Engineering Design Reviews

Protocols

Videos – Design Review

DESIGN REVIEW meaning & explanation
https://youtu.be/YKzCIqafx8w

Critical Design Review
https://youtu.be/iLDuTiF9Dwg

Engineering Design Reviews Introduction

- **Purpose** - Communication between the design team, management, customer and federal approval authorities (i.e. FDA) .
  - Management and the customer - insight into the technical status of the product
  - Design Team - Feedback on issues involving the design.
  - Approval Authorities – Documenting the design and the decision making process.
- **Objectives**
  - Ensure that all contributory factors and reasonable design options have been considered,
  - Design meets the requirements as outlined in the Product Development Specification.
- **Responsibility**
  - Design Team
    - Provide an accurate, concise overview of the design to-date
    - Facilitation of productive discussions.
  - Reviewers
    - Ensure that the design can be produced, tested, installed, operated and maintained in a manner that is acceptable to the customer.

Engineering Design Reviews Types

- **Informal / Formal Review**
  - Informal Review
    - Individuals directly involved in the design project
  - Formal Review
    - Individuals directly involved in the design project
    - Subject matter experts who are not directly involved in the design but can review and comment on the design
- **Technical / Project Review**
  - Technical Review
    - Technical Issues
  - Project Review
    - Summary of the technical review
    - Budget
    - Schedule
    - Resources.

Engineering Design Reviews
Timing & Types

- **Timing**
  - Proper junctures during a design project at which a design review can be conducted
  - All relevant information can be provided to the reviewers
  - Too Early - decisions being based on insufficient information
  - Too Late - Little impact since commitments to the design have already been made and cannot be changed without significant alteration to schedule or budget.
- **Types**
  1. Requirements Review
  2. System Design Review (SDR).
  3. Preliminary Design Review (PDR).
  4. Critical Design Review (CDR).
  5. Test Readiness Review (TRR).
  6. Final Design Review (FDR)
  7. Production Readiness Review (PRR).
  8. Ad Hoc Reviews

Engineering Design Reviews
Types – RR / SDR

- ***Requirements Review (RR)***
  - Ensure that all of the appropriate requirements and constraints have been clearly and completely identified.
  - Conducted with the Preliminary Design Review (PDR).

- ***System Design Review (SDR)***
  - Large systems
  - Examines the allocation of requirements to individual configuration items (sub system)

Engineering Design Reviews Types – PDR

- ***Preliminary Design Review (PDR).***
  - Design concepts are evaluated for
    - Feasibility
    - Technical adequacy
    - General compliance with requirements
  - Merits/weaknesses of different concepts are presented
  - Assumptions and calculations
  - Preliminary prototypes, mock-ups or sketches
  - Review of the technical progress
  - Budget Status
  - Schedule
  - Potential Risk Factors
  - Mitigation Plans

Engineering Design Reviews
Types – TTR / FDR

- ***Test Readiness Review (TRR)***
  - Examines the test plans for prototypes or pre-production units to verify the design against the requirements.
  - Reviewed for reliability and completeness.
- ***Final Design Review (FDR).***
  - Timing - Conducted after prototypes or preproduction units have been through verification testing.
  - Problems - Encountered problems during testing
  - Solutions - Respective solutions are examined.
  - Changes - Necessary changes to the product with respect to performance, cost, reliability and manufacturing issues are agreed upon prior to the initiation of full-scale production

Engineering Design Reviews Types – PRR / AHR

- ***Production Readiness Review (PRR).***
  - Critical for high volume products
  - Early stages PRR - High level manufacturing concerns
  - Late stages PRR – Detailed reviews as the product design matures
- ***Ad Hoc Reviews***
  - Critical Decisions **-** Obtain multidisciplinary inputs
  - Project Development - Problem
  - Drastically change of Deign Direction .

Engineering Design Reviews Preparation

• Schedule design review	1 month. prior
• Arrange for meeting facilities	1 month. prior
• Assign areas of responsibility to design team members	
• Publish agenda	3-4 wk. prior
• Invite subject matter experts and customers (if applicable)	3-4 wk. prior
• Distribute design review packages	2 wk. prior
• Conduct dry runs	1 wk. prior
• Distribute addendum to design review package	1 wk. to 2 days prior
• Arrange layout of room and ensure availability of seating.	1 day prior
• Confirm availability and functionality of equipment	1 day prior
• Final dry run	1 day prior

Engineering Design Reviews Participation

- **Number of participants** – 5-10 people
- **Maintaining the Number of Participants** - Few key people to participate in the entire review while others participate only during designated segments
- **Cancelations (Backup plan)** - Make alternate arrangements in advance, especially for key participants such as subject matter experts and customers, so that the productiveness of the review is not at risk.

Engineering Design Reviews Participation – Chairperson

- ***Role***
  - Coordinating, managing, and conducting the preparations
  - Monitoring the follow through of any actions resulting from the meeting.
- **Assigning a Chairperson**
  - Approach 1
    - Senior person with an engineering background and a solid understanding of the design process.
    - Not directly involved in the design project itself and therefore can remain objective.
  - Approach 2 (product is being developed for a particular customer)
    - Chairperson (lead) – Provided by the customer
    - ***Co-chairperson -*** senior or principal engineer or the project manager for the project
    - Maintain balance and objectivity

Engineering Design Reviews
Participation – Design Team

- **Role**
  - Providing details regarding the design and the design process,
  - Discussing and receiving feedback.
- **Participants**
  - ***Lead engineer*** **-** Principal engineer on the project responsible for introducing the details of the design project and leading technical discussions.
  - **Designers** – Based on the topic discussed

Engineering Design Reviews Participation – *Experts, Customers*

- ***Subject Matter Experts***
  - Experts are not directly involved in the development of the design
  - manufacturing, test, quality, finance, marketing, reliability, safety, human factors, purchasing, maintenance, etc.

