

PPPL	PRINCETON PLASMA PHYSICS LABORATORY	PROCEDURE		No. ENG-033 Rev 3 page 1 of 9
		Subject: Design Verification	Effective Date: Feb. 13, 2009	Initiated by: Associate Laboratory Director for Engineering and Infrastructure
		Supersedes: Rev 2 dated May 30, 2003	Approved: Director	

Applicability

This procedure is applicable to all design verification activities at PPPL. Such design verifications may be required by a Work Planning form (ENG-032), or by line management, or may be performed by the cognizant individual as good practice. Projects, Departments, or Divisions may develop their own procedure for these topics as long as all the requirements of this procedure are implemented and the Head, Engineering and Infrastructure is one of the approval signatures for the procedure.

Introduction

The design verification process is intrinsically a work planning process and therefore falls within the purview of the Work Planning Review Board. Design verification is often prescribed and expedited as part of a Work Plan that is approved by the Cognizant individual and the RLM. The WPRB Chair will monitor and evaluate the design verification process for compliance and consistency. As part of the design verification procedure, the Head of Engineering and Infrastructure shall select and maintain a roster of Design Review Chairpersons. The list is available on the Engineering web site. In conjunction with RLMs and these Design Review Chairpersons, the WPRB Chair will monitor and evaluate the results of Design Reviews for consistency and compliance with laboratory procedures and provide feedback to RLMs and Design Review Chairpersons for continuous improvement of Engineering work planning systems.

DOE Order 414.1, Quality Assurance, 4.b(2)(b)4, requires that "*The adequacy of design products shall be verified or validated by individuals or groups other than those who performed the work. Verification and validation work shall be completed before approval and implementation of the design.*" At PPPL, this requirement is implemented, in order of hierarchy, via the Institutional Quality Assurance Plan, Policy P-010 on Design Reviews, and this procedure. Design verification may be performed by a variety of tools including design reviews, peer reviews, design analyses and calculation checking, prototyping, and comparison to already working systems. Because hazards and uncertainties exist with prototypes just as with all other work, please note that the design and construction of prototypes shall be subjected to appropriate levels of review and design verification just as with all other work per the direction of line management and based on the graded approach established by the RLM.

Both **peer and design reviews** are performed to clarify and verify compliance with functional, project, ES&H, security and quality requirements. They should be performed at major project milestones prior to making decisions that may prove costly, time consuming, or difficult to reverse. They may be required by a Work Plan or by line management. Objectives of and input documentation for the various types of design reviews are contained in Attachment 4.

Human performance factors should be considered at every level of design. See Attachment 6. |

Calculation and design analysis checks provide for an independent review by a technically qualified individual prior to using the results for other significant design or fabrication activities. Drawing checks for technical content, dimensions, and tolerances are the responsibility of the Cog or designee.

Prototypes are performed to clarify requirements or to review the feasibility of a design approach prior to performing the comprehensive and time-consuming design. Prototyping may involve software simulations or hardware fabrications. Prototypes shall be reviewed per this procedure as with all other work using a graded approach per the RLM.

Comparison to already working systems may be used to validate a design.

This procedure defines the requirements for performing peer reviews, and design reviews and documenting verification of calculations and results of prototyping. Comparisons to already working systems are similar to a calculation check and share the same documentation form.

The actual validation and verification of the implementation of a design is performed via test mechanisms. Procedures for these tests are described in ENG-030, Instructions and Requirements for Writing, Reviewing, and Approving Technical Procedures.

Reference Documents

EQP-004	PPPL Institutional Quality Assurance Plan (QAP)
P-010	Design Reviews
ENG-010	Control of Drawings, Software, and Firmware
ENG-032	Work Planning Process
ENG-030	PPPL Technical Procedures for Experimental Facilities

Procedure

This procedure consists of five sections:

- A – Calculation and Design Analyses Checks
- B – Peer Reviews
- C – Design Reviews
- D – Prototypes
- E – Comparisons to Working Systems

In each case the above sections produce documentation that shall be forwarded to the Operations Center. In the event that a project creates and keeps its own centralized project files, the project shall register these project files with the Ops Center as satellite files. The project then has responsibility for maintaining these files until such time as the files are transferred to the Ops

Center. Each reference to the Ops Center in A through E below shall be understood to include these registered satellite project central files also.

