Quality Management System

ISO 9000

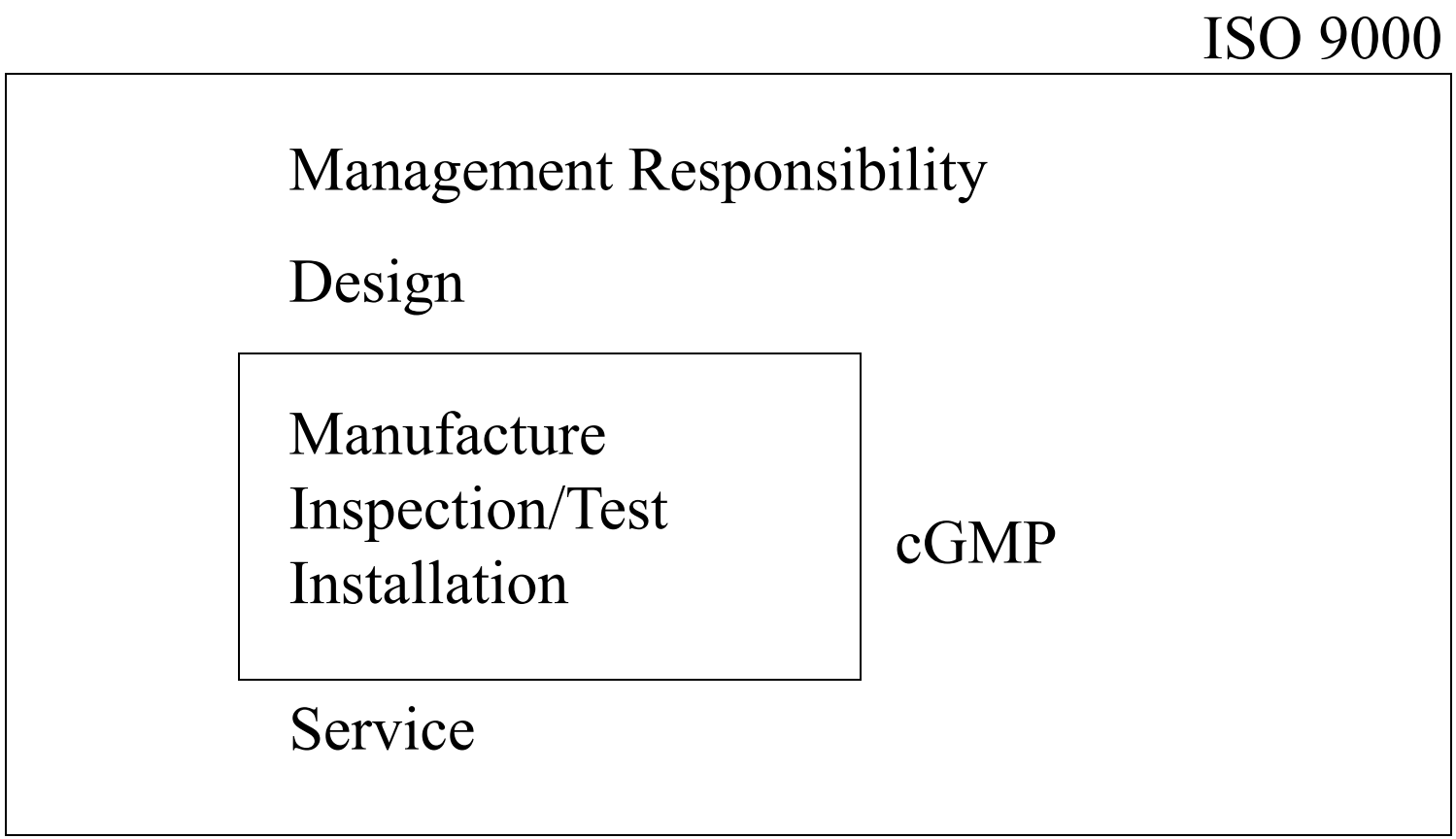
What is ISO 9000?

A series of standards that outline the requirements for a quality management system.