- ***Customer***
  - Loosely define as the entity who pays or fund the project
  - May mirror the subject matter experts with experts from their own organization.

Engineering Design Reviews Package

- Product Development Specification (PDS)
- Engineering Data such as calculations, simulations, test/experimentation results, and any other analyses performed
- Competitive analysis of existing products
- Drawings, schematics, layouts, breadboards, mock-ups and prototypes
- Cost and schedule status and projections
- Project risk analysis
- Description of unusual requirements and design elements with associated high-risk

Engineering Design Reviews Agenda

- **Length**
  - Hours
  - Days
  - Limitation by resources and budget
  - Something is better than nothing - abbreviated version is still more beneficial than no review at all
- **Scope**
  - Include items of significance or concerns
  - Be prepend to address questions not included in the agenda
- **Know Your Audience**
  - Communicate at the common denominator
  - Extend your explanations in response to questions
- **Feedback**
  - Accept constructive feedback
  - Use the feedback as a mechanism to improve the design

Engineering Design Reviews Agenda

- ***Welcome & Introduction*** (<5% of meeting; Responsibility: Chairperson)
  - The chairperson welcomes
  - Participants introduction including
    - Organization
    - Position
    - Area of expertise
- **Design Review Purpose & Process** (<5% of meeting; Responsibility: Chairperson)
  - Chairperson: States the purpose and objectives of the review.
  - Participants: Provide objective and constructive inputs
- ***Background*** (~10% of meeting; Responsibility: Lead Engineer)
  - Needs Statement - Circumstances that led to the project including the “needs statement”.
  - Objectives and Significant requirements – Outline
  - Overview of design
  - Key assumptions
  - Changes that have occurred since previous design review (e.g., requirements, design, project).
  - Competitive analysis.
  - Alternative concepts considered & rationale for selected design approach.
  - Significant problems or risks encountered or expected.

Engineering Design Reviews Agenda

- ***Detailed Interactive Discussion of Product*** (~60% of meeting; Responsibility: All facilitated by Lead Engineer)
  - Presentation and discussion of each critical requirement and how it is satisfied by the design.
  - Demo - Demonstration of the product or models (if available).
  - Processes - Processes used to arrive at the design (e.g., testing, simulation, and calculations).
  - Assumption Validation - Validation of assumptions used during design.
  - Risks - Assessment and abatement of product risk.
  - Concerns - Highlighting of areas of concern and associated recommendations
  - Uncertainty - Clarification of areas of uncertainty and answers to outstanding questions..
- ***Discussion of Project*** (<10% of time; Responsibility: Project Manager)
  - Schedule - Overview of schedule including significant milestones achieved and planned.
  - Status of budget (financial and time) including spending versus planned to date, and projected spending.
  - Resources required versus resources currently available.
  - Assessment and abatement of project risk.
- ***Wrap-Up*** (~10% of meeting; Responsibility: Chairperson with Lead Engineer and Secretary)
  - Identification and discussion of issues that should have and have not been addressed.
  - Discussion on recommendations whether to proceed with current design direction, pursue alternative design approaches or terminate the project.
  - Review of action items.
  - Present outline of post-review activities (e.g., schedule for distribution of Design Review Report)

Engineering Design Reviews
Responsibility of the Reviewers

- **Data & Conclusion** - Do the data and results support the conclusions drawn?
- **Assumptions** - Do the assumptions seem reasonable?
- **Risk Assessments** - Are there areas where the risks appear to be higher than normal?
- **Significant** - Are there items of significance that have not been addressed?
- **Requirements**
  - Does the design satisfy the applicable requirements?
  - Are there requirements that were intentionally not satisfied?
  - Is that acceptable?
- **Methods** - Are the design methods used appropriate for this product and its intended application?
- **Problems**
  - What problems remain to be solved?
  - Is there adequate assurance the problems can be solved in a reasonable manner and appropriate time frame?

Engineering Design Reviews
Design Review Meeting Minutes & Follow-up

- **Content**
  - DR Report - Basis of the Design Review Report
  - Decisions - Record decisions that have been made
  - Open Issues - issues that require resolution
  - Actions - Actions that have been identified during the course of the design review
  - Follow-ups – Responsibly Entity / Person & Time
  - Conclusions
- **Scribe**
  - Preassigned - One member of the design team
  - individual team members are advised to record in their personal log books any items that fall into their area of responsibility
- **Distribution**
  - Distribute the minutes within a day or two of the review
  - provides an opportunity to highlight any errors or omissions prior to the completion of the Design Review Report
- **Post Review Follow up**
  - **Designated Person –** Chairperson or lead engineer
  - All Items must be addressed objectively and in a timely manner
  - Resolution must be documented in the design review

Engineering Design Reviews
Post Mortem & Report

- **Post Mortem (Meeting)**
  - Brief meeting following the Design Review meeting
  - Subset of the reviewers
- **Design Review Report**
  - Time – Issued within a month of the meeting
  - Content
    - status of each issue or action item
    - resolution of these items
    - further investigation
    - testing or other analyses
  - Outcomes
    - Lead to changes (direction but also schedule and budget)
    - Impact of the changes

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