

# Advanced Photon Source

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ICMS Content ID:	APS_000031
DNS #:	APS-PPR-ADM-000-A022-000020
Revision #:	11
Effective Date:	7/1/19
Review Period:	1 year
Supersedes:	Rev. 10, 9/28/18
Last Reviewed:	6/19/19

## APS Design Reviews

### Changes made in this revision:

- The newly formed Photon Sciences Design Review Committee (PDRC) assigned to be the focal point for PSC design reviews.
- Appended list of committees replaced with embedded hyperlinks.
- The Beamline Safety Design Review Steering Committee (BSDRSC) superseded by the PDRC.

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## APS Design Reviews

### 1 INTRODUCTION

#### 1.1 Purpose

The Design Review procedure consists of a series of evaluations to determine the adequacy of a design in meeting performance, safety and operational objectives.

#### 1.2 Scope

This procedure:

- Defines the APS process to evaluate systems and component designs to determine their adequacy in meeting performance, safety and operational objectives.
- Defines a graded approach to determine the appropriate scope and level of formality and approval for a Design Review. Grading is based on the potential consequence of a failure in the implementation of a design (see Table 1). The grading considers the potential financial, operational, and ES&H consequences of a design failure. The criteria in this procedure was developed to meet the intent of LMS-PROC-305, mirroring a series of reviews functioning as stage gate milestones / hold points and providing the opportunity for critique of a design and its impact in operation.
- Applies to the safety, technical, and facility operational aspects of designs. Depending on the complexity and potential impact on the APS, internal and external panels and SMEs may be included in the review.
- Assigns reviews to one or more review committees within the APS or Argonne, or assigns ad hoc review committees, as needed.

This procedure is to be followed for:

- New systems and components and modifications to existing systems or components to be installed at APS.
- Mechanical, pressure, cryogenic, electrical, safety, and network systems and facility modifications.
- Designs created by internal and external parties. External designs include CAT facilities.
- Changes to credited controls (including shielding systems and components) unless the changes are equivalent changes.
- This procedure does not apply to experiment-specific, transient systems and components (see [APS Experiment Safety Reviews](#)).

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## 1.3 Definitions

### Accelerator Safety Envelope (ASE)

ASE: The physical and administrative bounding conditions and controls for safe operation based on the safety analysis documented in the Safety Assessment Document (see below).

### Credited Control

Engineered or administrative controls determined through safety analysis to be essential for safe operation directly related to the protection of personnel or the environment. APS credited controls, as referenced in the APS Safety Assessment Document (SAD) include:

- Radiation shielding and monitoring,
- Access Control and Interlock System (ACIS)
- Personnel Safety System (PSS).

### Equivalent Change

An equivalent change continues to meet the design requirements for the equipment, meets all interface requirements and does not impact the safety or design basis. Equivalent changes are made by personnel who have the responsibility, authority, skills, and competence to perform the technical evaluations. Changes that have the potential to modify the design basis are not “equivalent changes” and are subject to the USI process.

### Project Lead

The individual who is cognizant of the full scope of work and has overall responsible for executing a project. The Project Lead ensures that designs are approved per this procedure prior to executing the project. For CAT designs, the CAT will designate the Project Lead.

### Radiation Safety System (RSS) Component

Shielding, interlocks and other hardware that prevent the exposure of personnel to unacceptable levels of ionizing radiation (see [Change Control for Radiation Safety Shielding](#)).

### Responsible Manager

The individual with line management responsibility over a project. Group Leader or Cost Account Manager (CAM) or more senior level manager.

### Safety Assessment Document

A [Safety Assessment Document \(SAD\)](#) contains the results of a safety analysis for an accelerator facility pertinent to understanding the risks of operating the accelerator facility.

### Standing Committees

Argonne National Laboratory or APS management have chartered committees, charged with reviews of safety and facility operational aspects within their assigned subject matter (see [Argonne laboratory-wide committees](#) and [APS committees](#)).

### Subject Matter Expert (SME)

An SME is a person who is a domain expert or authority in a particular area or topic.

## Unreviewed Safety Issue (USI)

A significant increase in the probability of or consequences from (1) a planned modification that creates a previously unanalyzed postulated accident or condition that could result in a significant adverse impact or (2) a previously postulated accident or condition. Activities involving identified unreviewed safety issues must not commence before DOE has provided written approval.

