APS Design Reviews

This procedure implements and maintains controls related to the Safety Assessment Document (SAD) for the Advanced Photon Source and/or the APS Accelerator Safety Envelope (ASE).

Any changes made to this procedure should ensure these controls are maintained; see "APS Accelerator Safety Configuration Management Plan" (APS_1693025).

Changes made in this revision:

- Removed Technical Operations Specialist from preparers list and added PSC QAR
- Updated Section 1.3 to include terms from DOE O 420.2D
- Section 3.1, step 1, addition of LMS-MNL-20 requirement of the APS-1277 Design Plan Form
- Section 3.1, materials required in a final design report to include those for verification and validation testing
- Edits for clarity on provision of the APS-1277
- Updated hyperlink to General APS Design Review Checklist in Appendix B
- Added reference to PSC Design Review Committee (PDRC) Charter in section 4

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APS Design Reviews

1. INTRODUCTION

1.1. Purpose

APS design reviews assess the adequacy of a design in meeting performance, safety, and operational objectives.

1.2. Scope

This procedure:

- Defines the process to evaluate system and component designs, to determine their adequacy in meeting performance, safety, and operational objectives. It applies to the designs of new or modified components and systems.
- Provides a grading rubric to determine the appropriate scope and level of formality and approval for a design. Grading is based on the potential consequence of a failure in the implementation of a design and considers the potential financial, operational, and environment, safety, & health consequences of a failure.
- Identifies grading and Unreviewed Safety Issue determination requirements.
- This procedure does not apply to experiment-specific, transient systems and components (see APS Experiment Safety Reviews)

1.3. Definitions

Accelerator
A device and its components employing electrostatic or electromagnetic fields to impart kinetic energy to molecular, atomic, or sub-atomic particles and capable of creating a radiological area as defined by 10 CFR Part 835, Occupational Radiation Protection. Accelerator components include injectors, targets, beam dumps, detectors, experimental enclosures, accelerator enclosures, experimental areas, and experimental apparatus utilizing the accelerator. The accelerator also includes associated support and test facilities, equipment, systems, and utilities necessary to operate the accelerator or utilize the accelerated beam.

Accelerator Facility
The accelerator, plant, buildings, structures, and equipment supporting the accelerator and its operations that are under the direct control of the contractor.

Accelerator Operations
Activities within the accelerator facility that, over the lifecycle of the facility, support 1) production or utilization of accelerator beams; 2) research and experimental activities utilizing accelerator beams; 3) handling, storage and analysis of accelerator induced radioactive components and materials within the accelerator facility boundary; 4) receipt, preparation, assembly, inspection, and installation of samples into the accelerator beam; or 5) removal, disassembly, handling, analysis, and storage for radioactive dose minimization to meet the definition of ALARA in 10 CFR Part 835, Occupational Radiation Protection, or transportation requirements, and packaging of samples after use in the accelerator beam. Accelerator Operations excludes radioisotope processing activities that are not required to operate or maintain the accelerator.

Accelerator Readiness Review (ARR)
A structured method for verifying that hardware, personnel, and procedures associated with commissioning or routine operations are ready to permit the activity to be undertaken safely.

Accelerator Safety Envelope (ASE)
A documented set of verifiable physical and administrative requirements, bounding conditions, and credited controls that ensure safe operation and address accelerator specific hazards and risks.

Commissioning
A phase of an accelerator facility operation that is typically used to conduct initial beam testing and/or verify design specifications. Commissioning periods may be tailored to the needs of each facility and there may be great variations in their duration, breadth, and formality, but in all cases, the activities will be bounded by an ASE and preceded by an ARR and DOE approval.

Credited Controls
Controls determined through Safety Analysis to be essential for safe operation directly related to the protection of workers, the public, and the environment.

DOE Element:
First-tier organizations at DOE/NNSA HQ and in the field as listed in the Correspondence Style Guide, Office of the Executive Secretariat.

DOE Field Element Manager
The manager having overall responsibility for a DOE field element including execution of oversight policy implementation. The Field Element Manager directs activities of DOE/NNSA field or site offices and has line accountability for all site program, project execution, and contract management.