A. Calculation and Design Analyses Checks

Formal checks are to be performed when calculation and analysis checking is required by a PPPL Work Planning (WP) form or when required by line management. This checking process may be iterative as the design verification procedure progresses.

Responsibility

Action

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| Cognizant Individual | 1. Develops calculation in accordance with the format described in attachment 1. For software calculations using code or software applications, Cog shall so document the input and code used that a competent reviewer could determine validity of the calculation. |
| Responsible Line
Manager
Checker | 2. Appoints a qualified checker for the calculation. |
| | 3. Reviews the calculation using the minimum requirements of attachment 2. It is the responsibility of the checker to use methods that will substantiate to his/her professional satisfaction that the calculation is correct. |
| | 4. Resolves concerns with developer of calculation and signs calculation sheet. |
| Cognizant Individual | 5. Stores all calculations in a file location agreed upon by the RLM unless specified differently by a project specific procedure. Examples of such locations include the Operations Center files or server, or other central file locations, file cabinets in the responsible engineer's office, or electronic files on a specified computer or server. |

B. Peer Reviews

A peer review is a tool that provides a mechanism for a design engineer to utilize the technical expertise of others and communicate performance. A peer review may be required by a Work Planning Form or by line management, or may be performed as good practice. Peer reviews may be the foundation to other larger reviews or may be sufficient as the sole review of change if so deemed by the RLM. The scope of the review is determined jointly by the cognizant individual and the RLM.

Responsibility**Action**

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| Cognizant Individual
(Cog) | 1. Proposes the chair and attendees for the peer review. The chair may be the Cog or RLM. Consideration should be given to the need for representatives from ES&H, QA, security or other support organizations. |
| Responsible Line
Manager | 2. Approves chair and list of attendees. |
| Cognizant Individual | 3. Conducts peer review addressing the objectives of Attachment 4. |
| Attendees | 4. Document on a chit (attachment 3) questions, concerns, and recommendations raised during the review that were not adequately resolved. |
| Cog, RLM, and Chair | 5. Resolves chits or assigns action items immediately after completion of the review. |
| Cog, RLM, and Chair | 6. Documents the purpose and results of the peer review in a memorandum listing date, time, attendees, and chits and their resolution. If the peer review is associated with a Work Planning (WP) Form, clearly identifies the WP number on the first page of the documentation. |
| | 7. Distributes memorandum to attendees. Forwards memorandum to the Operations Center. If the peer review is associated with a WP Form, the memorandum may either be transferred immediately upon completion of the peer review or as part of the total package at the time of WP closure. |

C. Design Reviews

Design reviews (conceptual, preliminary, and final) are a formal review of a design by qualified individuals to verify compliance with functional and project requirements. They should be performed at major project milestones prior to making decisions that may prove costly, time consuming, or difficult to reverse. They may be required by a Work Plan or by line management. Objectives of and input documentation for the various types of design reviews are contained in attachment 4.

At each design review stage employed, but especially at the Final Design Review stage, a review represents a state of development that the review process has vetted. Subsequent departure from the design as presented at any level of review, but especially at Final Design Review, requires remedial review steps to reestablish the consensus that the state of development of the design has been properly vetted. The Cog must communicate such matters to the RLM. The RLM may determine that the changes are minor and do not undermine the integrity of the design and may allow the design process to continue unabated. However, in the instance that the RLM determines that the changes are of a nature to require attention, the RLM may require a Peer Review to discuss such changes or the RLM may require that the full level of the original review take place again with the new information.

In particular, after an FDR, a Cog may discover required changes or may have changes for chit resolution that significantly change the vetted design. In this case, the Cog must present such matters to the RLM. The RLM may require that the FDR Review be reconvened or that a Peer Review be convened to address the changes to the design after the FDR. In every case, the RLM has the full responsibility to discuss the state of the design at completion and approval of drawings with the Cog and assure that the design as presented and vetted has been captured in drawings and other documents.

