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CIDA COURSE ON QUALITY MANAGEMENT

" QUALITY in DESIGN"

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1. Objective Of Presentation :

This presentation deals with "Quality in Design" as it applies to development of products.
Specifically, the following design activities will be discussed :

- product development
- fitness for use
  - reliability
  - maintainability
  - safety
  - ergonomics
  - cost effectiveness
- review and validation of a design
- Quality Program as applied to design

2. Introduction .

2.1 Times have changed, products have changed. The change form traditional to modern products is reflected in planning and complexity of design and manufacturing required for each.

2.2 The traditional product is shoes, a garden tool , bread or a table. The modern product is a printed circuit board, an electronic computer or a nuclear reactor. The design requirements of each are vastly different.

2.3 Modern products have more exacting needs, and their design requires sophisticated managerial methods and technological tools.

- **Managerial methods** revolve around the need to apply Quality Management techniques and concepts to all phases of product design, development and production.
- **Technological tools** referred to are the modern techniques of analysis and testing, and the widespread application of computers.

2.4 The key requirements of a modern product are :

- functional performance
- fitness for use, such as reliability, maintainability and safety
- cost effectiveness, as determined over the "life" of the product

2.5 All of these are to a large extent **determined at the design stage** - which includes development and testing. It is for this reason that design should be afforded the utmost importance in the creation of modern products.

2.6 Numerous cost studies have demonstrated the value of good design in avoiding defects. As a general rule, the costs of finding and correcting a defect increase by a factor of 10 in each step, from design, through production, inspection, dealership and finally the customer. It therefore may be a 1000 times more expensive to identify and correct a defect in a customer's computer or an aircraft, than at the factory during production.

2.7 Similar considerations apply to design and delivery of services, which can also be divided into traditional and modern. An example of a traditional service might be operation of a bus line between two towns, and a comparable modern service would be operation of an international airline.

3. Product development.

3.1 For most modern products, the design is executed using the **"phase concept of product development "**, which breaks up the design process into a number of recognized phases.

3.2 Concept and feasibility phase : the known or anticipated need for a product is studied in sufficient detail to determine if it is feasible to design and manufacture a product responsive to the need. **"Marketing specification"** is produced, which defines in general terms the key characteristics of the product, including its timing and anticipated price range.

3.3 Detailed design phase : generalities of the marketing specification are converted into engineering specifics in the form of **"product requirement specification."** The quality of the product is also specified in terms of performance, reliability, maintainability and other "fitness for use" requirements.

3.4 Applicable codes and standards are specified and key performance parameters are defined. Alternative design concepts are studied and evaluated and the best one is selected.

3.5 Preliminary design is completed in sufficient detail to allow parts and materials to be ordered and planning for production to begin. Detailed engineering design and development is undertaken, including :

- preparation of drawings
- decisions on make/buy alternatives
- development of suppliers
- material specifications

3.6 Prototype phase : the first essentially complete units of the product are built and tested. The tests evaluate various important factors, such as for example the basic capability, effect of extreme environment, reliability. The units built must be sufficiently complete to permit meaningful testing and evaluation of the basic design.

3.7 Demonstration phase : a production design is prepared and is evaluated for productibility and performance. The production design differs substantially from the prototype. It is much more complete and representative of the final product and many of the changes identified during testing of the prototype have been incorporated.

3.8 Production : the product is released for production, sale and delivery to customers. During the "life cycle" of the product and based on experience gained in production, marketing and use of the product, design changes are made to improve product performance and to minimize field failures.

4. Fitness for use

4.1 Fitness for use **includes functional requirements**, such as power, speed, weight and similar. Unless these are provided at an adequate level, there is no product to market.

4.2 Designing for functional requirements can result in high complexity. High complexity is a breeding ground for problems in reliability, maintainability and ergonomics. Trade-off are often required between functional capability and **fitness-for-use parameters**, the more important of which are :

4.3 Reliability is the probability that an item will perform a required function under stated conditions for a stated period of time.

