus contain different error potentials.
 - Administrative procedures have the potential to contain embedded latent organizational weaknesses. These weaknesses may be difficult to identify from a cursory glance and may require an extensive evaluation of the procedure's intent and content.
 - Technical procedures direct activities at the man-machine interface. As such, they can directly impact human performance, and are more susceptible to error traps.

4.3.7 Develop Detailed Draft

- a. From the information gathered in the previous steps, the procedure writer creates a draft that will be used for the review process. In doing so, the writer performs the following actions:
 1. Determine the correct template based on hardware, software, the type of procedure being altered, and the type of alteration being made.
 2. Comply with the writers' manual (e.g., procedure numbering, organization, format, writing style).
 3. Update bases and references, if applicable.
 4. Assemble a procedure alteration package that includes the draft procedure, description of changes, and supporting documentation.
 5. Perform a self-check to ensure quality of the drafted procedure alteration.

4.3.8 Requestor Evaluate Draft

- a. The procedure writer provides the requestor a draft of the procedure and the opportunity to provide feedback on the proposed changes. Any feedback from the requestor is addressed before proceeding.

4.4 Review Procedure Draft

Process Summary: The procedure writer determines the appropriate review(s) for the procedure change and routes it accordingly. A determination should be made as to which reviews are in series and which may be performed in parallel. The procedure reviewers perform these reviews and provide documented comments. The procedure writer ensures that comments are resolved. To ensure usability, validation by a user or team of users is considered.

4.4.1 Determine Appropriate Reviews

- a. The procedure writer recommends the appropriate reviews to be implemented for the procedure alteration, gains concurrence, and routes accordingly. This recommendation considers which reviews are to occur in series and which may be performed in parallel.
- b. The following table is a list of possible reviews that may be required, depending upon the extent and type of alteration. This list is not all-inclusive.

Procedure Reviews	Workflow Type			
	Major and Limited	Minor	Editorial	Immediate
Independent Technical Review	R	O	O	R
10 CFR 50.59 and Design Basis Documentation (license compliance review including - EQ, UFSAR, Tech Spec, flooding, facility license renewal, heavy loads, instrumentation impact (NRC Reg. Guide 1.97), NRC Reg. Guide 1.33, 10 CFR 50 Appendix B, 10 CFR 50 Appendix R, etc.)	R	R	NA	R
Writers' Manual (provides for procedure use and adherence alignment [NRC Inspection Manual Part 42700 - Plant Procedures, Appendix A])	R	O	O	NA
10 CFR 72.48 and Design Basis Documentation	PS	PS	NA	O
Emergency Plan	PS	PS	NA	O
Environmental Compliance	PS	PS	NA	O
Security	PS	PS	NA	O
Industrial Safety	PS	PS	NA	O
Cross Discipline (ALARA, health physics, chemistry, engineering, etc.)	O	O	O	O
Probabilistic Risk Assessment and Maintenance Rule	PS	PS	NA	O
Operational Risk	PS	PS	NA	O
Reactivity Management	PS	PS	NA	O
Training	PS	PS	NA	O
Table legend: R - Required PS - Prescreen O - Optional NA - Not Applicable				

4.4.2 Perform Reviews

- a. The designated reviewers perform a review of the drafted procedure alteration and provide comments to the writer in such a manner that it can be tracked for resolution and verification.
 - Reviewers are to be knowledgeable of the information being reviewed.
 - Independent technical reviews are performed by persons not involved in authoring the change.

4.4.3 Resolve Review Comments

- a. The procedure writer ensures that comments are resolved by performing the following:
 1. Ensure sufficient reviews are obtained and comments incorporated, as appropriate.
 - Independent and thorough reviews are critical to ensure a quality product.
 - Significant changes incorporated during the review process may require the procedure be re-routed or additional reviews be obtained.
 - If problems occur during the review process indicating lack of or poor quality responses, the writer should stop further processing of the procedure and escalate the issue to higher management.
 2. Provide comment resolution to reviewers. If a comment cannot be resolved, the writer escalates the issue to higher management.

4.4.4 Validate Procedure

- a. A user or team of users performs a validation of the following procedure alterations:
 - New procedures
 - Technical procedures that are going through extensive change or revision
 - Support procedures for Emergency Operating Procedures and Abnormal Operating Procedures
- b. Typical validation methods include the following:
 - Performance on a mock-up or spare equipment
 - Simulator scenario
 - Walkthrough
 - Comparison
 - Table top

4.5 Approve Procedure

Process Summary: The procedure writer ensures that the procedure is ready for approval, the procedure owner is identified, and the applicable reviews were obtained and properly documented prior to submitting the procedure for approval. Procedures that impact nuclear safety may require review by the facility onsite safety review process. The designated approval authority then approves the procedure.

