AS IEC 61160—2008
IEC 61160, Ed.2 (2005)

AS IEC 61160—2008

Australian Standard®

Design review

STANDARDS
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Design review

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PREFACE

This Standard was prepared by the Standards Australia Committee QR-005, Dependability.

The objective of this Standard is to provide guidance on planning and conducting a design review during design and development, as a means of verifying that design input requirements are being met. Includes specific guidance on contributions by specialists in reliability, maintenance, maintenance support, availability and the life cycle of a product or system.

This Standard is identical with, and has been reproduced from IEC 61160, Ed.2 (2005), *Design review*.

As this Standard is reproduced from an International Standard, the following applies:

(a) Its number does not appear on each page of text and its identity is shown only on the cover and title page.

(b) In the source text 'this International Standard' should read 'this Australian Standard'.

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The terms 'normative' and 'informative' are used to define the application of the annex to which they apply. A normative annex is an integral part of a standard, whereas an informative annex is only for information and guidance.

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Design review

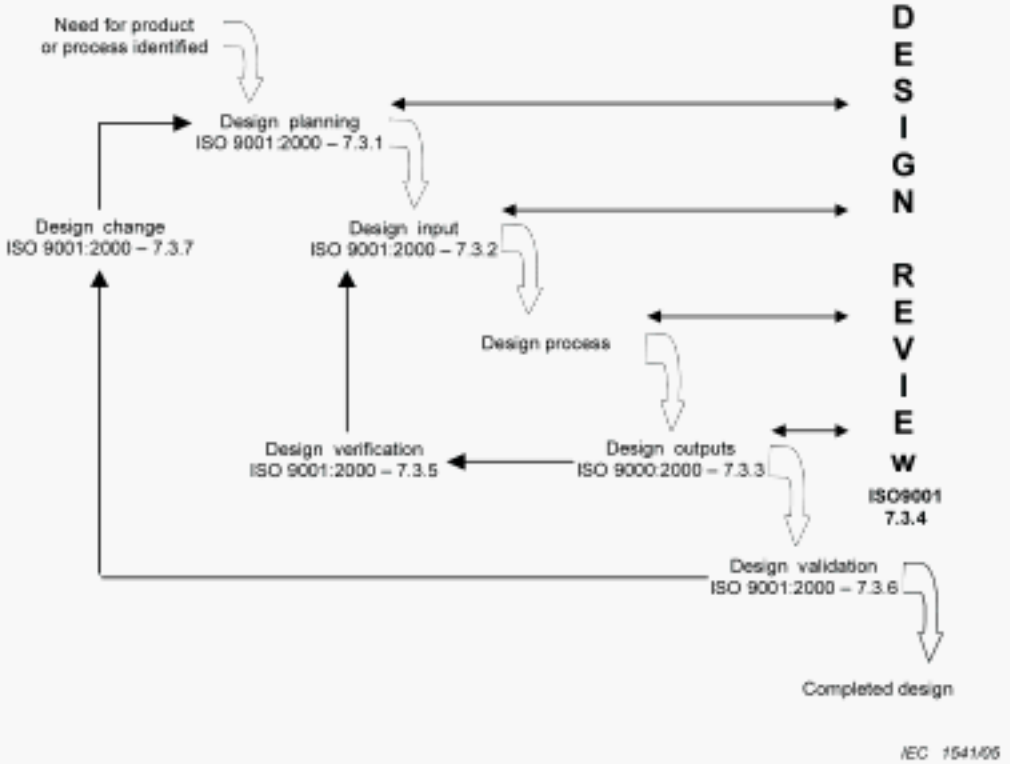
1 Scope

1.1 General

This International Standard makes recommendations for the implementation of design review as a means of verifying that the design input requirements have been met and stimulating the improvement of the product's design. The intention is for it to be applied during the design and development phase of a product's life cycle.

It provides guidelines for planning and conducting a design review and specific details concerning contributions by specialists in reliability, maintenance, maintenance support and availability.

The process for design and development is outlined in Figure 1 and requirements for management of the design and development process overall are given in ISO 9001:2000. The stages at which the design review or reviews are to be held should be determined during the development of the plan for the design.



NOTE Reference to the clauses of ISO 9001:2000 is for information only.

Figure 1 – Design and development process

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The objectives of a design review include:

- assessing whether the proposed solution meets the design input requirements that include, but are not limited to: specified general performance requirements, dependability, lifecycle costs, safety, endurance, environment, electromagnetic compatibility, human factors;
- assessing whether the proposed solution is the most robust, efficient and effective solution to achieve the product requirements;
- providing recommendations as required for achieving the design input requirements;
- assessing the status of the design in terms of the completeness of the drawings and specifications;
- assessing the evidence to support the verification of the design performance;
- proposing improvements.

Design review facilitates assessment of the status of the design against the input requirements, identification of opportunities for improvement and guides the design manager towards appropriate action. It accelerates maturing of the product by reducing the time needed to stabilize design details, and allows product realization to proceed without frequent interruptions. Design review can also stimulate early product improvement.

1.2 Application

The stage or stages at which a design review is to be performed should be determined in the design and development planning stage of a project or a design task. Influencing factors should include customer requirements, regulatory requirements, the size and complexity of the product, the use to which the product is to be put, and the consequences of failure.

The cost to correct deficiencies in a design and the potential consequences increase as the design nears completion. Also, as the design progresses towards completion, so the flexibility to implement a change to correct a deficiency or to optimize the design decreases.

Each organization undertaking design and development should adopt either a comprehensive design review programme as presented in this standard, or tailor a more limited one to meet specific product and/or process needs.

The design review should be incorporated into the organization's overall management system and, as applicable, each project's schedule.

Limitations of size and resources of the organization, project value, product benefits, risks and complexity, all influence the size and frequency of design reviews. In smaller organizations, it could be necessary to supplement staff with personnel from suppliers, consultants and other outside advisors.

1.3 Types of application

There are two types of application: either an in-house created requirement for a new design, or a design requirement from an external source. In the case of the latter, the risk of a misunderstanding is much greater. Any misunderstanding could become a contractual issue and design review meetings with the client will be of primary importance to ensure that the emerging design meets the client's requirements.