DOE Program Secretarial Officer (PSO)
An Assistant Secretary, Office Director, Head of Program Element, or NNSA Deputy Administrator to whom designated field offices directly report and who has overall landlord responsibilities for the assigned direct reporting elements.

Equivalent Change
An equivalent change continues to meet the design requirements for the equipment and does not impact the safety or design basis.

Project Lead
The individual, typically the scientist or engineer, who is cognizant of the full scope of work and has overall responsibility for executing a project. The Project Lead ensures that designs are approved per this procedure prior to executing the project.

Radiation:
Ionizing radiation, including the accelerated particle beam and the radiation produced when the beam interacts with matter or changes direction. Radiation includes alpha particles, beta particles, gamma rays, X-rays, neutrons, high-speed electrons, high-speed protons, and other particles capable of producing ions.

Radiation Safety Systems (RSS)
Shielding, interlocks and other hardware that prevent the exposure of personnel to unacceptable levels of ionizing radiation (see Change Control for Radiation Safety Systems for additional information on RSS).

Radioisotope Processing
Chemical, thermal, or physical actions taken to separate, isolate, refine, or enrich specific isotopes of a chemical element.

Residual Radioactivity
Radioactivity in structures, materials, soils, groundwater, and other media at a site resulting from the accelerator or accelerator operations.

Responsible Manager
The individual with line management responsibility over the Project Lead, and therefore the project. The Responsible Manager tasks/charges the committee with reviewing designs for projects in their respective area of responsibility. This is typically a Group Leader, Cost Account Manager (CAM) or more senior level manager. The AES Division Director acts as the Responsible Manager for Collaborative Access Team (CAT) designs.

Reviewed Safety Issue:
The outcome of the evaluation and determination phase of the USI Process.

Risk
A quantitative or qualitative expression of possible harm, which considers both the probability that a hazard will cause harm and the amount of harm; or, alternatively, an

estimate of the probability of occurrence of a hazard-related incident and the severity of the consequence associated with the incident.

Safety Analysis
A documented process to systematically identify the hazards of a given operation; including a description and analyses of the adequacy of measures taken to eliminate, control, or mitigate the hazards and risks of normal operation; and identification and analyses of potential accidents and their associated risks.

Safety Assessment Document (SAD)
A document containing the results of a Safety Analysis for an accelerator or accelerator facility pertinent to understanding the risks to workers, the public, and the environment of operating the accelerator.

Unreviewed Safety Issue (USI)
An activity or discovered condition with accelerator specific hazards that have yet to be evaluated to determine if the activity or discovered condition introduces accelerator specific hazards that are not adequately addressed by the current APS Safety Assessment Document (SAD) (APS_1188832) and approved Accelerator Safety Envelope (ASE). (APS_2278796).

Unreviewed Safety Issue (USI) Process
The process or methodology used to evaluate/review USIs to determine if the activity or discovered condition is adequately addressed by the current SAD and approved ASE (see the APS Unreviewed Safety Issue Determination policy and LMS-PROC-383, Facility-Specific Implementation of Unreviewed Safety Issue (USI) Procedure).

2. Photon Sciences Design Review Committee (PDRC)

The PDRC is charged with conducting design reviews and will:

- Perform reviews in accordance with the charge from the responsible manager.
- Ensure that the level of the review is commensurate with the complexity of the technical design and intended function, and that safety aspects of the design are considered.
- Check compliance with applicable codes, regulations, and other applicable standards.
- Ensure that any additional follow-on safety committee review(s) or subject matter expert consultations are completed.

The PDRC Chairperson will:

- Ensure that the design review committee includes appropriate stakeholders.

- Provide a report to the approver (see Table 3) including an explicit list of any actionable and pre-start recommendations.
- If a consensus on recommendations is not reached by the committee, the report should address the dissenting opinions.
- Archive records in the APS Document Management System (DMS) and the Integrated Content Management System (ICMS).
- Ensure that the Unreviewed Safety Issue determination process is followed if the design involves a change that may introduce accelerator specific hazards that are not adequately addressed by the current APS Safety Assessment Document (SAD) and associated approved Safety Envelope (ASE) and the change is not an "equivalent change".