4.5.1 Ensure Procedure is Ready for Approval

- a. The procedure writer ensures that review and comment resolution have been successfully completed and prepares a procedure approval package, including the updated procedure draft, description of alterations, and supporting documentation. In doing so, the writer ensures completion of the following actions, when applicable:
 - Concurrence has been obtained (includes cross-discipline concurrence when another work group is affected or involved in performing the process or procedure)
 - Procedure is in proper format, (e.g., revision number is correct, page numbering correct)
 - Owner of the process or procedure is identified
 - Verification and validation are satisfactory
 - Procedure alteration package documentation is complete
 - Controlled computer files are updated with the latest version of the draft

4.5.2 Determine if Onsite Safety Review is Required

- a. Using facility specific guidance, the procedure writer determines if an onsite safety review is required for procedures that impact nuclear safety.

4.5.3 Obtain Onsite Safety Review

- a. If the procedure alteration requires review by the onsite safety review committee, this committee uses a deterministic process to ensure that procedure alterations have not compromised nuclear safety.

4.5.4 Obtain Final Approval

- a. Once all necessary reviews have occurred, the procedure is approved by the designated approval authority or designee having responsibility for implementing the procedure.
 - Speed and simplicity of procedure approval are essential.
 - Appropriate approvals are necessary; however, multiple approvals dilute accountability and should be avoided.

4.6 Finalize and Implement Change Management Plan

Process Summary: While change management should be considered throughout the procedure process, the change management plan may not be finalized and the implementation tools put into place until the procedure change is approved. The resulting change management plan helps ensure a successful transition from the current state to a desired future state.

4.6.1 Evaluate Need for Change Management

- a. While change management should be considered throughout the procedure process, this step ensures that change management is evaluated. A change management plan is considered when the procedure change:
 - Affects training (tools and personnel qualifications).
 - Impacts other departments or facilities.
 - Impacts scheduled work.
 - Impacts routinely used work products or services (e.g., forms, software applications, databases).
 - Involves a new procedure or limited use procedure change.
 - Involves a safety significant, high risk (INPO SOER 92-1), or complex task.

4.6.2 Develop Final Change Management Plan

- a. The following are considered as the change management plan is developed:
 - Description of the alteration and the stakeholder impacts
 - Implementation schedule
 - Training needs
 - Effective date
 - Expiration date for limited use changes or infrequently performed procedures
 - Bases document update (e.g., drawings, Technical Specifications, Final Safety Analysis Report)
 - Coordination of alterations to related procedures
 - Transition plans for products or services that are started under the old procedure but will be completed under the new one
 - Completion of equipment modifications and changes
 - Special tools, aids, permits, and other items
 - Communication plan
- b. Appropriate change management implementation tools are identified and developed.

- c. Stakeholder concurrence is obtained and the change management plan is adjusted as necessary for specific stakeholder requirements.
- d. Work assignments to implement the change management plan are also made (e.g., training, line organizations).

4.6.3 Implement Change Management Plan

- a. The change management plan is implemented according to the previously developed implementation schedule and milestones are tracked to completion.
- b. Implementation feedback is factored into any necessary adjustments to the change management plan.

4.7 Issue Procedure for Use

Process Summary: Depending on the needs of the facility, a procedure may be approved and staged in advance of its intended effective date. Once approved, the procedure may be submitted for issuance and distribution with an immediate or delayed effective date. The effective date is based on completion of key change management activities.