A design review should be held:

- prior to order acceptance to ensure that the scope of work is established together with all the parameters that need to be met for an acceptable design;

- prior to detail design to ensure that the members of the design team have first-hand knowledge of all detail requirements. Interface provisions should be established and a list of defining documentation scheduled for submission and approval between the parties;
- at suitable points during detail design to review all interface provisions and agree on the test procedures for verifying that the design meets contract requirements.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

IEC 60050-191:1990, *International Electrotechnical Vocabulary (IEV) – Chapter 191: Dependability and quality of service*

IEC 62198:2001, *Project risk management – Application guidelines*

3 Terms and definitions

For the purposes of this document the terms and definitions of IEC 60050(191) apply, together with the following additional definitions.

3.1
action item
question to be resolved by the design manager or nominated person

3.2
review
activity undertaken to determine the suitability, adequacy and effectiveness of the subject matter to achieve established objectives

[ISO 9000:2000, definition 3.8.7]

3.3
design and development
set of processes that transforms requirements into specified characteristics or into the specification of a product, process or system

NOTE 1 The terms "design" and "development" are sometimes used synonymously and sometimes used to define different stages of the overall design and development process.

NOTE 2 A qualifier can be applied to indicate the nature of what is being designed and developed (e.g. product design and development or process design and development).

[ISO 9000:2000, definition 3.4.4]

3.4
design review
planned, documented independent review of an existing or proposed design

NOTE 1 Objectives include evaluation of the design's capability to fulfil the specified requirements, identify any actual or potential deficiencies, proposing enhancements.

NOTE 2 **Design review** by itself is not sufficient to ensure proper design.

NOTE 3 The design can be for a product or process.

NOTE 4 The design review can be achieved by means of a meeting or other documented process.

3.5
design manager
person responsible for the product or process' design and development

NOTE For the purposes of this standard, the term "design manager" is used. In practice, other titles are used for this function depending on the organization's size and structure, and/or the contractual arrangements.

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3.6
verification
confirmation, through the provision of objective evidence, that specified requirements have been fulfilled

[ISO 9000:2000, definition 3.8.4]

3.7
validation
confirmation, through the provision of objective evidence, that the requirements for a specified intended use or application have been fulfilled.

[ISO 9000:2000, definition 3.8.5]

4 Management of the design review process

4.1 General recommendations

The organization should establish and maintain a management system to direct and control those design review activities that are part of the organization's overall management system.

For designs reviews this should include:

a) identifying the functions and activities needed for the organization's design reviews;

b) establishing the design review objectives and plan to achieve these objectives during design planning;

c) ensuring timely implementation of the design review activities during all applicable design phases;

d) assessing the criteria and methods for performance assessment, evaluation and acceptance of the product;

e) providing resources and information necessary to achieve required design reviews;

f) monitoring the design review activities and, measuring and analysing the results for continual improvement.

4.2 Documentation requirements

The management system documentation for design review should include:

a) documented commitment and objectives for design review;

b) documented procedures for management of the design review process;

c) records arising from the design review activities;

d) records of completion of action items and recommendations.

5 Management responsibility

5.1 Top management

Top management of the design organization should communicate and demonstrate its commitment to the design review process to all personnel involved.

Achieving this includes:

- defining the management responsibilities and authorities for design review;
- ensuring the required resources for design reviews are available.

5.2 Design manager

The design manager's responsibilities should include but not limited to:

- developing and implementing a design plan that includes the points at which design reviews are required;
- selecting an independent suitably experienced person to chair the design review meeting or meetings, as applicable, or otherwise defined;
- preparing and providing the design data required for each scheduled design review's input package;
- ensuring that actions and recommendations arising from a design review meeting are responded to and completed in a timely manner.

NOTE For external designs, the contract may define requirements for some of these.

5.3 Management review

At planned intervals, top management should review its procedures and practices for design reviews to ensure their continuing suitability, adequacy and effectiveness. This can be carried out as a part of an organizational management review process. The design review records can be analysed for opportunities for process improvement.

6 Design review process

6.1 General

Design reviews require careful planning, organization and reporting. This clause provides a framework for implementation of the design review process itself. Specific details will depend on the product and the type of design review (see Annex A).

Care should be taken to prevent the design review from dictating the ultimate design. Decisions are made everyday which bear on the design of the product or process under review. If each decision is subjected to an independent review, the review team would, in essence become the designer with the potential for increased development time and costs. Conversely, if the first design review occurred only just before production or use, its benefit could be questionable as there may be little opportunity to influence the situation without a significant time or cost penalty.

The process for design review is outlined in Figure 2. The stages at which design reviews are held should be established during the development of the design plan. In determining the stage or stages at which a design review is to be held, factors to be taken into account include:

a) The size and complexity of the product. For example:
   - is it a simple design or a minor upgrade;
   - is it a product involving multiple systems;
   - is it a complex system?

b) What would be the impact of a delay in delivery or failure of the product? Project risk management tools given in IEC 62198 can be utilized in assessing this.

The most critical design stage will be the conceptual design. This is usually carried out in support of a submission for authorisation to proceed with a design project or to enable a proposal to be submitted to a client. The major objective will be to verify the design feasibility, estimate the cost and to plan its execution.

The design feasibility or risk can be ranked as follows:

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a) customized design based on the selection from a range of proven components and materials;