3. DESIGN REVIEW PROCEDURE

3.1. Step 1: Establish Scope of Review and Applicable Requirements

The Responsible Manager is encouraged to consult early with the Project Lead, responsible ES&H Coordinator, and Quality Assurance Representative (QAR), as appropriate, to provide for process oversight and develop a design plan and review roadmap. An APS-1277, Design Plan, form shall be completed by the project members with the PDRC Chair for APS records and in accordance with the LMS-MNL-20 requirements.

The Project Lead ensures the appropriate documentation is submitted for review. The scope of the review is to be provided, defining the extent and performance of the systems or components under review. Materials in a design report include, as appropriate:

- Drawings and specifications as appropriate to demonstrate functionality to reviewers.
- Identification of design standards, ES&H, and QA drivers.
- Analyses, qualification inspection, or acceptance testing used to verify that the component/system meets design requirements and standards
- Validation plans used to confirm the component or system meets intended functional/performance requirements.
- A hazard analysis with mitigations identified.

Much of the content of a design report should already be available as a routine part of the engineering process—a design report captures this information in a coherent package.

3.2. Step 2: Design Review Requirements Grading

The PDRC Chair, in consultation with the Responsible Manager/Project Leader as needed, determines the overall consequence rating—see Table 1.

To determine the requirements for reviewing and approving designs, there is a need to ask what can go wrong in a credible design failure scenario, including chain failures when integrated systems are involved.

The consequence levels are based on the credible, even if remote, chance for the consequence occurring during the life of the facility or operation.

Experience with a design must be considered in assessing the potential consequences. New designs, especially of complex systems, generally should be assumed to have a higher probability of more significant design failures and therefore fall into higher consequence grades. Designs based on proven designs generally may be assumed to have lower probabilities of significant design failures and therefore fall into lower consequence grades.

The overall consequence rating assigned should be the highest determination from any one category. For example, if a design change scores as a Major Consequence the financial category, but Serious in all other categories, then a Major Consequence rating shall be assigned overall.

Consistent with the importance in managing radiation shielding:

- Modifications, other than equivalent changes, of a RSS, should be graded at least as a serious consequence.
- Adding new or substantial modification to an RSS will typically be graded as a major consequence.

Table 1: Design or Design Modification Screening for Consequence Rating

Based on a Credible Likelihood of a Design Failure Consequence

	Negligible to Minimal Consequence	Moderate Consequence	Serious Consequence	Major Consequence
Category	***Consequence Threshold***	***Consequence Threshold***	***Consequence Threshold***	***Consequence Threshold***
Safety Personnel safety including radiation exposure	Injuries or ailments not requiring medical treatment	Minor injuries, first aid treatment, or minor medical treatment.	Injuries which require medical treatment without hospitalization, ES&H impacts or damage. Modification, other than equivalent changes, to RSS	Serious or life-threatening injury or multiple serious injuries requiring hospitalization
Examples	*Light mechanical work associated with routine component replacement, may involve the use of a pallet truck or experiment station hoists*	*Moderate mechanical work associated with routine component replacement may involve the use of an A-frame hoist or forklift.*	*Design change introduces electrical hazard e.g., Mode 2 work at minimum QEW2 voltages/current per the Electrical Safety Manual.* *Modification, other than equivalent changes, to radiation shielding, PSS, or ACIS.* *Small conventional construction.* *Installation of heavy (> 1,000 lbs.) component.*	*Design change introduces significant electrical hazard e.g., involves Mode 3 work* *Adding or a significant non-equivalent change to a safety system control such as radiation shielding, PSS, or ACIS.* *New beamline addition or significant conventional construction project*
Financial Loss Recovery costs including material and labor	Less than $50k	Greater than $50k and less than $100k	Greater than $100k and less than $250k	Greater than $250k
Examples:	*Minor part(s) replacement to return to service*			*Design error leading to major equipment damage (> $250k)*
Continuity of Operations Including accelerator, beamline downtime and facility modifications	Accelerator: < 1 hours or Beamline: < 0.5 days	Accelerator: 1 – 24 hours or Beamline: 0.5 – 2 days	Accelerator: 24 – 48 hours or Beamline: 2 – 7 days	Accelerator: > 48 hours or Beamline: > 7 days
Examples:	*Storage ring access not required.* *Minimal Service Request Order work*	*Small conventional construction modifications of plant facilities (<$50k total project cost).*	*Accelerator system modification during user run, no bake out needed.* *Limited conventional construction modifications of plant facilities (>$50K and <$1M total project cost).*	*Accelerator system modification during user run, with bake out.* *Significant conventional construction project*

As determined by the consequence rating, a progressive set of reviews may be required as designs mature—see Table 2. The steps in design reviews—conceptual, preliminary, and final—are based on design maturity and should be timed to most productively suit the project under review.