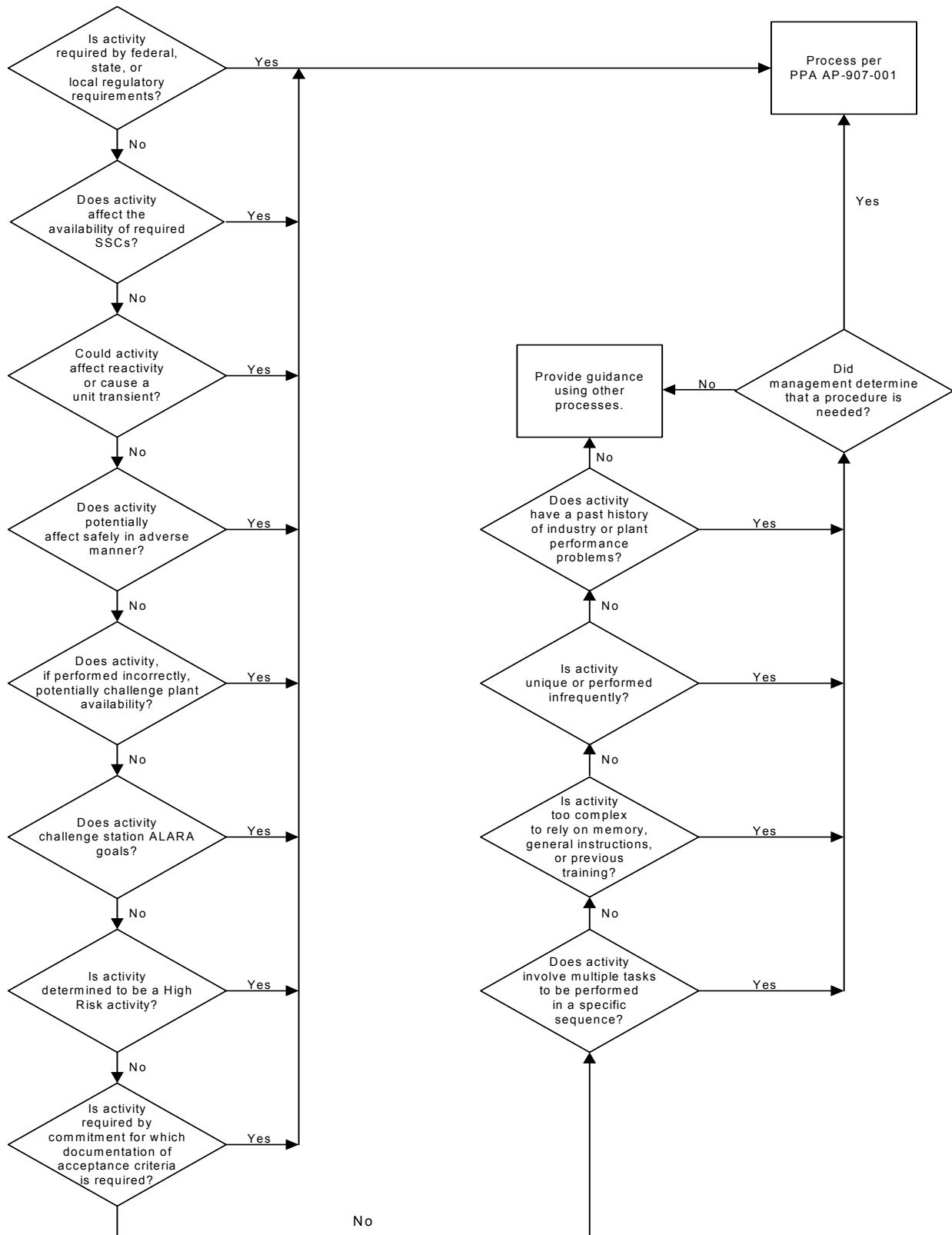
4.7.1 Authorize Issuance

- a. Once the procedure alteration package and implementation plan are approved, the procedure alteration package is prepared and authorized for issuance. This includes the following actions:
 - 1. Determine effective date.
 - 2. Release procedure alteration for use.

4.7.2 Submit for Issuance

- a. Once the procedure alteration is authorized for issuance, the following actions are performed:
 - 1. Submit approved procedure for issuance.
 - 2. Transfer completed procedure alteration package to the Document Management Process.
 - 3. Disposition completed change request(s).
 - 4. Provide feedback to the original requestor(s).

Attachment 1. Procedure Decision Tree
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Attachment 2. Procedure Process Performance Measures
(Page 1 of 4)

1. Industrywide Key Performance Indicators

Industrywide key performance indicators are provided for process performance comparison and as comparative analytical tools.

- The definition of the indicator clearly identifies the purpose for the measure, the quantity being measured, and the source of the data.
- Rolling averages may be used to correct aberrations in data caused by uneven schedule loading or brief periods of high emergent work.
- Indicator definitions are provided to help ensure consistent reporting to the extent possible.
- Measurement periods are based on individual site fuel cycle but are rolling periods covering the immediately preceding months equal to the site’s fuel cycle.

One procedure change request may affect multiple procedures. For the purposes of these performance indicators, each procedure requiring a change as the result of the procedure change request will be counted individually.