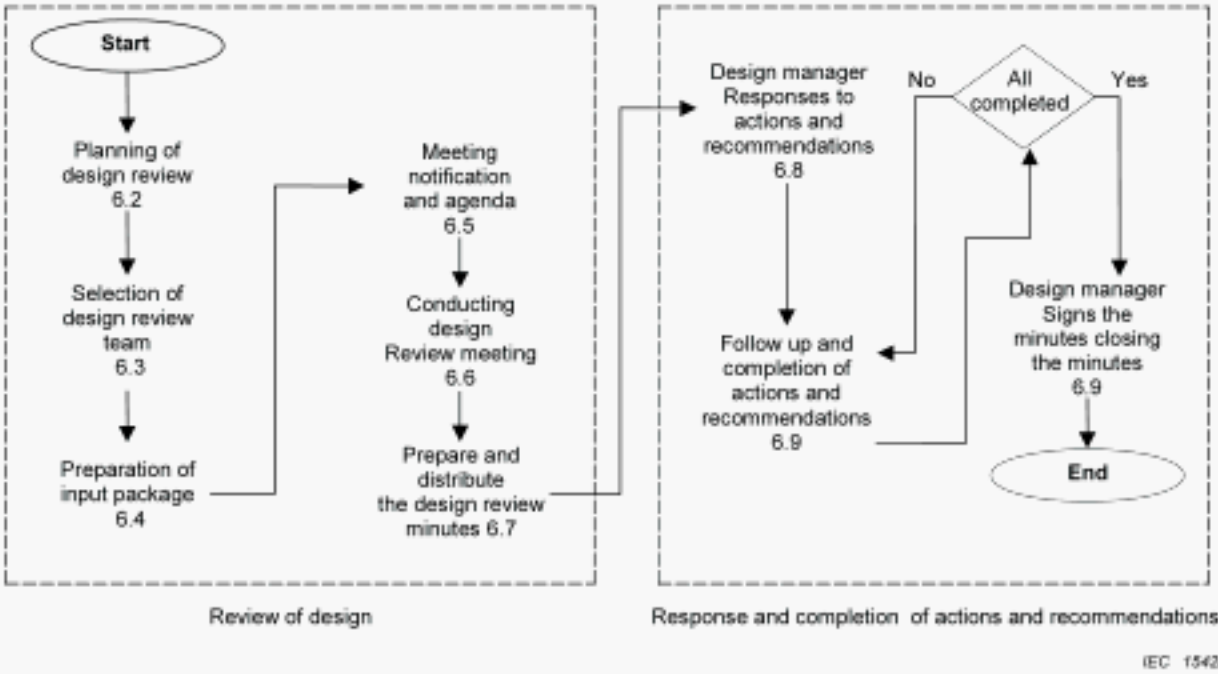
b) design that involves the use of an unproven component, material or subcontractor;

c) design based on the interpolation of existing experience;

d) design based on the extrapolation of existing experience;

e) a completely new design or application of unproven technology.

Designs that have a high risk will require more design reviews as a measure of risk management. In the case of a new design to be released for series production the detail design could be considered to be that of a prototype. The need for an intensive design review of the results of prototype testing will be critical for deciding on the features needed to ensure a reliable final design. In extreme cases it could even result in a decision for abandonment.



NOTE Numbers refer to the applicable clause in this standard.

Figure 2 – Design review process

The principal objectives of a design review are to provide confidence that the product's requirements have been identified and can be met in an efficient and effective manner, and will result in a dependable and useful product. In particular, the objectives of a design review include, but are not limited to:

1) the product meets specified requirements in a cost-effective manner;

2) the design and development plan includes the strategy for confirming and demonstrating that performance requirements can be met;

3) the design satisfies customer and interfacing requirements;

4) the product and its elements, as required, can be safely and economically disposed of;

5) required design, manufacturing and installation methods are being utilized;

6) costs have been optimized after considering all product requirements;

7) scheduling considerations are taken into account;

8) recommendations are provided for improvement of design;

9) components are used within their specified performance and stress ratings;

10) earlier recommendations have been addressed;

11) that the design's drawings, software codes and specifications is full and complete.

Normally only the recommendations from the review should be documented, but for safety issues it is important to list all the risks considered and the reason for recommending or not recommending actions.

As a result of the action items identified and recommendations made, matters the design manager should consider include, but are not limited to, changes in the design's concepts, specifications, plans, schedules, or, impact on safety or environmental requirements, product quality, manufacturing, installation, operation and maintenance procedures and costs.

For an effective design review, the subjects and results of discussions during each design review need to be documented to permit continuity and follow-up until design decisions have been completed. Sufficient documentation should be contained in the meeting's minutes so that successive design reviews avert repeated coverage of the same problems and avoid significant loss of insight and understanding of relevant issues. If continuity and follow-up are achieved, succeeding review effort can be directed to more pressing aspects of the product's design. The meeting's minutes supporting documentation and follow-up are discussed in 6.7 and 6.9.

The specific objectives depend on the type of design review being undertaken and the product or process being designed. Clear explanations by the chair of objectives and scope of each design review will focus attention on specific areas of the design, and minimize misplaced comments. Typical objectives and activities for each type of design review are given in Annex B.

Design review meetings are independent of those meetings undertaken as a part of the ongoing planning, scheduling and development of the design.

The design manager or those directly involved in the design should not chair design reviews.

Depending on whether the design project is internally or externally funded, the conduct of the review and the stances taken by the individuals can vary.

6.2 Planning for the design review

The point or points at which design review occurs should be determined during the design planning stage. Ideally design reviews should be conducted before taking a decision that can prove costly, time consuming, or difficult to reverse. This should take into account the identified risks for the design and/or project.

In this way any changes arising from a design review can be made with less impact on schedule or cost. Additionally, cost, schedule and performance improvements can more readily be adopted if reviews are conducted before making a significant commitment at major points in the design process.

The design manager should consider the conditions and constraints imposed by a particular project in the scheduling of design reviews and the optimum number should be determined to maximize return on time spent.

Only a few organizations or projects will have a need for all types of design review.

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6.3 Design review personnel

6.3.1 General

Design reviews are normally carried out by an independent review panel who receive presentations and information from those responsible for the design. The personnel involved are normally:

a) the design review panel that includes but is not limited to:
   - the chair;
   - the secretary;
   - persons representing functions which could affect the product or process quality, but not directly involved in the design;
   - relevant specialists, not involved in development of the product under review;
   - customer/users, as practical;

b) the design manager and the design team members as necessary to present the design and answer questions.

To avoid conflicts of interest the persons authorizing or approving further steps in the design process should normally not be a panel member.

The design review panel should include people with special knowledge and experience from different spheres. The composition should be such that the participants, collectively, cover a sufficiently wide and detailed field of knowledge to permit consideration of all pertinent aspects of the product. Care should be taken to keep the team to a workable size.

6.3.2 Design review chair

The chair should have broad technical knowledge and experience that includes design, the ability and confidence to manage personnel and to work equally well with technical and non-technical persons. Leadership and understanding in dealing with others is of utmost importance.

