# Guidelines For ISO-9000 Quality Systems Certification

**Wadhwa K.N.**

## INTRODUCTION

Quality Management systems to ISO-9000 series standards entails certain well defined systems, enveloping all possible aspects (both internal and external) which affect product quality. Certification of quality-systems against a particular chosen standard through an international third party called I.S.O. (International Organisation for Standardisation), enables the establishment to achieve a global recognition of its quality systems and thereby it achieves a status of 'World Class' company.

Relevant practical guidelines based on actual experience, as detailed here would help educate all concerned especially in the Paper Industry, and accelerate the progress in implementation of ISO-9000 systems as well as in seeking certification.

## HOW THE INTERNATIONAL ORGANISATION FOR STANDARDISATION (ISO) OPERATES

The international organisation for standardisation called I.S.O., operates with its Head Quarter at Geneva, with the objective to co-ordinate & unify the international standards, for facilitating the international exchange of goods & services.

The member bodies of I.S.O. are the national standardising bodies most representative of standardisation in each country and only one such body per country is admitted. The governing body of I.S.O is the General Assembly of all member bodies and it meets every three year. The chief administrative body is the I.S.O. council which consists of the nominees of 14 member bodies elected at each General Assembly. This council meets annually.

The I.S.O. council has set up a number of specialists advisory committees and consultative bodies to assist in the administration of standards work. The detailed work of establishing and maintaining international standards is allocated by the council to technical committees, each of which operates a heirarchy of sub-committees and working groups. Each technical committee is required to service the standards needs of a specific sector of industry.

Each member body of ISO can be a member of any technical committee or a sub-committee. Working group members are individual experts nominated by member bodies of technical or sub committee.

A working group initiates a draft for the proposed standard. The sub-committee produces a committee draft based on the comments/acceptance of majority of participating members through postal ballot. The technical committee brings out a draft International Standard (D.I.S.) based on the views/ agreement of the technical committee members through postal ballot. The document is submitted finally to ISO council for publication as an ISO standard.

## ISO-9000 QUALITY SYSTEM STANDARDS

### Background And General Awareness

The ISO-9000 series of standards for quality system developed in 1987 along with terminology standard ISO-8402, has brought harmonisation on an international scale and has supported the growing impact of quality as a factor in international business.

The ISO-9000 series embodies comprehensive quality management concepts and guidance together with several modes for external quality assurance requirements.

The series do not intend to standardise the system implementation part by the organisations. It only sets the guidelines.

The guidelines stipulate that quality of product is signified by the certification of quality systems, and complement the product and service specification (s), which depend on the type of organisation, type of product/services and the specific goals and practices. The guidelines are applicable to any organisation like industrial establishments, educational and finan-