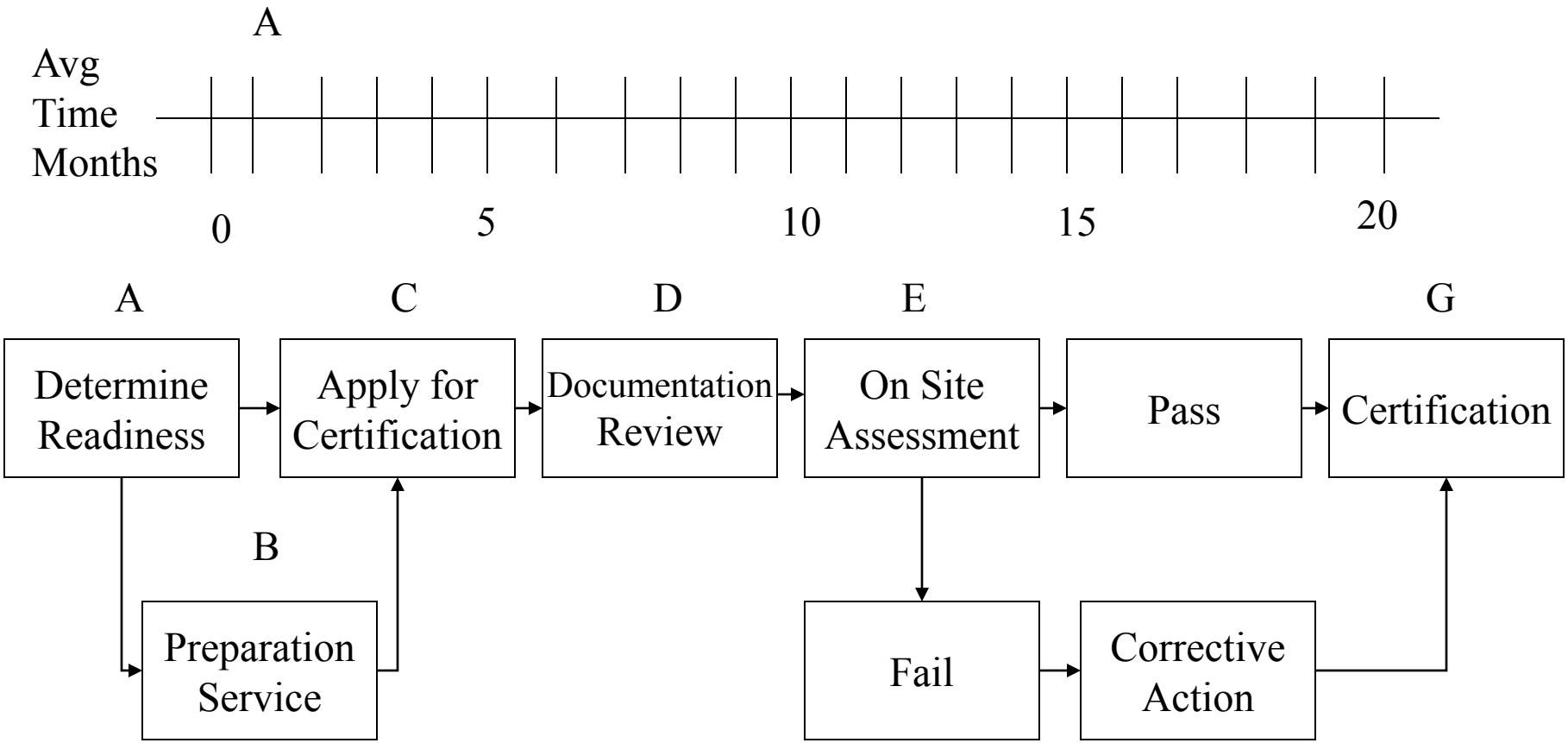
The ISO 9000 Series

- ISO 9000 - Quality Management and Quality Assurance Standards - Guidelines for selection and use
- ISO 9001 - Quality Systems - Model for Quality Assurance in Design/Development, Production, Installation, and Servicing
- ISO 9002 - Quality Systems - Model for Quality Assurance in Production and Installation
- ISO 9003 - Quality Systems - Models for Quality Assurance in Final Inspection and Test