The chair's responsibilities and authority should include:

a) agreeing to the objectives and scope for the design review;

b) agreeing to selection of panel members in consultation with management;

c) establishing meeting agendas for delegated meeting or meetings;

d) ensuring that participants understand what is required of them;

e) ensuring that sufficient time is allocated for design review activities;

f) ensuring that the meeting's input package is issued to designated persons;

g) assigning tasks to participants in preparation for meetings;

h) chairing the design review meeting;

i) ensuring that relevant issues from the meeting are recorded;

j) ensuring that actions and recommendations from earlier meetings have been satisfactorily addressed and closed, as appropriate;

k) ensuring that the focus of the meeting is the design and not individuals;

l) ensuring that there is input from all present;

m) reviewing and approving the design review meeting's minutes;

n) ensuring that the meeting's minutes are issued to designated persons;

o) striving for consensus in the review team in case of differences of opinion. If consensus cannot be reached forward minority as well as majority view(s) for decision.

To maintain the integrity and objectivity of the design review team, where possible, the chair should not be associated with the project's design activities. However, in a small company, an employee with all necessary qualifications and not participating in some way in the project may not be available. Consideration should then be given to engaging an outsider. In any event, the chair should be able to maintain the respect of all participants.

6.3.3 Design review secretary

A secretary should be appointed to record the results of the meeting and enable the chair to maintain focus on the meeting. Where possible, the same person should serve as the secretary for the defined design reviews for a specific product. The qualifications and experience for the secretary should be similar to those for the chair, but can be less stringent.

The secretary's duties and responsibilities should include:

a) sending out invitations with sufficient time for members to prepare for the meeting;

b) distributing agendas;

c) follow up on distribution of input data for review by participants;

d) organizing, assembling and distributing responses to inquiries or assignments;

e) taking minutes;

f) preparing the meeting's minutes;

g) issuing the meeting's minutes to designated persons;

h) assisting the chair in following up action items and recommendations, as applicable.

NOTE If a separate, independent, secretary cannot be appointed, it is usually better for a representative from the design team to act as the secretary.

If the organization is of sufficient size, the position of secretary can be used as training for future service as design review chair. In selecting a secretary, the following factors should be considered:

– previous participation in design review activity;

– technical training and comparable experience;

– communication skills;

– involvement in similar projects;

– non-involvement in work on the product or process under review.

6.3.4 Specialists

The specialists should be selected taking into account the product, the product's objectives, and the type of design review (see Annex A).

Specialists should be represented on the design review panel at the appropriate stage in the product's development. Their specializations can include, but are not limited to: reliability and maintainability engineering, performance estimation, testing and acceptance/certification, quality management, structures engineering, manufacturing engineering, safety, environmental engineering, legal matters, advertising and marketing, finance, logistics.

6.3.5 Design manager

The design manager, or at least one representative of the design team, needs to participate in the whole review in order to explain the rationale of the design decision taken, answer questions and help the review panel identified and evaluate potential problems, their probable consequences and possible actions. Representatives should be selected to attend design review meetings pertaining to their respective roles in the design and development process. It may not be possible for all such persons to attend throughout in light of team size restrictions. Participants can therefore be invited only to those portions of a meeting that pertain to the area where they should contribute. However, all potential participants should

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receive the agenda and any portion of the input data package that is relevant to their expertise. Additional representatives from the design team can participate as observers where agreed by the chair. These observers do not have the right to speak unless the chair gives permission.

6.4 Preparation of input package

The design manager is responsible for putting together the information relevant to the design review to be undertaken.

According to the design stage the input data package should include some or all of the following:

a) design plan;

b) original requirements (these can include: the customer's request for quotes, specifications, standards, regulatory requirements);

c) anticipated customer needs, developed and supported by market surveys and competitors' activities;

d) documented design assumptions;

e) design trade-off studies and analyses;

f) a list of any questions from the design review panel on the design to be reviewed;

g) reliability, availability and maintainability allocations and predictions;

h) planned logistics support;

i) designer's proposals and alternative considerations which include drawings and calculations;

j) information and data on similar products;

k) competitive product data;

l) cost estimates and trade-off rationale;

m) specifications and drawings;

n) manufacturing, tooling and producibility studies;

o) performance test reports, analyses and requirements;

p) field failure or malfunction reports;

q) quality control analyses of processes and supplies;

r) inspection reports;

s) life cycle targets and cost data.

6.5 Meeting notification and agenda

The secretary, in conjunction with the chair, should prepare a notification and agenda for the meeting and circulate them to participants, and as applicable, their supervisors, sufficiently in advance of the design review to allow participants to prepare for the meeting.

The notification and agenda should state:

a) the date, time and venue of the meeting

b) the scope and objectives for the design review meeting;

c) the project name and identification number;

d) participants and their functions;

e) the type and duration of the design review;

f) the section of the project under review, if appropriate;

g) topics to be discussed can include, for example:

- a review of the objectives of the design project;
- a description of the design features and performance characteristics of the product;
- a review of design and technical progress to date and problems encountered;
- a review of outstanding and future areas of work and any concerns arising;
- an assessment of all pertinent aspects of the design against a Design Review checklist;
- a summary of findings by the review panel;

h) the persons who will make presentations;

i) reference documents and the contents of any attached input data package.

6.6 Conduct of meeting

6.6.1 General

If the panel members are not experienced in design reviews, an orientation session should be conducted explaining the general objectives, philosophy, and practice.

The introductory comments should set a constructive tone and climate. The chair should review the objectives of the meeting and relate them to the overall objectives and procedures for the design review process. The chair should stress the need to ask questions and to avoid negative and personally oriented comments.

Questions that imply pre-judgement should be avoided.

Panel members should feel free to question their peers. They should not see their responsibility as being solely to ask why something was done in a particular way.

Whenever necessary, the review participants should be assured that all questions raised, subsequent investigations requested, and opinions expressed do not reflect on anyone's personality, ability or integrity. The entire team, under the direction of the chair, should ensure that the design review process does not become a personality contest either among the panel members or between the panel and the design team.

The panel members should always remember that they serve in an advisory capacity and that their prime purpose is to assist those responsible for the product's design in achieving the optimum result. They are not there to provide a solution to any deficiencies identified.