The conceptual design should establish a feasible scheme to meet project performance requirements and determine bounding and interface conditions for the design. At the preliminary design level, the overall project design is established and the performance and bounding/interface requirements for subcomponents and subsystems are defined. The final design will include the design of subsystems and subcomponents and allow for final refinements/adjustments prior to fabrication without extensive re-engineering.

Appendix A describes standard framework for conceptual, preliminary, and final design reports. Appendix B contains specific examples of design report requirements and tools. APS projects encompass a wide diversity of systems, structures, and components subject to design reviews and, as such, there is latitude for the percentage of design engineering completions that is appropriate for the conceptual, preliminary, and final designs.

Based on the overall consequence rating, Table 2 identifies the sequence of required PDRC reviews (Conceptual to Final Design Review).

Table 2: PSC Design Review Committee (PDRC) Required Reviews

Level of Design (typical % of technical system design engineering complete)	**Negligible to Minimal Consequence**	**Moderate Consequence**	**Serious Consequence**	**Major Consequence**
Conceptual Design (< 5%)	PDRC review **not** required	PDRC review **not** required	PDRC review required, but can be combined with Preliminary Design Review at the documented discretion of the approval authority	PDRC review **required**
Preliminary Design (~30%)	PDRC review **not** required	PDRC review **not** required	PDRC review **required**	PDRC review **required**
Final Design (~80%+)	PDRC review **not** required	PDRC review **required**	PDRC review **required**	PDRC review **required**

3.3. Step 3: Review

Table 3 identifies requirements for organizing a review, documentation, and who has the authority to approve the design.

For negligible/minimal consequence projects, the Responsible Manager (typically the Group Leader or CAM) is responsible for Design Reviews. A PDRC review remains an option for these low consequence projects but is not required.

For higher consequence (moderate or above) projects, the Responsible Manager charges the PDRC with performing the review. The PDRC will utilize Argonne and APS standing committees as well as Subject Matter Experts as appropriate.

Table 3: Design Review Requirements

	Negligible to Minimal Consequence	Moderate Consequence	Serious Consequence	Major Consequence
Organizers and Reviewers	Project Lead advises respective Group Leader/CAM of proposed design or design change.	Responsible Manager, in consultation with the Project Leader, charges the PDRC with review. PDRC empanels team appropriate to the review including PDRC members, advisory standing committees, and SMEs as deemed appropriate by the Committee.	Responsible Manager, in consultation with the Project Leader, charges the PDRC with review. PDRC empanels team appropriate to the review including PDRC members, advisory standing committees, and SMEs as deemed appropriate by the Committee.	Responsible Manager, in consultation with the Project Leader, charges the PDRC with review. PDRC empanels team appropriate to the review including PDRC members, advisory standing committees, and SMEs as deemed appropriate by the Committee.
Review Documentation	Current work group method for updating system configuration record.	PDRC Chair files reports in DMS/ICMS including charge, review reports, recommendations, response to recommendations, and final approval.	PDRC Chair files reports in DMS/ICMS including charge, review reports, recommendations, response to recommendations, and final approval.	Chairperson files report in DMS/ICMS including charge, review summary, recommendations, response to recommendations, and final approval.
Final Approval of Design	Group Leader/CAM of Project Lead	Associate Division Director (ADD), equivalent or delegate	Division Director or APS-U Project Manager	Deputy ALD for Operations or APS-U Project Director

If the design (at any consequence level) may introduce accelerator specific hazards that are not adequately addressed by the current SAD and approved ASE, the PDRC Chair advises the PSC Safety Manager of potential USI. As appropriate, a USI determination process will be completed per Advanced Photon Source Procedure, Unreviewed Safety Issue Determination and Argonne Procedure LMS-PROC-383, Facility-Specific Implementation of Unreviewed Safety Issue (USI) Procedure with the review. The PSC Radiation Safety Committee (PRSC) can advise on conformance to APS shielding

standards and potential safety impacts of the designs. Equivalent changes generally do not require a USI determination. For new or non-equivalent radiation shielding designs, the PDRC Chair may consult with PRSC on the potential consequences of proposed radiation safety shielding designs.