ISO 9000 Versus cGMP



Certification Time Line



Certification Maintenance

- Initial Certification
- Semi-Annual Audits
- 3 -Year Recertification

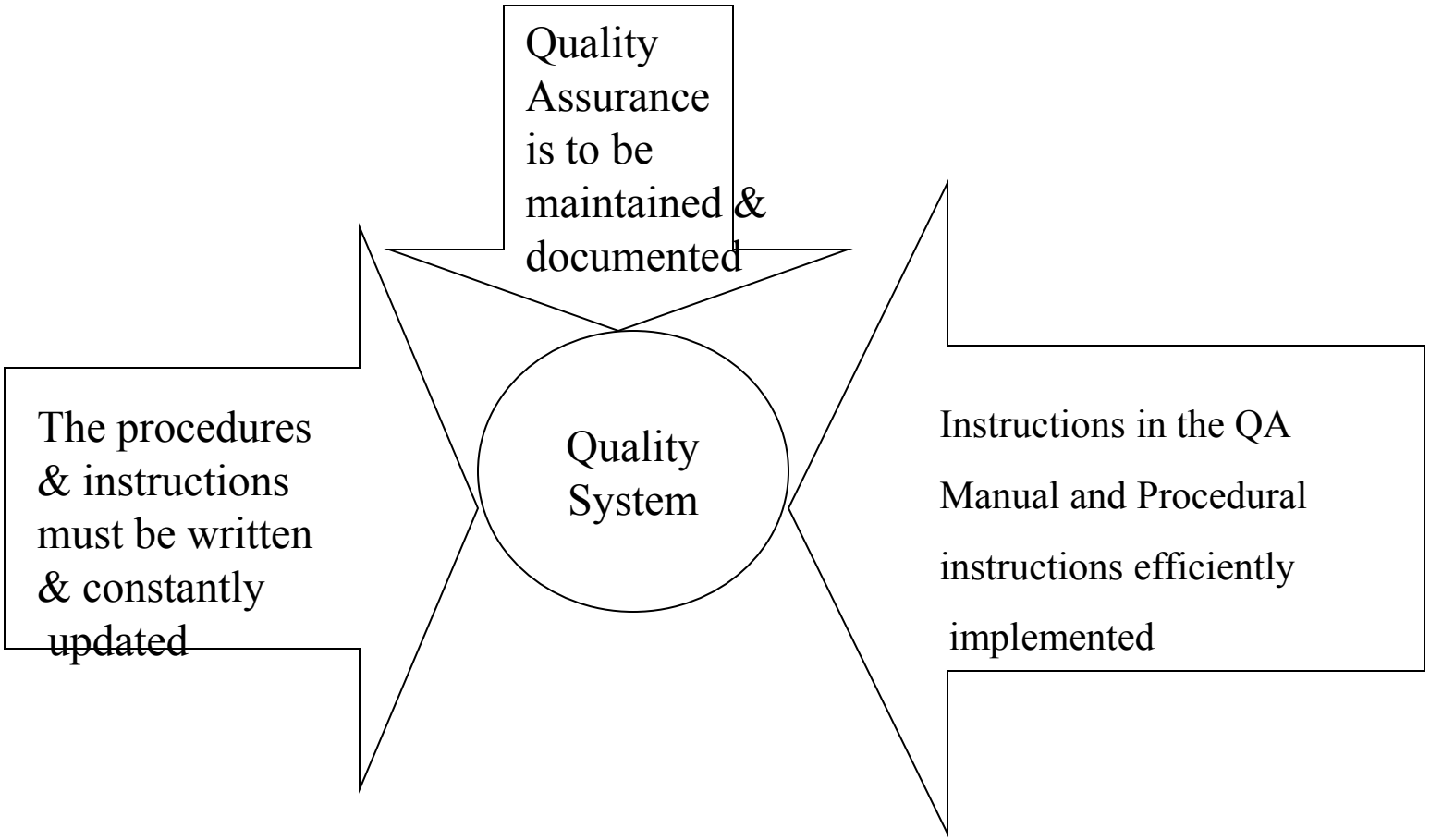
Benefits of ISO 9000 Certification and Registration

- Use of Recognized Certification Label in Marketing and Promotions
- Registered in dept of Trade and Industry Directory
  - Accessibility to EC Market
  - Visibility
- Overall Improved Competitiveness

Elements of ISO 9001 - 4.1 Management Responsibilities

- Are there established quality policies & are they communicated to all employees?
- Who has the responsibility & authority for quality?
- Are people trained to perform their function?
- Are people responsible for implementing & maintaining standards?
- Is management involved with quality issues?

Elements of ISO 9001 - 4.2 Quality System



Elements of ISO 9001 - 4.3 Contract Review

- Are contracts reviewed for intent and capability?
- Are there records maintained to verify this review?
- Is there a system for resolving differences?