## Unreviewed Safety Issue Determination

A USI process supports configuration management efforts that helps to ensure facility and supporting safety documentation are current and periodically updated. The process evaluates proposed changes or as-found conditions to determine if a USI exists or would exist if a proposed change were made (see [APS Unreviewed Safety Issue Determination](#) and Accelerator Safety, [LMS-PROC-188](#)).

## 2 RESPONSIBILITIES

Responsibilities concerning implementation of Design Reviews as defined in this procedure are as follows:

### Project Lead

The Project Lead will:

- Ensure designs meet ES&H and QA/QC requirements;
- Assist line management in developing a charge for PSC Design Review Committee (PDRC) reviews;
- Ensure adequate documentation is prepared and submitted for Design Reviews;
- Coordinate presentations to the reviewers; and
- Prepare a response to findings and recommendations from Design Reviews to the line manager approver (see Table 3) and the PDRC chairperson.

### Responsible Manager

Tasks/charges the PDRC with reviewing designs for projects in their respective area of responsibility.

### Photon Sciences Design Review Committee (PDRC)

The PDRC is charged with conducting design reviews on behalf of PSC and will:

- Perform reviews in accordance with the specific charge from the approving line manager (see Table 3).
- Ensure that the level of the review is commensurate with the complexity of the technical design and intended function, and that all safety aspects of the design are considered.
- Ensure that any additional follow-on safety committee review(s) or subject matter expert consultations are completed.

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The PDRC Chairperson will:

- Ensure that the design review committee includes appropriate stakeholders, as per LMS-PROC-305, Section 3.2, step 5.
- Provide an advisory report to the approver (see Table 3). The report responds to the charge, integrating the input from all reviewers. The advisory report will include an explicit list of actionable recommendations.
- If a consensus on recommendations is not reached by the committee, the report should address the dissenting opinions.
- Archive relevant records from the review with a unique, retrievable identification in the APS Document Management System (DMS) and Integrated Content Management System (ICMS). Relevant records include committee meeting records, review materials (e.g., reports from advisory committees or SMEs), and the committee advisory report.
- Ensure that an Unreviewed Safety Issue Determination has been performed if the design involves a change to or a new credited control and the change is not an “equivalent change”.

## **Associate Laboratory Director or designee**

The Associate Laboratory Director will:

- Provide final approval of this Design Review procedure; and
- Identify and provide final decisions for projects that require ALD design approval.

## **Division Director, APS Upgrade Project Manager or equivalent**

All APS Division Directors or APS Upgrade Project Manager:

- Provide final decisions for projects that require their approval;
- May designate an individual to be responsible for design approval and oversight of Design Reviews on a one-time or continuing basis;
- Ensure that Design Reviews are properly conducted in accordance with this procedure.

## **Associate Division Directors, APS Upgrade Associate Project Manager and Group Leaders**

Associate Division Directors, APS Upgrade Associate Project Managers and Group Leaders are responsible for bringing to the attention of the Division Director or APS Upgrade Project Manager any new or significantly expanded projects, in order to agree on the appropriate level of review formality and/or oversight.

## Division Quality Assurance Representative (QAR)

QARs participate in Design Reviews as follows:

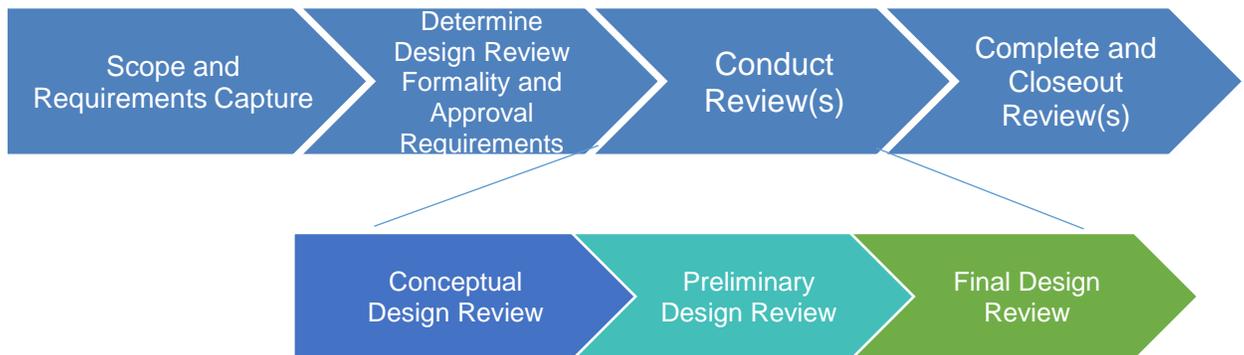
- Provide independent process oversight of this procedure's requirements
- Determine if the appropriate acceptance criteria have been included in the engineering drawings and specifications;
- Recommend improvements or corrections to the acceptance criteria; and
- Verify QA recommendations have been satisfactorily addressed.