Each stage of the designs (e.g., Conceptual/Preliminary/Final) will be documented in a design review report issued by the PDRC Chair that will be archived in DMS / ICMS.

Often various aspects of a system design will have been previously reviewed, and the findings of the review are to be made available to the PDRC. For example, the optical configuration of a new or reconfigured beamline, the mechanical designs of optical instruments, and the thermal analysis of a heat-absorbing masks and shutters typically will be reviewed prior to a beamline design review and the findings of the optics and thermal reviews will be incorporated with the beamline design report.

If an analysis is part of the review (e.g., thermal or radiation safety shielding analysis), the submission should include clearly identified design inputs, including modeling assumptions and applicable standards; an identification of the analysis methods and/or software used; calculations or the results of calculations; and a statement if the analysis shows the designs do or do not meet APS design standards. *As appropriate, an independent review (i.e., reviewer not part of preparing the analysis) will be made of the analysis for completeness and correctness.*

A cohesive, integrated final design report should be prepared for designs rated at Serious or Major Consequence (versus, for example, a collection of presentation slides from reviews).

Commonly, a list of Design Review questions, in the form of a checklist will be prepared to summarize the determinations of the review. Model checklists are available in Appendix B. An abbreviated version of these questions may be submitted to the review committee in the form of charge to the committee.

Formal Design Review action items / recommendations should be tracked in the APS Action Item Tracking System, the APS-U Recommendations Database, or through the Commissioning Readiness Review Process.

Documentation, especially in the final Design Review package, shall be a complete record of review activity, detail, and outcome, and include at a minimum, all files/records, or relevant citations to archived records. Following a Final Design Review, the archived and approved documentation shall include, at minimum:

- Documents identified in Step 1 of this procedure, including the APS-1277 Design Plan Form.
- Design Report including final drawings and design files (e.g., virtual models and other linked part, assembly or system design files).

- Test procedures, work instructions, methods or plans with associated results.
- List of any applicable pre-start requirements.
- Documented approvals for Design Reviews conducted.

All Design Review packages / reports must be archived in the DMS / ICMS system. While other archival systems will continue to exist for specific file types e.g., PDMLink for virtual models, DMS / ICMS shall be the archive of record that demonstrates traceability to any and all related design records.

4. REFERENCES

Unless otherwise noted, the current revisions of the reference documents should be used.

- Advanced Photon Source Safety Assessment Document
- Advanced Photon Source Procedure, Unreviewed Safety Issue Determination
- Advanced Photon Source Procedure, Change Control for Radiation Safety Systems
- Advanced Photon Source the PSC Design Review Committee (PDRC) Charter (APS_2285913)
- Argonne National Laboratory Quality Assurance Program Plan
- Argonne National Laboratory Electrical Safety Manual
- Design Manual (LMS-MNL-20)
- LMS-PROC-383, Facility-Specific Implementation of Unreviewed Safety Issue (USI) Procedure
- DOE O 414.1D, “Quality Assurance”
- DOE O 420.2D, “Safety of Accelerator Facilities”
- DOE G 420.2-1A, “Accelerator Facility Safety Implementation Guide for DOE O 420.2C, Safety of Accelerator Facilities”
- DOE-STD-1073-2016, “Configuration Management”

5. DOCUMENTS/RECORDS CREATED BY THIS PROCEDURE

The documents/records listed below will be created in the execution of this procedure and must be retained as indicated.