6.6.2 Presentations

The design manager and the other members representing the design and development team should present, as required, aspects of the design under review.

6.6.3 Meeting protocol

The chair should ensure that presentation and questioning proceed systematically.

The review process is one of constructive questions and answers. Derogatory questions or responses should not be permitted, nor should there be a flat refusal to discuss a topic unless there are specific issues of commercial confidentiality or national security involved. Questions should be framed in terms of requests for information or inquiry as to reasons for design and development decisions.

Panel members can submit questions to the chair in advance to allow for a prepared response. These questions can be considered complex or minor. To facilitate progress of the meeting, minor questions can be closed before start of the meeting. These questions would be a part of the meetings input package.

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Information contained in the minutes should include:

a) a copy of the meeting's notification and agenda;

b) list of attendees;

c) identification of the product or process being reviewed;

d) a summary of the findings, an abbreviated schedule of action items, and where appropriate, details of the design review;

e) pertinent questions and responses;

f) if a checklist is used, a copy of the checklist and as appropriate the answers to questions;

g) list of action items for unresolved questions;

h) person to whom responsibility for an action was assigned;

i) dates for completion of action items;

j) list of recommendations;

k) list of design actions or recommendations requiring priority;

l) status or disposition of action items and recommendations from previous meetings;

m) list of reference documents.

6.8 Actions and recommendations

Although the review may generate many recommendations, the design manager is bound only to review all the recommendations and can reject those for which a reason can be provided. For example, many recommendations may be wise and of general benefit to the design but it possible that some will, on further examination, prove to be undesirable or impractical.

Thus the design manager is responsible for determining the response to each of the design review's actions and recommendations. In a timely manner the design manager should:

- provide a response to each of the meeting's actions and recommendations within an agreed time frame;
- take action to resolve any difference of understanding;
- formally advises the chair when actions and recommendations have been addressed and closed if this is appropriate to the organizational arrangement in which the design review is held.

6.9 Follow-up and completion of action items and recommendations

The design review process is not complete until all action items and recommendations arising from it have been addressed and completed as determined.

The design manager should ensure that action items are completed, and that recommendations are resolved in the agreed time frame.

When all arising actions and recommendations have been completed the design manager should sign and close the design review meeting's minutes action and recommendations list. This should then be lodged with the organization's top manager responsible for design activities.

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Annex A
(informative)

Example of design stages and type of design review

An example of the design stage and type of design review are given in Table A.1.

Table A.1 – Example of design stages and type of design review

Design stage	Activity	Review type	Example of when
Design inputs	Establish the customer/user requirements for the product or process together with interfacing requirements	Input Design Review	♦ After proposal request is received. ♦ After a design contract or authorization is received. ♦ After completion of the input requirements
Conceptual design and definition	Define product basic requirements; perform concept and operational and other required studies	Conceptual Design Review	♦ After completion of conceptual design. ♦ For large projects at point defined in design plan. ♦ To provide sufficient detailed information for planning and cost estimate purposes
Detail design and development	Develop hardware and software; prepare manufacturing specifications, operational and maintenance instructions	Detail Design Review	♦ After completion of detail design. ♦ For large projects at the points defined in design plan. ♦ Verify design by prototype testing as applicable
Final design		Final Design Review	♦ After completion of the design of sub units. ♦ After completion of the complete design of the product

NOTE 1 The number of stages at which a design review is held and the number within a stage depending on the product or process in question.

NOTE 2 Various titles are given to the design review held at different points such as 'preliminary design review' and 'critical design review'. These tend to be particular to the organizations involved. The titles given in the table above are thus indicative rather than definitive and users of this standard should adhere to the titles in use on an actual design project

Annex B
(informative)

Example of objectives for design review at different stages of a design's development

B.1 General

The following provides examples of possible objectives to be addressed, as appropriate, at the different stages of a design's development.

B.2 Input design review

The objectives for an input design review include:

- assessing whether customer requirements have been identified and clarified where necessary;
- assessing whether applicable regulatory requirements have been identified;
- assessing whether other required technical requirements have been included in the design inputs;
- assessing whether organizational and technical interfaces have been identified;
- assessing whether risks associated with the design have been assessed.

B.3 Conceptual design review

The objectives for a conceptual design review include the need to:

a) interpret, evaluate and agree on customer's requirements and needs and on the requirements for product;

b) establish mandatory, desirable and optional characteristics;

c) assess the communication among the members of the project team responsible for design, sales, manufacture, testing, inspection, installation, operation and maintenance, etc.;

d) review conditions and technology currently available to satisfy customer, market and safety requirements;

e) review performance, operation and liability information, from the organization's field records on similar products, or from industry;

f) review development and design plans and schedules;

g) evaluate proposed concepts for the design.

B.4 Detail design review

The objectives for a detail design review include the need to:

a) verify that the proposed design continues to satisfy product input requirements;

b) confirm that actions and recommendations from the previous review have been assessed, addressed and closed;

c) examine results of analyses, calculations and tests;

d) evaluate the proposed product for cost effectiveness, and to ensure that the product will perform as expected;

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e) assess whether the proposed product can be manufactured, inspected, assembled with adequate tolerances, stored, shipped and installed reliably, safely and cost effectively;

f) review the supporting documentation showing the detail experience and data used in the development of the product;

g) evaluate the system design, partitioning of functions (e.g. the block diagram – see IEC 61078) and the interfaces between modules

h) assess the establishment of a hierarchical ladder of characteristics such as cost, performance, physical parameters, dependability, environmental constraints, delivery requirements and contract incentives from where trade off decisions can be made to establish mandatory, desirable and optional characteristics.