## 3 DESIGN REVIEW PROCEDURE

### 3.1 Overview

The procedural steps below provide guidance for documenting the scope of the design / design change, determining the applicability of each type of design reviews, and ensuring that the reviews are adequately conducted, and closed out after addressing all action items assigned.

The process by which design reviews are conducted within the APS follows a simple flow as follows:



### 3.2 Design Review Procedure

#### Step 1: Scope and Requirements Capture

Early consultation by Responsible Manager, with the Project Lead, responsible ES&H Coordinator, and Quality Assurance Representative (QAR), is encouraged to provide process oversight and develop a design review roadmap.

The Project Lead ensures the appropriate documentation for a Design Review or series of Design Reviews is prepared including:

- Scope of work that defines the extent of the systems or component to be reviewed and identifies if the scope involves a credited control.
- The performance requirements of the system or component.

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- Applicable design standards; ES&H and QA requirements, and acceptance criteria,
- Analyses that show how the design will meet performance requirements and standards. (This may include previously executed design reviews and responses to recommendations from the review).
- A hazard analysis with mitigations identified.

## Step 2: Determine Design Reporting Formality and Approval Requirements

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.

Table 1 below is intended to serve as a minimum standard APS assessment of the consequence of failure for a proposed design or design change.

The consequence levels in this table are based on the remote, yet credible, chance for the consequence occurring.

For the purposes of this document, a credible chance is defined as an event that could take place during the life of the facility or operation but is unlikely to occur.

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.

All design work shall be screened by the Responsible Manager, in consultation with the Project Leader, in order to recommend an overall consequence rating (see Table 1).

The Responsible Manager and Project Leader can concur on the overall consequence rating or raise the question of the rating to the relevant Associate Division Director, APS-U Associate Project Manager, or equivalent.

ES&H Coordinators provide oversight of rating assignments.

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.

**Table 1: Design or Design Modification Screening for Consequence Rating**  
 Based on a Credible Likelihood of a Design Failure Consequence

	<b>Negligible to Minimal Consequence</b>	<b>Moderate Consequence</b>	<b>Serious Consequence</b>	<b>Major Consequence</b>
<i>Category</i>	<i>Consequence Threshold</i>	<i>Consequence Threshold</i>	<i>Consequence Threshold</i>	<i>Consequence Threshold</i>
<p><b>Safety</b></p> <p>Personnel safety including radiation exposure</p>	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
<i>Examples</i>	<i>Light mechanical work associated with routine component replacement, may involve the use of a pallet truck or experiment station hoists</i>	<i>Moderate mechanical work associated with routine component replacement may involve the use of an A-frame hoist or forklift.</i>	<p><i>Design change introduces electrical hazard e.g. Mode 2 work at minimum QEW2 voltages/current per the Electrical Safety Manual.</i></p> <p><i>Modification, other than equivalent changes, to a credited control such as radiation shielding, PSS or ACIS.</i></p> <p><i>Small conventional construction.</i></p> <p><i>Installation of heavy (&gt; 1,000 lbs.) component.</i></p>	<p><i>Design change introduces significant electrical hazard e.g. involves Mode 3 work</i></p> <p><i>Adding or a significant change to a credited control such as radiation shielding, PSS or ACIS.</i></p> <p><i>New beamline addition or significant conventional construction project</i></p>
<p><b>Financial Loss</b></p> <p>Recovery costs including material and labor</p>	Less than \$50k	Greater than \$50k and less than \$100k	Greater than \$100k and less than \$250k	Greater than \$250k
<i>Examples:</i>	<i>Minor part(s) replacement to return to service</i>			<i>Design error leading to major equipment damage (&gt; \$250k)</i>
<p><b>Continuity of Operations</b></p> <p>Including accelerator, beamline downtime and facility modifications</p>	<p>Accelerator: &lt; 1 hours or Beamline: &lt; 0.5 days</p>	<p>Accelerator: 1 – 24 hours or Beamline: 0.5 - 2 days</p>	<p>Accelerator: 24 – 48 hours or Beamline: 2 – 7 days</p>	<p>Accelerator: &gt; 48 hours or Beamline: &gt; 7 days</p>
<i>Examples:</i>	<p><i>Storage ring access not required</i></p> <p><i>Minimal Service Request Order work</i></p>	<i>Small conventional construction (&lt;\$50k total project cost).</i>	<p><i>Accelerator system modification during user run, no bake out needed.</i></p> <p><i>Limited conventional construction (&gt;\$50K and &lt;\$1M total project cost).</i></p>	<p><i>Accelerator system modification during user run, with bake out.</i></p> <p><i>Significant conventional construction project</i></p>