**Star Paper Mills Ltd.**
**SAHARANPUR-247001 (U.P.) INDIA**

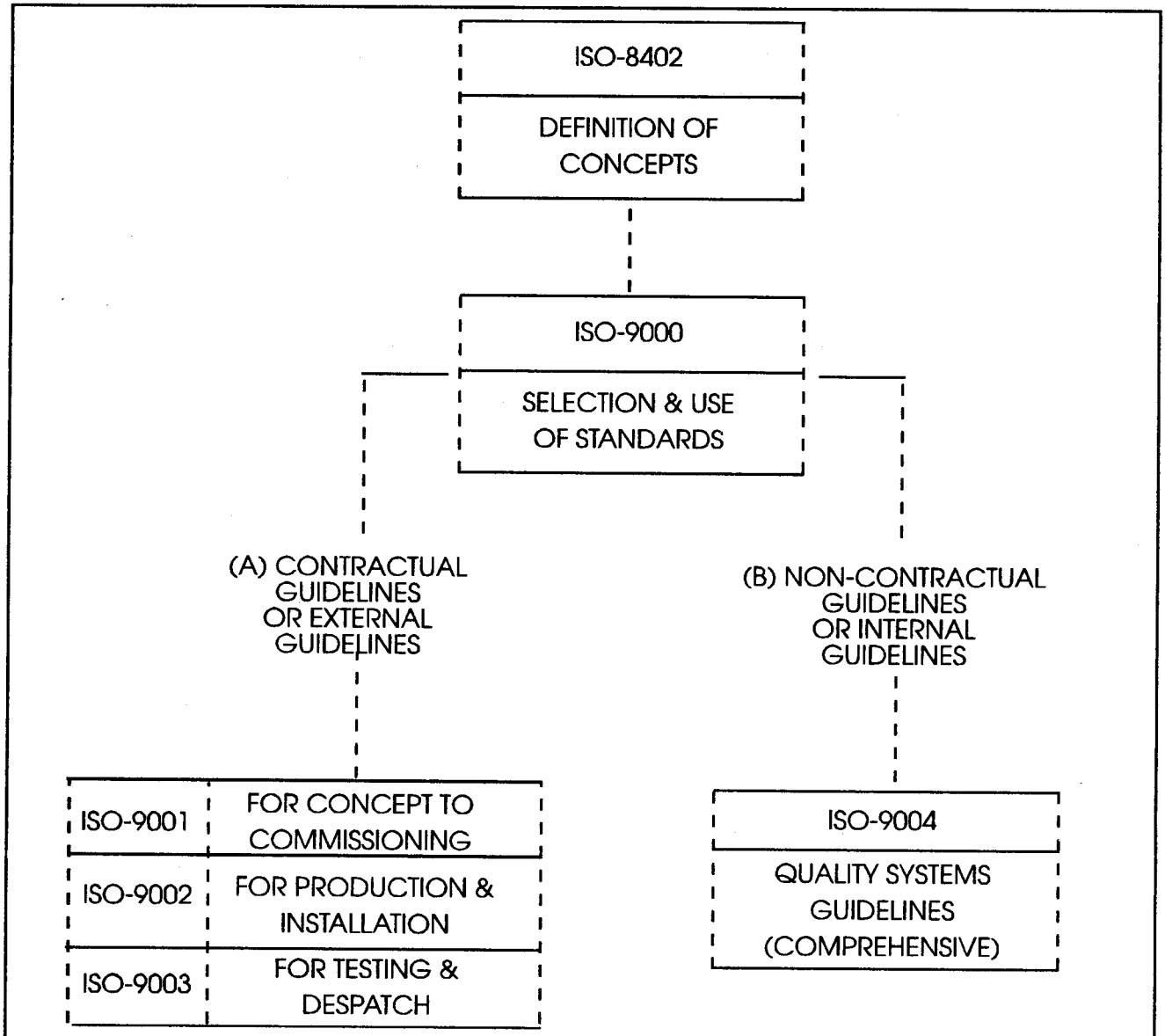


**Fig.1. Structure of ISO-9000 series.**

cial institutions, banks, hotels, hospitals, airlines, transport and other services. The certification alone, is just a small step to 'world class' quality. Management leadership and commitment, self directed work teams and continuous improvement in all operational areas are a must to achieve quality perfection. It therefore, forms a first step towards 'Total quality.

**Structure of ISO-9000 Series Standards And Their Application**

Structure of ISO-9000 series of standards is given in **Fig.1**

**Contractual Guidelines**

**IS0-9000** is applicable to those industries/organisations/ establishments which have the infrastructure and facilities for design, production, testing, despatch and after-sales services. This is the stringent standard and encompasses ISO-9002 and ISO-9003 and almost all clauses of ISO-9004. It has 20 chapters under the sections of quality systems control, operating processes and support activities. This is shown in **Table-1.**

**ISO-9002** is applicable to those industries/ organisations, which have infrastructure and facilities for production, installation and