Diagnostic Title	Procedure Quality
Definition	Total number of procedure content problems identified as adverse to quality in the corrective action system during the previous month. If more than one procedure is affected by the original request, for the purposes of performance measures they are counted as multiple requests. For reporting at a facility (site), the number of corporate content problems should be added to the facility (site) number.
Unit of Measure	One per procedure affected by change request
Frequency	Monthly
Reason for Reporting	Tracked by monitoring corrective action reports written and to identify technical or functional deficiencies uncovered in approved procedures, this indicator ensures that adequate and accurate reviews and approvals are occurring before procedures are released for use.
Calculation	Total quantity per month per facility (site)
Note	For EUCG reporting, the 12 month rolling average

Diagnostic Title	Incoming Change Request Quantity
Definition	The total number of change requests received during the measurement period
Unit of Measure	One per procedure change request
Frequency	Monthly
Reason for Reporting	Provide an indicator of a healthy environment for continuous quality improvement
Calculation	Total number of change requests received in the previous month
Note	For EUCG reporting, the 12-month rolling average

Attachment 2. Procedure Process Performance Measures
(Page 2 of 4)

Diagnostic Title	Incoming Change Request Quantity
Definition	The total number of change requests received during the measurement period
Unit of Measure	One per procedure change request
Frequency	Monthly
Reason for Reporting	Provide an indicator of a healthy environment for continuous quality improvement
Calculation	Total number of change requests received the previous month
Note	For EUCG reporting, the 12-month rolling average

2. Suggested Procedure Process Diagnostic Measures

The following diagnostic measures are useful indicators for assessing the procedure process. The measures are provided and intended to be used as a menu of possible analytical tools to be selected and used by process owners when performing self-assessments of the procedure processes. The expectation is that measures will be selected based on the need of the organization. It is a good business practice to have a minimum set of diagnostic measures for each major process area. It is recognized that some current systems may not support measurement of all the diagnostic measures suggested.

One procedure change request may affect multiple procedures. For the purposes of these diagnostic measures, each procedure requiring a change as the result of the procedure change request will be counted individually.

Diagnostic Title	Completed Quantity
Definition	Number of procedure change requests closed
Unit of Measure	Quantity
Frequency	Monthly
Reason for Reporting	Ensure processes within the procedure program are conducive to execution of work
Calculation	Count of closed procedure change requests
Note	Includes rejected procedure change requests

Attachment 2. Procedure Process Performance Measures
(Page 3 of 4)

Diagnostic Title	Refueling Outage Readiness
Definition	Refueling outage procedure change request completion rates
Unit of Measure	Percentage
Frequency	Variable based on proximity to refueling outage
Reason for Reporting	Indicate if procedure change requests are ready for the refueling outage by the established freeze date
Calculation	Number of requests completed divided by number of requests required for the outage, times 100

Diagnostic Title	Online Readiness
Definition	Measure of the integration of the work planning process with the procedure change request processes
Unit of Measure	Quantity
Frequency	Weekly
Reason for Reporting	Ensure procedures are ready to support scheduled surveillances, maintenance, or plant modifications (e.g. T-4)
Calculation	Number of work orders on hold for procedure issues

Diagnostic Title	Customer Satisfaction
Definition	Measure customer satisfaction with procedures and procedure-related processes
Unit of Measure	No quantitative values
Frequency	Annually (self-assessment)
Reason for Reporting	Ensure procedures and procedure-related processes meet the needs of users
Calculation	Self-assessment

Diagnostic Title	Total Backlog Quantity
Definition	Total quantity of uniquely identified and approved procedure change requests within the single tracking system
Unit of Measure	One per procedure affected by change request
Frequency	Monthly
Reason for Reporting	A large backlog may be indicative of procedure change requests that are not being completed in a timely manner. The increasing backlog challenges the ability to perform proactive improvements.
Calculation	Total quantity

Attachment 2. Procedure Process Performance Measures
(Page 4 of 4)

Diagnostic Title	Priority Backlog Percentage
Definition	Ratio of priority procedure change requests within the single tracking system as compared to backlog quantity. Priority change requests are defined as following: <ul style="list-style-type: none"> • Procedure can not be used as written • Procedure works but has caused significant identifiable technical or functional challenges • Any conditions adverse to quality
Unit of Measure	One per procedure affected by change request
Frequency	Monthly
Reason for Reporting	Priority change requests are broken out because they represent actual risk to the facility. A rising trend on these items may indicate insufficient attention on procedure deficiencies. This indicator helps maintain a balance between priority change requests and other activities that may draw the facility's attention.
Calculation	Procedure quality divided by total backlog quantity, times 100

Diagnostic Title	Average Age by Priority
Definition	Average age of approved change requests sorted by priority (typically four priority levels)
Unit of Measure	Days
Frequency	Monthly
Reason for Reporting	Identify procedure change requests are incorporated in a timely manner
Calculation	Total number of days for each change request divided by the total number of change requests