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

	<b>Negligible to Minimal Consequence</b>	<b>Moderate Consequence</b>	<b>Serious Consequence</b>	<b>Major Consequence</b>
Conceptual Design Review (< 5% design maturity)	PDRC review <b>not</b> required	PDRC review <b>not</b> required	PDRC review required, but can be combined with Preliminary Design Review at the documented discretion of the approval authority	PDRC review <b>required</b>
Preliminary Design Review (~30% design maturity)	PDRC review <b>not</b> required	PDRC review <b>not</b> required	PDRC review <b>required</b>	PDRC review <b>required</b>
Final Design Review (~80%+ design maturity)	PDRC review <b>not</b> required	PDRC review <b>required</b>	PDRC review <b>required</b>	PDRC review <b>required</b>

### Conceptual Design Reviews [~ up to 5% Design Maturity]:

- Evaluate proposed design approaches
- Ensure that the proper requirements are identified (requirements should include functional, ES&H, regulatory, reliability, project specific, test, cost, and schedule)
- Review design and development plans and schedules
- 

### Preliminary Design Reviews [~30% Design Maturity]:

- Verify that the proposed design is consistent with its design objectives and design standards
- Review the results of analyses, calculations, and tests conducted to obtain additional information for the design
- Ensure that records of design analyses, calculations and testing are being maintained
- Review the ability to implement the proposed design taking into consideration capabilities, tolerances, costs, reliability, ES&H and QA.
- Review test methods and plans
- Review updated design and development plans and schedules
- Ensure that an Unreviewed Safety Issue Determination has been performed if the design involves a credited control and the change is not an equivalent change.
- Ensure the appropriate incorporation of recommendations from previous Design Reviews
- Document the review findings and recommendations

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## Final Design Reviews [~80%+ Design Maturity]:

- Verify that the final design satisfies design requirements
- Ensure that detailed analyses, calculations, and tests were performed to validate the design
- Verify that records of analyses, calculations, and tests have been maintained
- Verify, as appropriate, that the final product can be manufactured, inspected, assembled, stored, delivered, and installed reliably, safely, and cost effectively
- Verify that procurement strategy (e.g., build vs. buy) is appropriate
- Verify that appropriate documentation is available for producing the final product (e.g., drawings, installation procedures)
- Verify that appropriate acceptance criteria have been established for validating the design including any readiness review requirements or criteria
- Ensure the appropriate incorporation of recommendations from previous design and safety reviews have been addressed

## Step 3: Conduct Reviews

For negligible/minimal consequence projects, the Responsible Manager (typically the Group Leader/CAM) is responsible for design reviews. A PDRC review is an option, not a requirement, for these low consequence projects.

For higher consequence (moderate or above) projects, the Responsible Manager charges the PDRC with performing the review. The PDRC Chair is the point of contact.

The PDRC Chair will work with stakeholders and put together a review team appropriate to the systems under review. Each stage of the designs (conceptual/preliminary/final) will be documented in a design review report that will be archived in DMS/ICMS. A report will be issued by the PDRC Chair for each design review and Table 3 identifies who has the authority for design approval.

The PDRC will ensure that safety is integrated into each stage of the design review process. In addition to the members of PDRC, Argonne and the APS have a number of standing committees that are available for supporting design reviews:

- Laboratory-wide committees: <http://inside.anl.gov/divisions/committees>
- APS standing committees: <https://www.aps.anl.gov/About/Committees>

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.