**Table-1**

20 Elements of ISO-9001 Systems

| QUALITY SYSTEMS CONTROL | | OPERATING PROCESSES | | SUPPORT ACTIVITIES | |
|---|---|---|---|---|---|
| 01 | Management responsibility | 03 | Contract review | 06 | Purchasing |
| 02 | Quality systems | 04 | Design control | 08 | Product identification & traceability |
| 05 | Document & data control | 07 | Purchaser supplied product | | |
| 14 | Corrective and preventive action | 09 | Process control | 11 | Inspection, measuring & test equipments. |
| 17 | Internal quality audits | 10 | Inspection & testing. | 16 | Quality records |
| | | 12 | Inspection & test status | 18 | Training |
| | | 13 | Control of non-conforming products | 20 | Statistical techniques |
| | | 15 | Handling, storage, packaging, preservation & delivery | | |
| | | 19 | Servicing | | |

after-sales services. Design part is excluded and stress is mainly on the production/ installation. This standard is less stringent than ISO-9001.

For services organisations, the services offered by them are treated as their products and hence they become eligible for ISO-9002.

**ISO-9003** is applicable to those industries/ organisations, which have infrastructure and facilities for testing and despatch only. This standard is least stringent. Design, production and installation activities are excluded.

**Non-Contractual Guidelines**

**ISO-9004** standard contains internal/non-contractual exhaustive guidelines on Quality Management Systems. These in full or part (as applicable) are required to be followed by an organisation for internal preparedness.

## MAJOR ACTIVITIES TOWARDS QUALITY SYSTEMS IMPLEMENTATION AND CERTIFICATION

The activities towards implementing the ISO-9000 quality systems and certification have been as under:-

- Appreciation of quality as a vital element of business by top management.
- Formation of steering committee.
- Appointment of management representative (MR).
- Formulation of corporate quality policy and its effective communication.
- Appreciation of ISO-9000 and selection of appropriate model for adoption.
- Training of lead auditors and internal auditors.
- Training managers on systems documentation, and bringing general awareness upto grass root level.
- Collecting data and assessing the existing quality procedures.
- Setting a time bound program for completion of the project.
- Review and re-design of system and procedures pertaining to
  - Design control (for ISO-9001).

- Contract review.
- Purchasing system.
- Product identification and traceability.
- Inspection and testing of incoming materials/ components in process and finished product stage.
- Control of non-conforming products.
- Preventive and corrective action.
- Handling, storage, packaging, preservation and delivery of products.
- Preparation, indexing, filing, storage mainte nance and issue of quality records.
- internal quality audit and mgt. review(s).
- Establishing of procedure for applying SQC techniques/process capability studies.

- Consolidation of quality manual.
- Formation of internal quality audit teams and schedules.
- Adequacy, compliance and effectiveness (ACE) audit.
- Modification and review of procedures and instructions based on audit reports.
- Corrective action on non-conformities observed.
- Finalisation of quality manual, procedures and work instructions, and issue to all concerned.
- Pre-assessment by external auditor (certification body).
- Certification.
- Periodic reviews by the certification body.
- Plan for surveillance visits and follow up for certification maintenance and continuous improvements.

## BENEFITS OF CERTIFICATION TO ISO-9000 QUALITY SYSTEMS

The tangible benefits accruing to an organisation through implementation of quality management systems based on ISO-9000 series standards in general, are:

(i) Better product design.

(ii) Improved product quality.

(iii) Reduction in scrap, rework and customer's complaints, resulting in economy and reduced price.

(iv) Efficient utilisation of men, machines and materials, resulting in higher productivity.

(v) Elimination of bottlenecks in production and generation of tension-free work environment, leading to good human relations.

(vi) Creation of quality awareness and greater job satisfaction among employees, improving the company's quality culture.

(vii) Improvement of confidence among customers.

(viii) Improvement of company's image and credibility in the market.

## SPECIFIC ISSUES TO HELP IMPELENTATION

In reference to the activities mentioned in section 4.0 earlier required towards ISO-9000 quality systems implementation certification, the following aspects and activities need specific attention as non-conformities generally, fall in these areas as per the past experience.

### Company's Quality Policy And Objectives

Company's quality policy needs to be framed up by the responsible senior executives authorised by the chief executive. The policy alongwith the objectives, reflect the direction and the goals which the company wants to aim at, keeping in view the requirements of the particular standard of ISO-9000 series adopted.