Responsibility

Action

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| Responsible Line Manager | 1. Determines, in consultation with the appropriate Engineering and Infrastructure Department Division Head, the individual to be Chairperson and the individuals to serve on the Design Review Board. The chairperson shall be independent of the design work being reviewed and must either be on list of approved design chairpersons or be approved by the Head, Engineering and Infrastructure. The current list is available on the Engineering Department home page. |
| Cog Individual | 2. Briefs Chairperson regarding the work to be reviewed. |

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| Cog Individual | <p>3. Determines, in consultation with the Chairperson and the RLM, the composition of the Review Board, the input documentation for the review, and the criteria for success. The Design Review Board shall consist of:</p> <ul style="list-style-type: none"> - Chairperson - Cognizant Individual - Engineers or physicists with background and skills required to thoroughly assess the functional needs and design adequacy. - Representatives from interfacing or impacted organizations. - Others, such as QA, ES&H, or recognized experts from outside the Laboratory, as appropriate. - Reviewers from other National Laboratories, other fusion facilities, or universities with relevant experience. |
| | <p>4. Secures a room for the review meeting and issues an invitation to the Board and invitees. Invitees shall include, if not part of the Board, QA, ES&H, security and organizations impacted by or interfacing to the design.</p> |
| | <p>5. Supplies a documentation package to the Review Board members before the review meeting.</p> |
| | <p>6. Presents and defends the design at the review.</p> |
| Design Review Board | <p>7. Conducts review addressing objectives of attachment 4.</p> |
| Attendees | <p>8. Document on a chit (attachment 3) questions, concerns, and recommendations raised during the review that were not adequately resolved.</p> |
| Design Review Board | <p>9. Resolves chit(s) or assigns action items immediately after completion of the review.</p> |

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| Chairperson | 10. Prepares a report using attachment 5 which includes the list of attendees, chits with the Design Review Board’s recommendation, and a summary conclusion which states whether the design review was successful as well as any significant observations or recommendations. (A design review is considered to be successful if it is the consensus of the Review Board that the objectives defined in attachment 4 have been satisfied and no major unresolved issues were identified.) If the review is held as the result of an Work Planning Form, documents the WP number on the front of the report. |
| Chairperson | 11. Distributes the report to the attendees, QA, security and ES&H. |
| Cog Individual | 12. Responds to the recommendations of the Design Review Board by completing the “Cognizant Design Engineer’s Response/Disposition” section of the Chit form. |
| Responsible Line Manager | 13. Reviews completed chit form and documents review by signing form. |
| Cog Individual | 14. Forwards completed package to PPPL Operations Center within five working days. If the design review is associated with a WP Form, the package may instead be transferred as part of the total package at the time of WP closure. |
| Cog Individual | 15. Forwards all chits to the PPPL Operations Center when all of the chits have been completed . |
| Responsible Line Manager | 16. Assures that the Cog has captured the vetted design in final documentation. |

D. Prototypes

Prototypes are used to obtain further information for the design. They may be used to develop a “strawman” user interface in order to clarify requirements or demonstrate an interface approach or may be used to test a design concept prior to incorporating it into the full design. Because hazards and uncertainties exist with prototypes just as with all other work, please note that the design and construction of prototypes shall be subject to the same levels of review and design verification as with all other work per the direction of line management and based on the graded approach established by the RLM.

Responsibility**Action**

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| Cognizant Individual | 1. Documents the prototype in memorandum format listing the objective for the prototype, technical information about how the prototype was performed, the results of the prototype, and the impact of the results on the design. |
| Responsible Line Manager | 2. Reviews the documentation and indicates concurrence with the results by signing the memorandum. |
| Cognizant Individual | 3. Transfers original signed memorandum to the Operations Center for storage. If associated with a Work Planning form, the memorandum may either be transferred immediately upon completion or as part of the total package at the time of WP closure. |

E. Comparison to Working systems

Comparisons are a valuable tool for demonstrating confidence that a selected design will work.