As noted above, the PDRC reviews are required for modifications, alterations and manipulations to any credited control, including beamline components identified in the ASE.

A list of Design Review questions, in the form of a model checklist, is available in the Appendix.

<b>Table 3: Design and Safety Review Requirements</b>				
	<b>Negligible to Minimal Consequence</b>	<b>Moderate Consequence</b>	<b>Serious Consequence</b>	<b>Major Consequence</b>
<b>Organizers and Reviewers</b>	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.
<b>Review Documentation</b>	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: Review summary, recommendations, response to recommendations, and final approval
<b>Final Approval of Design</b>	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

### Step 4: Complete and Closeout Review(s)

Formally documented response memos to review recommendations are a preferred method of capture, especially for Design Reviews required because of a Serious or Major Consequence rating. Formal action item / recommendation tracking remains available in the Argonne [Issues Management Tracking System \(IMTS\)](#).

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 the Final Design Review, the archived and approved documentation shall include, at minimum:

- Documentation of the criteria listed in Step 1 of this procedure
- 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
- Documented approvals for design reviews conducted

The records must be complete in order that the final design, drawings and models, design basis/bases, review comments and resolution, design approvals, etc., can all be easily retrieved and reproduced upon demand.

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

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.

Documentation of the Review meeting and recommendation to the to the approver (see Table 3) shall follow the best practice of the former Beamline Safety Design Review Steering Committee (BSDRSC now PDRC) memo format, with numerous examples available in DMS/ICMS archive.

## 4 REFERENCES

- Advanced Photon Source Conduct of Operations Manual, APS-3.1.1.1.0, Rev. 3, June 2006 or successor document
- Advanced Photon Source Safety Assessment Document, Rev. 5, June 2017 or successor document
- Advanced Photon Source Procedure APS\_PPR\_ESH-000-A021-000025, “Unreviewed Safety Issue Determination”, Revision 3, March 1, 2016 or successor document
- Advanced Photon Source Procedure APS\_1685081, “Change Control for Radiation Safety Shielding”, Revision 0, 30 November 2017 or successor document
- Argonne National Laboratory Quality Assurance Program Plan, Rev. 10, July 18, 2018 or successor document
- Argonne National Laboratory Electrical Safety Manual, Rev. 1, July 2, 2018 or successor document
- Argonne National Laboratory Work Planning and Control Manual, Rev. 0, September 24, 2018 or successor document
- Argonne Procedure LMS-PROC-125, Rev. 5, “Applying the Graded Approach to Quality for Procured Items or Services”, Effective Date Sept 8 2016 or successor document
- Argonne Procedure LMS-PROC-30, Rev. 3, “Engineering Services”, Effective Date Aug 31 2012 or successor document
- Argonne Procedure LMS-PROC-52, Rev. 3, “Research, Development, and Engineering”, Effective Date Oct 28 2015 or successor document
- Argonne Procedure LMS-PROC-305, Rev. 0, “Design Review”, Effective Date Nov 23, 2016 or successor document
- Argonne Procedure LMS-PROC-188, Rev. 2, “Accelerator Safety”, Effective Date October 6, 2016 or successor document
- DOE G 413.3-9, “US Department of Energy Project Review Guide for Capital Asset Projects”, September 23, 2008 and Administrative Change dated October 22, 2015 or successor document

- DOE O 413.3B Chg 5 (MinChg), Program and Project Management for the Acquisition of Capital Assets, April 12, 2018 or successor document
- DOE O 414.1D Chg 1 (Admin Chg), Quality Assurance, May 8, 2013 or successor document
- DOE G 420.2-1A, “Accelerator Facility Safety Implementation Guide for DOE O 420.2C, Safety of Accelerator Facilities”, August 1, 2014 or successor document
- DOE O 420.2C, “Safety of Accelerator Facilities”, July 21, 2011 or successor document
- DOE-STD-1073-2016, “Configuration Management”, December 2016 or successor document
- Fermi National Accelerator Laboratory, “Engineering Manual v. 2.0”, October 2015 or successor document
- Thomas Jefferson National Accelerator Facility, “Conduct of Engineering Manual”, Rev. C, ENG-AD-01-001, June 8, 2018
- SLAC National Accelerator Laboratory, “SLAC Conduct of Engineering Policy”, July 24, 2012 or successor document

## 5 DOCUMENTS/RECORDS CREATED BY THIS PROCEDURE

Description of Document/Record	Custodian	Storage Location	Retention Requirement
Designs and supporting documents submitted for review	Requesting division or WBS lead division / project	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: Design Review Checklist Example

The Design Review Checklist example below is intended to serve as a supplement for Design Reviews and is not all inclusive. The examples and criteria are oriented towards mechanical design hazards / criteria but, when the checklist is used, reviewers are strongly encouraged to consider all hazard classes, such as electrical, radiological, pressure/hydraulic, material movement (e.g. critical lift), etc. for a given topic.