4.4 This definition has four elements:

- quantification of reliability in terms of probability
- definition of the required performance
- statement of the required operating time between failures
- definition of the environmental conditions in which the equipment must operate

4.5 To achieve the required level of reliability, certain tasks are necessary. They constitute the **"reliability program".** The program needs positive assignment of responsibilities and formal planning if the work is to be done on time.

4.6 Inherent in the establishment of reliability requirements is the need to **estimate reliability in advance of manufacture.** While the visible outcome of the prediction procedure is to quantify the reliability numbers, the process of prediction is usually as important as the resulting numbers. This is so because the prediction cannot be made without obtaining detailed information on the mission, environment, critical component history etc. Acquiring this knowledge gives the designer information not previously available

4.7 It is also necessary to examine the proposed design for possible ways in which failure can occur. Two of the most popular techniques are :

- **Failure Mode, Effect and Criticality Analysis (FMECA).** Potential failures are identified in terms of failure modes. For each mode, the effects on the total system is then studied.
- **Fault Tree Analysis.** The starting point is the list of failure modes for which the designer must provide a solution. Each event on the list then becomes a failure mode requiring analysis. The analysis considers possible direct causes that could lead to the event. Next, it looks for the origin of these causes. Finally it looks for ways to avoid these origins and causes.

4.8 Maintainability refers to the ease with which preventive and corrective maintenance can be achieved. Users want products which are available when they need them. Availability depends on how often failures occur, how long it takes to fix them and the amount of maintenance support required.

4.9 Maintainability prediction provides a quantitative tool for :

- evaluating the proposed design for maintainability
- identifying areas of the design requiring improvement

4.10 Three approaches can be used :

- secure data of past experience on similar equipment and extrapolate to the new design
- break down the maintenance tasks into elemental tasks needed to carry out maintenance. Acquire data representing standard times needed to accomplish these tasks and correct for circumstances relating to the product in question.
- use specialist check-sheets developed to score the design on its maintainability characteristics.

4.11 Safety which is incorporated into the design through a **Safety Program.** The objectives of a typical safety program are:

- safety should be designed into the product to a degree consistent with mission requirements
- hazards associated with the product and its components are to be identified, eliminated or controlled to an acceptable level, so as to protect personnel, equipment and property
- risks involved in the use of new materials, production or testing techniques are to be minimized

4.12 Tools for safety analysis are :

- Hazard Analysis, which is similar to FMECA
- Fault Tree Analysis, which in this case starts by supposing that an accident takes place. It then considers the possible direct causes which could lead to this accident

4.13 Human factors (Ergonomics) which is the evaluation of the product for compatibility with capabilities of humans. As products have become more complex, this interaction has assumed increasing importance.

4.14 The interaction between person and product has two impacts for fitness for use :

- the effect that the design has on the ease with which the user can install, operate and maintain the product
- the effect of the design on the reliability of the performance of the human being using the product

4.15 Some failures of the product are due to mistakes made by the user. Other product failures are due to designs that make human errors more likely.

4.16 The early applications of ergonomics were in the aerospace industry. Other applications now include industrial control rooms, telephones, cameras and other modern consumer items and industrial equipment.

Cost effectiveness

4 17 Attainment of fitness for use involves achieving a balance among competing parameters and costs. **Cost effectiveness concept** deals with the optimization of these parameters and costs from the inception of design to the end of operational life, including disposal .

4.18 Life - cost analysis is one of the tools used to evaluate cost effectiveness of competing products.

4.19 Steps in life-cost analysis are:

- identification of life cycle
- identification of cost structures
- acquiring the cost data
- analysis of relationships
- formulation of criteria for decision making

4.20 Major benefits in terms of cost reduction can be realized by the application of cost effectiveness concept. These benefits arise from changes to strategies in operation, maintenance and procurement.

5. Review and validation

5.1 The frequency and severity of problems caused by less than adequate design has stimulated companies to develop methods of **early warning of impending troubles.** In addition, much has been done to evolve special quality-oriented tools to help evaluate designs and to improve the design process itself.