Responsibility**Action**

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| Cognizant Individual | 1. Documents the comparison in memorandum format listing the objective for the comparison, technical information about how the comparison was performed, the results of the comparison, and the impact of the results on the design. |
| Responsible Line Manager | 2. Reviews the documentation and indicates concurrence with the results by signing the memorandum. |
| Cognizant Individual | 3. Transfers original signed memorandum to the Operations Center for storage. If associated with a Work Planning form, the memorandum may either be transferred immediately upon completion or as part of the total package at the time of WP closure. s |

Attachments

1. PPPL Calculation Form.
2. Minimum Requirements for Checking of Calculations.
3. Design Review Chit Form
4. Objectives of and documentation for design reviews.
5. Design Review Results Form
6. Human Performance Improvement/Factors Considerations in Design Reviews

PPPL Calculation Form

Calculation # _____ Revision # _____ WP #, if any
(ENG-032) _____

Purpose of Calculation: (Define why the calculation is being performed.)

References (List any source of design information including computer program titles and revision levels.)

Assumptions (Identify all assumptions made as part of this calculation.)

Calculation (Calculation is either documented here or attached)

Conclusion (Specify whether or not the purpose of the calculation was accomplished.)

Cognizant Engineer's printed name, signature, and date

I have reviewed this calculation and, to my professional satisfaction, it is properly performed and correct.

Checker's printed name, signature, and date

Minimum Requirements for Checking of Calculations**Page 1 of 1**

1. Assure that inputs were correctly selected and incorporated into the design.
2. Calculation considers, as appropriate:
 - Performance Requirements (capacity, rating, system output)
 - Design Conditions (pressure, temperature, voltage, etc.)
 - Load Conditions (seismic, wind, thermal, dynamic)
 - Environmental Conditions (radiation zone, hazardous material, etc.)
 - Material Requirements
 - Structural Requirements (foundations, pipe supports, etc.)
 - Hydraulic Requirements (NPSH, pressure drops, etc.)
 - Chemistry Requirements
 - Electrical Requirements (power source, volts, raceway, and insulation)
 - Equipment Reliability (FMEA)
 - Failure Effects on Surrounding Equipment
 - Tolerance Buildup
3. Assumptions necessary to perform the design activity are adequately described and reasonable.
4. An appropriate calculation method was used.
5. The results are reasonable compared to the inputs.

NOTE: BY SIGNING CALCULATION, CHECKER ACKNOWLEDGES THAT THE CALCULATION HAS BEEN APPROPRIATELY CHECKED AND THAT THE APPLICABLE ITEMS LISTED ABOVE HAVE BEEN INCLUDED AS PART OF THE CHECK.

PPPL DESIGN REVIEW CHIT

WP # _____ (ENG-032)

CHIT # _____

COMPONENT/SUBSYSTEM/SYSTEM _____

COGNIZANT DESIGN ENGINEER _____ DATE OF REVIEW _____

- PEER
- CDR
- PDR
- FDR

SUBJECT: (CHECK AS APPLICABLE)

- | | | |
|---------------------------------------|--|--|
| <input type="checkbox"/> REQUIREMENTS | <input type="checkbox"/> HARDWARE | <input type="checkbox"/> SAFETY |
| <input type="checkbox"/> ANALYSIS | <input type="checkbox"/> CONFIGURATION | <input type="checkbox"/> SECURITY & SAFEGUARDS |
| <input type="checkbox"/> PERFORMANCE | <input type="checkbox"/> RELIABILITY/MAINTAINABILITY | <input type="checkbox"/> COST/SCHEDULE |
| | | <input type="checkbox"/> QUALITY |

COMMENT/CONCERN/RECOMMENDATION

ORIGINATOR _____

NAME/ORGANIZATION

REVIEW BOARD COMMENT/RECOMMENDATION

(Address technical, cost, and schedule impacts as appropriate. If CHIT is not adopted, provide technical reason - do not simply state "out-of-scope or N/A" without explaining.)

- 0 CONCUR
- 0 DISAGREE
- 0 OTHER

CHAIRPERSON _____ DATE: _____

COGNIZANT DESIGN ENGINEER'S RESPONSE/DISPOSITION:

SIGNATURE _____ DATE: _____

RESPONSIBLE RLM REVIEW

- 0 APPROVE COG DISPOSITION
- 0 DISAPPROVE COG DISPOSITION

SIGNATURE _____ DATE: _____

COGNIZANT DESIGN ENGINEER CLOSE-OUT

Sign when action required by disposition is complete.