### DESIGN REVIEW CHECKLIST

Title: \_\_\_\_\_

Date: \_\_\_\_\_

DMS Design Review Collection ID: \_\_\_\_\_

Design Review Chairperson (if applicable): \_\_\_\_\_

Design Review Team (if applicable): \_\_\_\_\_

ES&H / QAR Process Oversight: \_\_\_\_\_

Design Review Type (check one):

- Conceptual Design Review     
  Preliminary Design Review     
  Final Design Review

Respond to each question by marking the block in front of the question “YES”, “NO” or “N/A”. Items that are questionable or incomplete should be marked “NO” and explained briefly. Items marked “N/A” should be minimal in number, and reflect lack of relevance or applicability to this particular Design Review. In preliminary versions of the form, you may respond as if all action items are satisfactorily resolved.

Design Objectives	Yes, No, N/A
1. Is the Charge suitable for the level and type of review?	
2. Is there a clear statement as to what the design is intended to do or achieve?	
3. Is there a quantitative assessment that shows that the intent of the design is likely to be accomplished?	
4. If any of the motivation for the design is economic (e.g., reduce manufacturing cost), has the design been evaluated to confirm that the increment of improvement is justified by the development cost and/or the potential economic incentive?	
5. Have questions of intellectual property, patentability or patent infringement been considered in developing the design?	
6. Have all action items been suitably addressed and approved by responsible party?	

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Functional Requirements	Yes, No, N/A
1. Are the functional requirements for the design clearly identified and complete?	
2. Are assumptions adequately described and reasonable?	
3. Have appropriate regulatory or performance requirements been invoked for the design?	
4. Have pertinent interface requirements been defined / identified?	
5. Has compatibility with other resident components or systems and impact on respective design margins been considered?	
6. Does the design team fully understand the environment in which the product is to operate and how that environment may change over time and the resulting impact on the functional requirements of the design?	

Design Requirements and Design Bases	Yes, No, N/A
1. Are the design requirements and design bases appropriate, complete, and quantitative (e.g., with specific acceptance criteria or limits) including but not limited to: <ol style="list-style-type: none"> <li>Interfaces with other components or systems, especially dimensional interfaces.</li> <li>Stress, strain, and load limits for all structural components under normal operating conditions, accident conditions, and shipping and handling conditions.</li> <li>Limits on the cumulative effect of cyclic mechanical or thermal loadings (e.g., fatigue) on the structural members.</li> <li>Environmentally induced effects on materials or components (e.g., oxidation, hydriding, corrosion, water chemistry)</li> <li>Dimensional changes (e.g., bowing, dimensional growth, creep)</li> <li>Integrity of encapsulated components considering credible failure mechanisms (e.g., collapse, burst, heat transfer).</li> <li>Worst case pneumatic or hydraulic loads under normal operating conditions</li> </ol>	

Design Drawings and Documents	Yes, No, N/A
1. Have all necessary drawings, specifications, test reports, etc., been approved and released?	
2. Have all necessary calculations, tests, or analyses been performed and documented?	
3. Has all review and independent verification of design documents been completed?	
4. Have all necessary changes to design manuals or the equivalent been initiated?	

The current version of this procedure is accessible from <https://www.aps.anl.gov/Document-Central>. Print or electronically downloaded copies may be obsolete. Before using such a copy for work direction, employees must verify that it is current by comparing its revision number to that shown in the online version.