Description of Document/Record (include ID number, if applicable)	Custodian	Storage Location and Medium	Retention Requirement
Designs and supporting documents submitted for review	PSC Design Review Committee Chair	DMS record, archived in ICMS	Until the equipment / facility is removed from service
Review meeting minutes			
Design review reports			
Design approvals			

6. FEEDBACK AND IMPROVEMENT

If you are using this procedure and have comments or suggested improvements for it, please go to the APS Policies and Procedures Comment Form* to submit your input to a Procedure Administrator. If you are reviewing this procedure in workflow, your input must be entered in the comment box when you approve or reject the procedure.

Instructions for execution-time modifications to a policy/procedure can be found in the following document: Field Modification of APS Policy/Procedure (APS_1408152).

* https://www.aps.anl.gov/Document-Central/APS-Policies-and-Procedures-Comment-Form

APPENDIX A: Design Report Content

Design reports should include a clear and concise scope of work to be reviewed. Reports are also to include a description of overall performance requirements to provide a context for reviewers for the already approved project. Design reviews are not intended for detailed schedule and resource reviews, inclusion of this information allows for a reality check based on the knowledge and experience of the reviewers and captures a reference for operations and facility planning.

Materials in a design report include, as appropriate:

- Drawings and specifications as appropriate to demonstrate functionality to reviewers.
- Analyses that show how the design will meet performance requirements and standards.
- A hazard analysis with mitigations identified.

Much of the content of a design report should already be available as a routine part of the engineering process—a design report captures this information in a coherent package.

Conceptual Design Report (CDR)

A CDR will include:

- A clear and concise scope of work and a description of performance requirements and how the requirements will be met. The plans should be detailed at a level to demonstrate project feasibility.
- Identification of bounding interfaces, special facility requirements, and ESH requirements. The report shouldn't list all applicable standards but should identify those that impact or constrain the design.
- Exceptions and waivers need to implement the proposed design.
- High-level design and implementation schedule and resources baseline.

Preliminary Design Report (PDR)

A PDR describes the overall design and the performance requirements that will be used to detail subsystems and subcomponents designs. The PDR should be submitted early enough to minimize re-engineering effort if changes are required as a result of the review. A PDR will include:

- A clear and concise scope of work and a description of overall performance requirements. This will provide a context for reviewers for an approved project.
- Identify changes from CDR and the resolution of issues identified in the CDR review.

- Specification of the overall design.
- Identification of performance requirements for subsystem and subcomponents.
- Description of conformance with safety requirements. Identify new or non-equivalent modifications to radiation safety shielding, ACIS, or PSS (PSC Safety Manager will evaluate for an Unreviewed Safety Issue).
- Updated high-level schedule.

Final Design Report (FDR)

The FDR will specify the overall design and the designs of subsystems and subcomponents. The level of design should allow for final, limited scope design changes prior to fabrication or construction. The FDR will include.

- A clear and concise scope of work and a description of performance requirements.
- Identify changes from PDR and the resolution of issues identified in the PDR review.
- The overall system design and subsystem/subcomponents designs.
- Analysis, calculations, and acceptance requirements that demonstrate that the performance requirements will be met.
- APS records repository references to design and design basis records not included in the FDR.
- Updated high-level schedule.

APPENDIX B: Design Report/Review Examples

1. General APS Design Review Checklist

2. Checklists tailored specifically to the sequential beamline design reviews:

   Experience has shown that beamline design reviews at ~5%, 30%, and 90% of engineering effort are appropriate.

   - APS Beamline Conceptual Design Report Guide
   - APS Beamline Preliminary Design Report Guide
   - APS Beamline Final Design Report Guide

3. APS-Upgrade

   The APS-Upgrade Project encompasses a wide diversity of elements and, consistent with this broad scope, affords latitude for the percentage of design engineering completions that is appropriate for the conceptual, preliminary, and final designs:

   - Conceptual Design – 15-30%
   - Preliminary Design – 30-60%
   - Final Design – 60-90%

   (Production/Procurement Readiness – 100%)

   The standard conceptual, preliminary, and final design review process and guides do not apply to APS-Upgrade. Records of Decision (ROD) on the Upgrade Review Process can be found here:

   - ROD for Remaining APS-U Project Beamline Design Reviews (APSU_2176588)
   - ROD for Beam Size Monitor Review Process (APSU_2177104)