B.5 Final design review

The objectives for a final design review include the need to:

a) verify that the final design contains design input requirements;

b) confirm that actions and recommendations from the previous review have been assessed, addressed and closed;

c) assure that detailed analyses, calculations and tests were carried out and that documentation for manufacturing, safety, installation, operation and maintenance of the product was produced in useable form;

d) evaluate the final design for life cycle cost-effectiveness;

e) verify that the final design can be manufactured, inspected, assembled with adequate tolerances, stored, delivered and installed reliably, safely and cost effectively, and that it will perform as expected;

f) ensure delivery, compatibility, quality and dependability of purchased components;

g) review supporting documentation showing detailed experience and data used for the design;

h) assess the status of the drawing set, software codes and design specifications for completeness and applicability to the intended product or process;

i) verify that adequate study was conducted before adoption and incorporation into the design of the accepted recommendations from previous design reviews.

e) assess whether the proposed product can be manufactured, inspected, assembled with adequate tolerances, stored, shipped and installed reliably, safely and cost effectively;

f) review the supporting documentation showing the detail experience and data used in the development of the product;

g) evaluate the system design, partitioning of functions (e.g. the block diagram – see IEC 61078) and the interfaces between modules

h) assess the establishment of a hierarchical ladder of characteristics such as cost, performance, physical parameters, dependability, environmental constraints, delivery requirements and contract incentives from where trade off decisions can be made to establish mandatory, desirable and optional characteristics.

B.5 Final design review

The objectives for a final design review include the need to:

a) verify that the final design contains design input requirements;

b) confirm that actions and recommendations from the previous review have been assessed, addressed and closed;

c) assure that detailed analyses, calculations and tests were carried out and that documentation for manufacturing, safety, installation, operation and maintenance of the product was produced in useable form;

d) evaluate the final design for life cycle cost-effectiveness;

e) verify that the final design can be manufactured, inspected, assembled with adequate tolerances, stored, delivered and installed reliably, safely and cost effectively, and that it will perform as expected;

f) ensure delivery, compatibility, quality and dependability of purchased components;

g) review supporting documentation showing detailed experience and data used for the design;

h) assess the status of the drawing set, software codes and design specifications for completeness and applicability to the intended product or process;

i) verify that adequate study was conducted before adoption and incorporation into the design of the accepted recommendations from previous design reviews.

Annex D
(informative)

Example of design review meeting topics

The type of design review, its objectives and scope, as well as the nature of the product should determine the topics to be discussed. This standard cannot, therefore, establish a universally applicable agenda. However, guidelines and examples of typical design review topics can include:

NOTE 1 These examples should not be taken to limit the scope of activity.

1 Design inputs

Have required inputs been identified? This includes voluntary and mandatory specifications at all levels, e.g. customer, organisation, national and international legislation and regulation, national and international codes and standards. Conflicts between specifications and regulations, and their interpretation, require resolution in the light of performance and safety requirements.

2 Product attributes

Does the product have the attributes required by the design inputs?

3 Safety

Safety should be considered for anyone who can come in contact with the product or process. This includes those involved in the supply, use and disposal of the product as well as those interfacing with it.

4 Property damage

The effect of a fault on a product and surrounding environment should be considered.

5 Human factors engineering

The product should be examined to assure that the design accommodates the users' needs and limitations.

6 Reliability

Attention should be given to numerical allocations, estimates and requirements for each product and subassembly, and for alternative designs. All reasonable effort should be made to avoid the negative impact on future utilization due to intermittent failures or product that does not meet a customer's expectations for useful life.

7 Maintainability

The maintenance philosophy or concept of each assembly, and of the whole system, should be examined, planned, and applied from the outset. This philosophy should take into account whether the supplier is in the service or repair business and, if so, the profitability of that activity. Maintainability, like reliability, should be designed in as it cannot be added on.

8 Availability

There are cases where a product must be available for immediate service, e.g. a standby lighting or power system. Trade-off can be, for example, considered between many outages of short duration and fewer outages of long duration. Maintainability and reliability are involved.

9 Environmental effects

The product should be able to survive dust, heat, cold, vibration, corrosion, fungus, dampness, transport, and other natural and human environments to which it will be predictably subjected. Early identification of weaknesses aids the designer in planning. The degree of survival and resistance to environmental effects should be examined.

Also, there should be examination of what is the potential impact of the product or one of its by-products on the environment.

10 Product life cycle

Where life cycle analysis is applied in the design process, life cycle data, targets and design options may be reviewed. This may include issues such as material selection, producibility data, installed cost, service life, operating costs, and disassembly and disposal costs.

11 Costs

Value engineering factors critical to the product should be examined at the conceptual design review. The design review can introduce economies from the outset by the early consideration of cost requirements.

12 Action item report

Each action item should be concluded by the person responsible with a report to the designer recommending a decision. Copies should be sent to the design review team.

13 Legal approval

Organization policy could require written approval of reports detailing the decisions by the legal department or adviser, for conformity to contracts, laws, regulations and specifications.

14 Checklists

To assist in maintaining focus checklist(s) can be prepared and utilized by the various expert members of the review team. Annex F provides example of possible questions for a number of different areas of expertise.

NOTE 2 A checklist is not a substitute for an expert's knowledge and experience.

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Annex E
(informative)

Example of team member responsibilities

Table E.1 provides an example of some of the responsibilities at possible stages of a design.

Table E.1 – Examples of responsibilities

Team Member Specialization	Responsibilities	Type of design review		
		Conceptual design review	Detail design review	Final design review
Chair	Calls, conducts meeting of team and issues interim and final reports	X	X	X
Secretary	Collects and distributes data and documents; prepares reports, assists chair	X	X	X
Designer of the product	Presents design and reasons for decisions with data from tests and calculations	X	X	X
Independent designer or designers	Constructively reviews adequacy of design and configuration to meet all requirements customer	X	X	X
Reliability	Evaluates and verifies design for optimum reliability consistent with requirements	X	X	X
Maintainability and maintenance	Ensures that the installation, maintenance and operator considerations are included in design	X	X	X
Quality	Provides quality plan; ensures that inspection, control and test can be efficiently carried out	X	X	X
Logistics	Provide logistics support plans and integration	X	X	X
Environmental effects	Evaluates impact of manufacturing activities, use and disposal of product	X		X
Product safety	Concerned with regulations, warnings, data collection, corrective action and testing results	X	X	X
Human factors	Evaluates convenience practicality of design based on human capabilities and limitations	X	X	X
Legal	Evaluates conformance of the design with contractual and legal provisions, legal effect of design compromises and issues arising out of use and disposal	X		X
Manufacturing	Ensures that the design is producible at minimum cost and on schedule	X	X	X
Procurement (supplier, optional)	Assures that acceptable items. parts and materials are available to meet cost and delivery schedules	X	X	
Materials	Ensures that materials selected will perform as required	X	X	
Tooling	Evaluates design in terms of tooling costs required to satisfy tolerance and functional requirements	X	X	X
Packing and transport	Assures that the product is capable of being handled and transported without damage.			X
Marketing/ sales	Assures requirements of customers are realistic and fully understood by all parties	X		X
Customer (optional)	Can voice opinion as to acceptability of design and could request further investigation on specific items	X		X

Annex E
(informative)

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Table E.1 provides an example of some of the responsibilities at possible stages of a design.