SIGNATURE _____ DATE: _____

Design Review Objectives and Input Documentation

– addition of human performance in the objectives for each type of review.

The table below lists the objectives and design review inputs for each type of design review. This list was developed based on PPPL experience in design reviews and using ANSI/ASQC D1160-1995, *Formal Design Review*, as guidance. It is recognized that the nature of systems under review may vary significantly and that, as a result, the inputs required may differ somewhat from what is listed. For each review, the specific inputs are subject to negotiation between the Cognizant Engineer, the Responsible Line Manager, and the design review Chairperson.

Level of Review	Objectives	Inputs for Design Review
Peer Review	<p>The objectives for any peer review might include a subset of the following:</p> <ul style="list-style-type: none"> ▪ Communicate a proposed change to a requesting or performing group. ▪ Assure that the proper requirements are identified. Requirements should include functional, ES&H, regulatory, quality, reliability, interfaces, project specific, test, cost, human performance and ergonomics and schedule. ▪ Identify hazards associated with the work or its impact on operations and appropriate mitigation. ▪ Alert others (e.g. ES&H, QA, ER/WM) security of a proposed change in order to clarify group responsibilities within the change ▪ Alert impacted organizations or systems of the change ▪ Discuss resources, schedule, and cost. 	<ul style="list-style-type: none"> ▪ Updated Work Planning form, if applicable. ▪ Documented requirements, if required by WP. Otherwise, requirements presented as part of review presentation. ▪ Identified hazards and appropriate mitigation techniques. ▪ Resource, schedule, and cost considerations.
Conceptual (CDR)	<ul style="list-style-type: none"> ▪ Assure that the proper requirements are identified and can be satisfied within acceptable envelopes. Requirements should include functional, ES&H including human performance and ergonomics, regulatory, security, quality, reliability, interfaces, project specific and test ▪ Review development and design plans and schedules. ▪ Review cost and schedule estimates, including contingencies. ▪ Review configurations or designs that are novel to PPPL. ▪ Obtain input when competing design approaches exist. ▪ Identify hazards associated with the work or its impact on operations and appropriate mitigation ▪ Review and assure that appropriate design 	<ul style="list-style-type: none"> ▪ Updated Work Planning form, if applicable. ▪ Requirements. ▪ Design and development plan. ▪ Resource, schedule, and cost considerations. ▪ Resolution of chits from prior reviews, if any.

	and development plans and schedules have been developed.	
Preliminary (PDR)	<ul style="list-style-type: none"> ▪ Verify that all requirements are being addressed. Identify requirements or design conflicts and potential "show-stoppers" ▪ Review the results of analyses, calculations, and tests conducted to obtain additional information for the design. ▪ Review the ability to implement the proposed design taking into consideration capabilities, tolerances, costs, quality, reliability, human performance and ergonomics, security, and ES&H security. ▪ Review procurement issues, e.g. build vs. buy. ▪ Review test requirements and plans. ▪ Review updated design and development plans and schedules. ▪ Assure the appropriate incorporation of recommendations from previous design reviews. ▪ Review manufacturability. 	<ul style="list-style-type: none"> ▪ Updated Work Planning form, if applicable. ▪ Resolution of CDR Chits, if any ▪ Requirement changes since CDR, if held. Otherwise, requirements. ▪ Documentation defining proposed design approach. ▪ Design and development information. ▪ Results of calculations upon which design is based. ▪ Design plans. ▪ Updated cost & schedule estimates. ▪ Drawings, as appropriate. ▪ List of identified procurements and build vs. buy decision.
Final (FDR)	<ul style="list-style-type: none"> ▪ Verify that the final design satisfies the requirements and is ready for implementation. ▪ Assure that detailed analyses, calculations, and tests to validate the design are complete and documented. ▪ Verify, as appropriate, that the final product can be manufactured, inspected, assembled, stored, delivered, and installed reliably, safely, and cost effectively ▪ Verify that human performance and human factors considerations are appropriately addressed in the design. Further information about human factors in designs may be found in attachment 6 ▪ Verify that procurement issues have been identified and resolved. ▪ Verify that appropriate documentation is available for producing the final product (e.g. drawings, installation procedures). ▪ Verify that appropriate test plans for the 	<ul style="list-style-type: none"> ▪ Updated Work Planning form, if applicable. ▪ Resolution of PDR Chits, if any ▪ Requirement changes since PDR, if held. Otherwise, requirements. ▪ Documentation defining final design approach. ▪ Documented and checked calculations upon which design is based. ▪ Formal drawings, to level required to proceed with procurement/ fabrication/ assembly as applicable. Examples are P&IDs and schematics. Drawings should be checked but need not be signed pending outcome of review and chit resolution. ▪ Revised cost and schedule estimates. ▪ Documentation of tests to be performed. ▪ Drawings, as appropriate.