Elements of ISO 9001 - 4.4 Design Control

- Are there procedures for controlling and verifying product or service design?
- Are the design reviews performed by an independent source?
- Does the design output satisfy the design input?
- Is the design properly controlled?
- Is software design controlled?

Elements of ISO 9001 - 4.5 Document Control

- Who is responsible for issue & review of all documents?
- Are current documents in place, where they are needed?
- Is there a master list of documents?
- How are documents reviewed and changed?
- Is there control of temporary changes?

Elements of ISO 9001 - 4.6 Purchasing

- Are there specifications for all purchased goods and services?
- Is there a system to insure they conform to requirements?
- Is there a system for selection and control of suppliers?
- Are requirements clearly defined on the contracts/PO's?
- Are contracts/PO's reviewed to insure requirements listed?
- Can customers verify that the supplier meets requirements?

Elements of ISO 9001 - 4.7 Purchaser Supplied Product

- Is there a system for controlling materials supplied by customers?
- Is there a system for recording & reporting loss, damage and defects?

Elements of ISO 9001 - 4.8 Product Identification and Traceability

- Are there unique identifications on raw materials and products?
- Are adequate records kept for traceability
- Are in-process material clearly identified?

Elements of ISO 9001 - 4.9 Process Control

- Are there procedures for how to run the process or perform a task?
- Are there standards for acceptability?
- Are the variables of the process which are important for quality known?
- Are these variables controlled and monitored?
- Is the equipment used capable of control?
- Is the capability of new equipment known prior to installation?
- Are special processes properly controlled?

Elements of ISO 9001 - 4.10 Inspection and Testing

- Is there a system for insuring the quality of raw materials?
- Does this system handle releasing, rejecting & quarantining?
- Are “in process” inspections & testing defined?
- Do the procedures cover the handling of rejects?
- Are customer requirements met before shipment?
- Are inspection and testing records maintained?

Elements of ISO 9001 - 4.11 Inspection, Measuring and Test Equipment

- Is all quality related equipment calibrated?
- Are there calibration records for equipment?
- Are there calibration procedures & specifications?
- Is calibration equipment traceable to a national standard?
- Is the frequency of calibration documented?
- Is the calibration status known to the person using the equipment?
- How is verification of calibration performed?

Elements of ISO 9001 - 4.12 Inspection and Test Status

- Do people using raw material know its quality acceptability?
- Is the quality status of “in-process” and finished goods known?
- Who has the authority to release nonconforming materials?

Elements of ISO 9001 - 4.13 Control of Non-Conforming Product

- Are non-conforming materials identified?
- Are non-conforming materials segregated?
- How are non-conforming materials dispositioned?
- Are reworked non-conforming materials reinspected?
- Are customers notified of non-conforming material shipments?

Elements of ISO 9001 - 4.14 Corrective Action

- Is the cause of non-conforming material determined?
- Are corrective actions taken to prevent recurrence?
- Is there a follow-up to insure they are effective?
- Are systems changed as a result of corrective actions?
- Is there a system to detect and prevent problem areas?

Elements of ISO 9001 - 4.15 Handling, Storage, Packaging and Delivery

- Are there procedures in place for raw materials & products?
- Do systems prevent damage or deterioration?
- Is it defined who removes product from storage areas?
- re there systems to maintain packages :Fit-for-Use”?
- Is material protected after inspection to delivery?

Elements of ISO 9001 - 4.16 Quality Records

- Is there a system for maintaining quality records?
- Are records properly marked?
- Are the records retrievable?
- Is there a retention system?

Elements of ISO 9001 - 4.17 Internal Audits

- Are there independent audits of each department?
- Is there a documented audit schedule?
- Are the results of the audit communicated?
- Are there corrective actions as a result of the audit?

Elements of ISO 9001 - 4.18 Training

- Are training needs identified?
- Are people trained to perform their job?
- Are records maintained of the training?
- Who maintains the training records?
- Are there training materials?

Elements of ISO 9001 - 4.19 Servicing

- Are there procedures for performing serving?
- Are there documented results indicating that servicing meets the specified requirements?
- Are corrective actions taken as a result of service calls?

Elements of ISO 9001 - 4.20

- Are appropriate statistical techniques used to determine process capability?
- Is it understood how the process variables affect the product quality, statistically?
- Are the statistical techniques used being used properly?