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<b>Design Evaluation</b>	<b>Yes, No, N/A</b>
1. Were appropriate design methods used, and were design inputs correctly incorporated?	
2. Has applicable manufacturing and operating experience been considered?	
3. Have adequate provisions been included for qualifying new materials, suppliers, and manufacturing processes/methods?	
4. Have changes from prior proven designs been justified (e.g., risk versus potential benefit)?	
5. Has design been evaluated against comparable facility or national lab designs?	
6. Have historical problems and the potential for aggravating old problems been considered?	
7. Have reasonable alternatives to the proposed design been adequately evaluated and considered?	
8. Have past performance issues been identified and addressed?	
9. Have any new analytical methods/models been appropriately verified?	
10. Has applicability of old methods/models been appropriately verified?	
11. Has adequate margin been provided to account for uncertainties of tests, measurements, analyses and assumptions?	
12. Are the major risks, uncertainties and development items documented and evaluated?	
13. Have recommendations from previous applicable Design Reviews been addressed?	
14. Do the design criteria satisfy generic functional requirements as opposed to specific operating cycle requirements?	
15. If a technology from a similar design is being applied, were appropriate scaling and other assessments considered and evaluated?	
16. Has a risk assessment been performed for the overall design?	
<b>Testing, Inspection and Surveillance</b>	<b>Yes, No, N/A</b>
1. If any aspects of the design are being verified by test or demo operation, are the proposed tests necessary and sufficient for the intended purpose?	

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<b>Testing, Inspection and Surveillance</b>	<b>Yes, No, N/A</b>
2. Have unique testing and inspection requirements for any new manufacturing process and/or supplier been considered and documented in the design specification?	
3. Has the applicability of existing specifications been reviewed for the design?	
4. Do the tests adequately address variability arising from the drawing tolerances with regard to design criteria/parameters?	
5. Has sufficient testing been performed to verify the consistency or repeatability of complying with design parameters?	
6. Have shipping requirements for any new manufacturing process been considered?	
7. Have material handling e.g. hoisting and rigging requirements been considered?	

<b>Quality Assurance</b>	<b>Yes, No, N/A</b>
1. Has the design been created in accordance with the applicable engineering procedures and design standards?	
2. Are records of the design calculations, tests, or analyses being maintained?	
3. Has the adequacy of the design been verified by individuals or groups other than those who created the design?	
4. Have the quality issues from the design reviews been adequately addressed?	
5. Does the procurement include a method for managing design changes after the design has been released for fabrication?	
6. Does the procurement include acceptance criteria that can be validated through inspection, testing, or document reviews?	

<b>Manufacturing Considerations</b>	<b>Yes, No, N/A</b>
1. Do manufacturing development efforts effectively support the design for any new or unique manufacturing processes needed (e.g., scope, depth, schedule)?	
2. Have any unique material availability problems been adequately considered?	
3. Is the design complete and acceptable with regard to manufacturing process control?	

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<b>Manufacturing Considerations</b>	<b>Yes, No, N/A</b>
4. Has a risk assessment been performed on the manufacturing process?	

<b>Safety Considerations</b>	<b>Yes, No, N/A</b>
1. Have all requisite safety reviews been completed by the responsible committee?	
2. Do the design features or methods avoid increasing the probability of occurrence or consequences of an accident or malfunction?	
3. Have any personnel safety concerns been adequately considered and resolved?	
4. Have interface evaluations been performed by the impacted groups, or has the scope of effort required for specific application been identified? Have generic evaluations been performed, where applicable?	

<b>Change Control</b>	<b>Yes, No, N/A</b>
1. Have core interface features of the design been compared to existing standards and/or limits?	
2. Do new/changed features of the design represent an acceptable departure from existing standards or limits? If so, how are approval of these departures documented?	
3. If the design adds or changes a credited control and the change is not an equivalent change, has an Unreviewed Safety Issue Determination been performed?	

<b>Maintenance / Repairability</b>	<b>Yes, No, N/A</b>
1. Have design features adequately addressed specific functional requirements for repair and maintenance of the product?	
2. Do criteria for repair facilitate simple, economical and prompt correction of product deficiencies?	
3. Are interface organizations which may be ultimately involved in a repair program familiar with the design features?	

<b>Methodology</b>	<b>Yes, No, N/A</b>
1. In case methodology changes or amendments are proposed have they been properly described or reviewed or are they part of the design package?	
2. Has the supporting testing been evaluated and necessary correlations for design purposes been established?	

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Readiness Reviews	Yes, No, N/A
1. Have the type and timing of readiness reviews (Installation Readiness Review, Instrument Readiness Review, Accelerator Readiness Review, Commissioning Readiness Review, etc.) been established for the design?	