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Team Member Specialization	Responsibilities	Type of design review		
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Independent designer or designers	Constructively reviews adequacy of design and configuration to meet all requirements customer	X	X	X
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Maintainability and maintenance	Ensures that the installation, maintenance and operator considerations are included in design	X	X	X
Quality	Provides quality plan; ensures that inspection, control and test can be efficiently carried out	X	X	X
Logistics	Provide logistics support plans and integration	X	X	X
Environmental effects	Evaluates impact of manufacturing activities, use and disposal of product	X		X
Product safety	Concerned with regulations, warnings, data collection, corrective action and testing results	X	X	X
Human factors	Evaluates convenience practicality of design based on human capabilities and limitations	X	X	X
Legal	Evaluates conformance of the design with contractual and legal provisions, legal effect of design compromises and issues arising out of use and disposal	X		X
Manufacturing	Ensures that the design is producible at minimum cost and on schedule	X	X	X
Procurement (supplier, optional)	Assures that acceptable items. parts and materials are available to meet cost and delivery schedules	X	X	
Materials	Ensures that materials selected will perform as required	X	X	
Tooling	Evaluates design in terms of tooling costs required to satisfy tolerance and functional requirements	X	X	X
Packing and transport	Assures that the product is capable of being handled and transported without damage.			X
Marketing/ sales	Assures requirements of customers are realistic and fully understood by all parties	X		X
Customer (optional)	Can voice opinion as to acceptability of design and could request further investigation on specific items	X		X

m) the intended plan for reliability determination and compliance tests, e.g. number of units, test period, test conditions, life cycle phase for testing.

F.3 Maintenance

Maintenance questions could include:

a) review of maintenance policy concerning maintenance echelon and level of maintenance in relation to the specification and operational requirements;

b) use of replaceable units: identification, interchange ability benefits and risks, accessibility, removability, shipping package and labelling, test equipment requirements;

c) detection and diagnosis of fault by use of built-in, plug-in and general test equipment;

d) provision for non-invasive inspection and measurement.

F.4 Maintainability

Maintainability questions could include:

a) maintainability requirements at each maintenance echelon and level of maintenance including any quantitative requirements in terms of mean time to restoration (MTTR) and maintenance man hours (MMH);

b) compatibility of maintainability predictions and design with requirements, or comparison of maintainability targets and allocations with observed maintainability;

c) maintainability design analyses, e.g. trade-off analyses between reliability, maintainability, maintenance support performance, accessibility and diagnostic equipment;

d) maintainability verification by maintainability demonstration tests;

e) maintainability performance history of similar and competitive products or processes.

F.5 Maintenance support

Maintenance support questions could include:

a) identification of maintenance support requirements, i.e. resources for satisfying proposed maintenance policy and customer specifications or expectations;

b) adequacy of maintenance support plan and identification of interfaces with other engineering tasks;

c) maintenance personnel, skills and number;

d) specialized diagnostic, repair and test equipment and tools required at each level of maintenance;

e) technical manuals, availability and clarity of maintenance and repair procedures;

f) facilities needed for repair, storing of spares, material handling, administration and training;

g) spare parts, initial inventory at each maintenance echelon for corrective and preventive maintenance, availability and time delays in replenishment of spares, including assumptions, models and data sources, shipping package and labelling requirements, e.g. identification and shelf life;

h) performance and maintenance activity reporting system and procedures;

i) maintenance and maintenance support experience with earlier and similar products;

j) maintenance and maintenance support cost, effect on cost of ownership – life cycle cost, including identification of most significant cost factors and possible areas of improvements.

F.6 Availability

Availability questions could include:

a) the most likely causes, e.g. top ten, for the product being down for an unacceptable period as identified by failure modes and effects analysis (FMEA) and/or fault tree analysis (FTA);

b) availability requirements, e.g. mean availability, instantaneous availability, useful life;

c) comparison of predicted availability of the product or process with requirements, including assumptions, models and data sources;

d) actions for improving availability, e.g. modularization, introduction of redundancy, component substitution, de-rating, control of environment, use of quick disconnects;

e) performance history of similar and competitive products;

f) effect of operating environment and field service on availability;

g) special equipment and tools for operation and maintenance;

h) effect of user factors on availability, e.g. personnel training and availability, equipment misuse, misappropriation of tools and components;

i) the intended plan for availability determination and compliance tests, e.g. number of units, test period, test conditions, life cycle phase for testing.

F.7 Quality assurance

Quality assurance questions can include but are not limited to:

a) items pertaining to customer needs and satisfaction:

b) comparison of customer needs with technical specifications for materials, products and processes;

c) validation of design through prototype tests;

d) ability to perform under expected conditions of use and environment;

e) unintended uses and misuses;

f) compliance with regulatory requirements, national and international standards, and corporate practices;

g) comparisons with competitive designs;

h) comparison with similar designs, especially analysis of internal and external problem history to avoid repeating problems;

i) items pertaining to product specifications and service requirements;

j) permissible tolerances and comparison with process capabilities;

k) acceptance/rejection criteria;

l) ease of assembly and installation, storage needs, shelf life and disposability;

m) benign failure and fail safe characteristics;

n) aesthetic specifications and acceptance criteria;

o) ability to diagnose and solve problems;

p) labelling, warnings, identification, traceability requirements, user instructions and document control;

q) review and use of standard parts;

r) items pertaining to process specifications:

s) manufacturability of the design, including special process needs, mechanization, automation, assembly and installation of components;

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t) capability to inspect and test the product, including special inspection and test requirements;

u) calibration requirements;

v) specification of materials, components and subassemblies, including approved supplies and suppliers as well as deliverability;

w) shipping package, handling, storage, and shelf life requirements, especially safety factors relating to incoming and outgoing items;

x) items pertaining to design verification:

y) alternative calculations, made to verify the correctness of the original calculations and analyses;

z) testing, e.g. by model or prototype tests, definition of test programmes and documentation of results;

aa) independent verification of correctness of original calculations and other design activities;

bb) configuration control, adequacy of identification system;

cc) serialization or date of manufacture, evaluation and verification of information on product, location of records and cross references, recording of coded or uncoded information.