5.2 One of the methods to provide the early warning, improve the design process and to validate the design is the **"Design review" (DR).**

5.3 The Design Review is a technique of evaluating the proposed design to assure that it :

- will perform successfully with respect to functional requirements
- meets the requirements of "fitness for use "
- will meet the requirements of the "customer", who are often the operations department.

5.4 A **structured review and validation program** is usually centered around Design Reviews (DR's), as follows :

- DR's are mandatory at specified stages of product development, such as :
  - conceptual DR, to confirm that the design concepts satisfy product specification
  - detailed DR, to ensure that requirements for the product are correctly defined and that identified requirements are met
  - prototype DR, to verify that the detailed design conforms to the requirements, specifications and operating criteria
  - operational DR, to be held after the product has been in operation for some time. The objective is to enable designers to evaluate their designs in the light of operational experience.
- DRs are conducted by a team of specialists who are not directly associated with the development of the design. Selection of

the DR team is of utmost importance. Genuine commitment on the part of the participants required and it must be complemented by mature, relevant and seasoned experience.

- the ultimate decision on incorporation of inputs from the review rests with the designer, in other words the DR has an **advisory role**. A DR cannot replace good design and good engineering practices. When properly done, a DR increases confidence that the design and engineering activities were conducted with regard to all pertinent requirements. The designer (or a design organization) must listen to the inputs, but he retains the monopoly of decisions.
- DRs are formal. They are planned and scheduled like any other activity. The review meetings are run in accordance with a procedure, which requires a prepared agenda, advance distribution of relevant documentation and a formal report containing a list of actions to be dealt with. All actions arising from a DR must be formally resolved.

5.5. Timing of DRs is important. they should be scheduled such that :

- design documentation has been sufficiently developed to allow for a meaningful review
- system and equipment design is still flexible enough to allow for modifications

5.6 It is clear that DRs represent a major effort in terms of commitment of expensive and limited engineering resources and should therefore be judiciously applied. However, the benefits arising form DRs may be of such significance as to make it all worthwhile.

6. Quality Program.

6.1 A well developed and consistently applied Quality Program is a prerequisite to achieving satisfactory and cost effective designs. Quality Management techniques supported by a Quality Assurance (QA) program can significantly contribute to good management.

6.2 Participants in the design effort need to understand and use Quality Assurance techniques in their work. For this to occur, they have to have received **training in QA** and also have to be aware of firm support of QA requirements from the management.

The Quality Program must address the following issues :

Organization :

6.3 The organizational structure must be clearly defined :

- responsibilities of various departments within the design organization and of individuals in particular positions must be clearly spelled out
- the organization should include, and define the role of , "specialist " departments charged with application of "new" disciplines, such as , for example :
  - application of computers,
  - reliability and maintainability engineering
- organization must be structured to provide effective service to the "customer" with minimum organizational overlap or hindrance

Interfaces :

6.4 Since it is usual for several organizations to participate in a design, the QA program shall identify interfaces between these organizations and also identify the interface procedures required to control them. Procedures shall be prepared and approved by the interfacing departments.

Procedures :

6.5 The design department must operate in accordance with procedures. Procedures serve to define processes to be used while at the same time allowing for exercise of judgment in their detailed application.

6.6 Upkeep of procedures is very important. Work of good quality can rarely be consistently performed if procedures are known to be incorrect. Staff will attempt to compensate for them and take short-cuts, resulting in inevitable mistakes.

6.7 A **"procedure maintenance process"** shall be in existence to ensure that all procedures are periodically reviewed at a frequency related to their importance and use. This review should be jointly undertaken by the Design Organization and other affected departments.

Computer software

6.8 Computers are a tool which can contribute to **dramatic improvement in efficiency of work and reductions of errors.** Computer software is a specialized kind of a procedure.

6.9 Much of the design work for modern products - calculations and evaluations - is done using computers. It is therefore important that computer software used in

this work is maintained in a configuration which is relevant for the work at hand and that its integrity is not compromised.

6.10 Methods must be implemented to ensure proper use of computer programs in design activities, so that their use complies with the original requirements , assumptions and constraints , and that the solutions are valid.