Design Review Objectives and Input Documentation**Page 3 of 3**

	<p>final product have been established.</p> <ul style="list-style-type: none">▪ Assure the appropriate incorporation of recommendations from previous design reviews.▪ Review manufacturability.	
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Design Review Results Form**Page 1 of 1****DESIGN REVIEW DOCUMENTATION – RESULTS**

Title: _____ WP#: _____ (ENG-032)

Type of Review: Peer CDR PDR FDR

Cog Individual: _____ Date of Review: _____

Review Board Members:**Invited attendees :****Other Attendees:**

Chairperson _____	QA _____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____

Regulatory Compliance _____

Items Reviewed:	Sat.	Unsat.	Comments or n/a if not applicable
Appropriate requirements identified	<input type="checkbox"/>	<input type="checkbox"/>	_____
Development plans and schedules	<input type="checkbox"/>	<input type="checkbox"/>	_____
Regulatory compliance including USQD and NEPA	<input type="checkbox"/>	<input type="checkbox"/>	_____
Disposition of CHITS from previous reviews	<input type="checkbox"/>	<input type="checkbox"/>	_____
Cost objectives	<input type="checkbox"/>	<input type="checkbox"/>	_____
Other review objectives addressed (attachment 4 of ENG-033)	<input type="checkbox"/>	<input type="checkbox"/>	_____

SUMMARY OF RESULTS:**Disposition:** [check one]_____ **Acceptable**_____ **Acceptable pending resolution of concerns-** CHITS identified above must be resolved prior to installation._____ **Incomplete** - Additional design work is required prior to another design review.**Chairperson Signature:** _____ **Date:** _____**Distribution:** Review Board Members, Operations Center, Cognizant Design Engineer, System Engineer(s), Attendees, QA, ES&H, Security

Potentially relevant design review questions are listed below. However, the reader should not limit the human performance aspects of a review to these questions.

1. Have potential human or mechanical failures been identified? If so, is there adequate defense in depth¹ to either assure that these failures do not occur or, if they do, the consequences of these failures are minimized?
2. Does this design result in latent errors² that should be corrected?
3. Does the design take into consideration the human factors associated with fabrication, installation, testing, and operation? Considerations include:
 - a. Are the human interfaces and displays consistent with the work to be done, consistent with other interfaces and displays that the same individuals must use, easy to understand, properly labeled, considerate of human limitations such as color blindness, etc.?
 - b. Can the final fabrication or construction be safely performed? Are unique tools required that may not be available? Are there excessive lifting or carrying requirements? Does the design require people to work in an awkward position?

¹ An approach to facility safety that builds in layers of defense against release of or exposure to hazardous materials so that no one layer by itself, no matter how good, is completely relied upon. To compensate for potential human and mechanical failures, defense in depth is based on several layers of protection with successive barriers to prevent the release of or exposure to hazardous materials. This approach includes protection of the barriers to avert damage to the plant and to the barriers themselves. It includes further measures to protect the public, workers, and the environment from harm in case these barriers are not fully effective. Defense in depth controls include engineering controls, administrative processes, and personnel staffing and capabilities. [DOE M 450.1]

² An error, act, or decision that results in organization-related weaknesses or equipment flaws that lie dormant until revealed either by human error, testing, or self-assessment. [DOE M 450.1]