F.8 Environmental effects on product

Environment effect on product questions could include:

a) identification of environmental conditions likely to affect the product or process, such as climatic factors of temperature, humidity, wind and precipitation, effect of radioactivity, chemicals and their reactions over time, dust, electromagnetic radiation and radio frequency interference;

b) determining whether relevant environmental conditions are clearly reflected in the specification;

c) determining whether environmental effects on electronic components, mechanical parts, printed board material, connectors, mechanical structures, magnetic media, etc. have been properly considered;

d) determining whether the anticipated conditions at the location of use are in agreement with the specification;

e) comparison of the actual environmental conditions at the location of use with the conditions anticipated during the development cycle;

f) consider whether the most important environmental parameters (e.g. temperature, humidity) at a given location of use should be monitored and to recommend action;

g) skill of operating staff to work safely in the environment;

h) robustness against external noises of power sources, lightning and facilities for guarding against these disturbances;

i) effect of contamination and pollution of water, snow, sand and dust;

j) effect of having the product's environmental limits exceeded during maintenance or during an outage condition of the heating/cooling component;

k) consider whether the product needs special environmental protection or qualification testing;

NOTE IEC 60721-2 and 60721-3 provides relevant guidance on the environmental phenomena to be reviewed.

l) consider laboratory simulation for evaluating product performance under various environmental conditions;

m) consider testing criteria that correlate with actual conditions;

n) determine the adequacy of environmental testing acceleration factors.

F.9 Product safety

Safety questions could include:

a) assurance that emergency cut-off switches, lockout controls, signs, placards, circuit breakers, ground fault interrupters, sensors for fume and smoke, are appropriately included;

b) the intended use of the product, user access and categories, including age groups, user awareness of potential hazards and physical limitations of users;

c) environmental conditions, e.g. temperature ranges, humidity, direct sunlight and rain;

d) laws, regulations and standards governing the safety of the design for all locations of use;

e) safety approvals from outside agencies;

f) safety hazards, e.g. chemical characteristics (corrosiveness, toxicity and flammability), explosion, implosion, electrical shock, fire, overheating, radiation and mechanical characteristics (entrapment and sharp edges);

g) hazards from misuse or abuse;

h) contingency of safety on manufacturing or quality control process;

i) difficulty and operator error sensitivity of safety tests performed on the product;

j) degradation of product safety between manufacture and use;

k) feasibility and adequacy of warnings and instructions;

l) evaluation of purchased components for potential hazards, third party testing and certification;

m) evaluation of fail safe characteristics.

F.10 Human factors

Human factors questions could include:

a) nature and complexity of the information used by the operator to handle, control and adjust the product or process;

b) effectiveness of the information outputs, including the media of presentation, used by the operator to control the product or process;

c) behaviour of the product with relation to human expectations, and normal and emergency reactions;

d) adequacy and suitability of warnings and instructions for operation, installation, maintenance, assembly and disposal;

e) review of human interface with operation, maintenance and support requirements in relation to expected and foreseeable environmental conditions (maintenance, markings, work space);

f) consideration of operator comfort when using product,

g) visibility of instruments associated with product,

h) accessibility of product controls;

i) evaluation of degree to which the skill and training of likely installers, operators and maintainers has been taken into account in designing the product or process;

j) specific evaluation of display requirements (format, number, scrolling);

k) ease of use of product software programs and documentation;

l) need for and type of auditory and visual alarms to indicate performance, status and faults;

m) review of criteria to improve the adequacy of human performance and to simplify the interaction difficulties between man and the product;

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n) adequacy, accuracy, ambiguities, ease of use and understanding of all documentation and illustrations required for product operation and maintenance;

o) skill of operating staff to be considered in developing training needs;

p) potential difficulty of unskilled operators having access to the product;

q) potential difficulty due to operators misusing the product.

F.11 Legal matters

Legal questions could include:

a) legal relationship with and obligations owed to buyer, suppliers, subcontractors and end users;

b) conformity of proposed design to contract (including any specification);

c) conformity of proposed delivery schedules to contract requirements;

d) determining penalties for non-compliance with contract requirements;

e) definition of responsibility for loss during shipment, storage and installation;

f) review of ownership and/or licensing of designs, patents, trade marks, trade secrets and tooling;

g) review of information concerning reports and legal findings of defects in like, related, or competitive products or processes;

h) review of information (e.g. literature, internally generated test data) concerning hazards associated with like, related, or competitive products or processes;

i) examining how information concerning reports and legal findings regarding defects and hazards has been taken into account in the design of products or processes;

j) determining whether hazards discovered in buyer-specified products have been adequately communicated to the buyer;

k) determination of adequacy of communication methods to and from the direct purchaser, end-users, and regulatory agencies, if necessary, of hazards discovered after delivery of the product;

l) legal considerations affecting whether to recall or retrofit product;

m) adequacy of procedures employed for recall or retrofit programme (including traceability of components);

n) adequacy and comprehensibility of warranty provisions delivered to customer;

o) review of retained records concerning product design, development, manufacture and sale for appropriate content and compliance with legislation and contract provisions;

p) adequacy of retention periods of records concerning product;

q) evaluation of data sheets, advertising information, instruction and installation manuals, warnings, labels, and other literature for appropriate content and efficacy;

r) adequacy of insurance for key personnel on project and facilities utilized;

s) evaluation of potential product liability and other legal consequences of use and disposal of product.

n) adequacy, accuracy, ambiguities, ease of use and understanding of all documentation and illustrations required for product operation and maintenance;

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r) adequacy of insurance for key personnel on project and facilities utilized;

s) evaluation of potential product liability and other legal consequences of use and disposal of product.

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