6.11 These methods shall ensure that :

- computer programs are validated before use and periodically verified for accuracy
- only these physical states are analyzed with a computer program that are within the documented range of applicability
- computer programs are used with due consideration for the assumptions inherent in the numerical techniques they employ
- the input data are verified to ensure that they accurately reflect the physical system or process to be analyzed
- the derivations and sources of input data are fully documented in a form which facilitates review by an independent organization
- the configuration of the computer program and the input data are completely identified such that results could be reproduced
- the output of the program is compared with the result of hand calculations, reference material or other independently obtained results to reaffirm that the solutions are valid

Grading of QA processes

6.12 The extent to which QA requirements are to be applied should be consistent with the significance of the activity or a process. A graded approach is desirable which can satisfy the necessary and appropriate requirements for each activity and at the same time ensure the required quality.

6.13 The objective of grading is to identify the activities essential for functional and fitness for use requirements and to concentrate on those. Other activities and processes will be required to satisfy less stringent quality requirements which are nevertheless adequate for their importance and function.

Competence of designers

6.14 To attain excellence designers need continued training, especially in

- techniques on use of design experience
- use of design tools which have their origin in other disciplines

6.15 Design experience is retained through :

- design standards manuals
- standard checklists
- usage and failure data

6.16 Design tools from other disciplines include:

- tools for economic analysis
- quantification of reliability and other fitness for use parameters
- quality oriented methods, assessments and evaluations
- analysis of process capability
- problem analysis and solving methodologies

6.17 The application of these techniques is best achieved by bringing designers to a state of proficiency and understanding, supported by specialist as required.

Verification.

6.18 Effective verification of work shall be carried out to assist in prevention of errors and omissions and the associated cost or impact of deficiencies

6.19 A document defining the verification function shall be prepared and **training shall be periodically conducted** to ensure that all staff understand the verification concept and the procedure for its application.

6.20 Verification shall be applied to activities , services and processes such as, for example

- preparation of documentation, procedures and plans
- revisions to procurement specifications (material substitutions)
- engineering calculations and analysis
- computer software

Deficiencies and corrective actions:

6.21 There shall be a process to **identify and record deficiencies** in design work. These deficiencies shall be followed up and resolved with appropriate corrective actions. They shoul also be trended.

6.22 Appropriate corrective actions are often difficult to determine. **"Root cause analysis"** is an analytical technique which helps to define root causes of deficiencies and thus the appropriate corrective action. This analysis is sometimes complicated and lengthy, but nevertheless is absolutely necessary if the deficiency is to be resolved permanently.

Documentation and records.

6.23 Documentation control shall be based upon simple, user friendly, preferably computer based methods that are clear to all involved. This includes documentation being easily traceable and retrievable.

6.24 Control of documentation shall be executed in a consistent manner throughout the design organization. This includes preparation, change, review, approval, release and distribution of documentation. Responsibility for documentation control system shall be clearly established.

6.25 Record requirements shall be defined with respect to their contents (what shall be kept) classification (permanent or non-permanent) and the retention period.

Assessments and audits.

6.26 The importance of audits arises from the need of management to have an **impartial objective evaluation of quality of performance.** In the absence of such evaluation, the management might persuade itself that everything is going very well while in fact performance has deteriorated badly.

6.27 Responsible attitude to audits manifests itself when the management :

- is willing to listen to and learn from audit findings
- evaluates findings for root causes
- implements corrective actions
- confirms long-term effectiveness of corrective actions

Role of the Quality Group.

6.28 The **Design Manager is the "champion "** of the Quality Management program. It is his program and he must carry the responsibility for its effectiveness. The Quality Group should **never make the mistake of accepting ownership** and responsibility for the quality program.

6.29 Notwithstanding the above the **Quality Group** has a vital role to play - they **are the "keeper "** of the Quality Program.

6.30 The quality group's objectives and role are :

- independently assess the effectiveness of management processes
- assess effectiveness of the QA Program
- provide expert advice to plant management on matters pertaining to the QA and QM programs
- maintain and update Quality Program documentation
- conduct and coordinate audits and assessments