If a company has design capabilities and the relevant infrastructure i.e. necessary laboratories and pilot scale developement facilities as well as competent R&D personnel, they would be right in choosing ISO-9001 as the standard for certification. The policy shall then be accordingly framed up, and the objectives set and defined to meet this policy. One of the objectives for achieving company's quality policy for instance, could be "a regular evaluation of suppliers/ sub-contractors" for the input materials to ensure a

consistency in quality of product. Likewise, many objectives could be framed up in line with the stipulation of quality policy and ISO requirements.

Once the quality policy and objectives are firmed up, the activities of the organisation must be in accordance with the same.

**Training of The Lead Auditors And Internal Auditors**

It would be in the interest of the company to get 3 to 4 appropriate qualified personnel exposed to 'lead auditors course' through a recognised programme for the purpose. This should be done as early as possible so that the work initiated in the form of documentation as well as further audit is done in accordance with the norms and procedural guide lines. For a small and medium scale company, one or two persons could only be considered reasonable for such a specialised training.

The training of the internal auditors for carrying out the audits should either be done through the specialised courses offered by many agencies of repute, or alternatively by the lead assessor (s) themselves who have already obtained the specialised training for carrying out the audits. A batch of say 20 executives be trained to help carry out the internal audit on a company wide basis, having a manpower of around 2000 to 2500. The training of internal auditors shall culminate in a written test. The persons who qualify the test shall only be employed for the purpose, and a record of their qualifying the internal auditors course shall also be maintained.

**Documentation**

The documentation is required to cover the following major catogeries and need to be as fool proof as possible so as not to have frequent changes in them.

**(a) Company Level Quality System Manual**

This Document would contain the company policy, the overall organisation of the company, indicating the key positions, their roles and functional responsibilities alongwith detailing out of the elements of ISO-9000 standard choosen, broadly clarifying the ways and means as to how the company's policy and objectives would be met with.

This document is authorised by the Company's Chief executive for issue to all the key personnel as a controlled copy through MR, nominated by the chief executive.

This document is not a confidential document and can be passed on to the customers on their requests, as uncontrolled copy. The uncontrolled copy means that the same as and when revised, would not be required to be sent in update version to the persons whom such a copy has been given earlier.

**(b) Departmental Procedure Manual (DPM)**

This document is a second level document authorised by the departmental head (s), issued and maintained as a controlled document. It contains the departmental organisation, and functions of the responsible key personnel alongwith the departmental person controlling and issuing the document. The document is a confidential one and must be issued only to the departmental functional/sectional incharges, for reference and use by their staff as a controlled document.

**(c) Departmental Work Instructions (DWI)**

This document is a third level document and authorised by departmental heads or by the concerned sectional/functional incharges. It is a confidential document and must be issued only to the concerned department/section personnel as a controlled document, through a responsible person, earmarked for the purpose.

The document covers step by step the various functional work instructions pertaining to the sections/departments concerned. It would also high-light the record formats whereby the specifications, quality statements and records pertaining to each of the functions shall be maintained to serve as objective evidences for the auditors.

It is also imperative that the documents are fool-proof, leaving no ambiguities and gaps. All the documents representing different categories as defined above, shall have linkages for easy cross reference and understanding.

In small and medium range companies generally departments are relatively much less and limited and there are only a few

key positions. In these cases, all departmental procedures and work instructions could be clubbed into one or two documents.

**Document And Data Control**

The persons ear-marked for the document and data control in each department, shall ensure that all documents and data sheets are properly numbered with revision and date for easy identification and traceability. These shall be issued and recorded in a register or a file against the distribution list of the identified key personnel and their signatures on receipt of documents shall also be taken for record. Each person receiving the document would be allocated a control number. As and when the document or its parts get revised, the same in revised version shall be made available to the concerned functional personnel for their use against their alloted control numbers. It would have to be ensured that the latest document is made available at the work places and the obsolete documents are destroyed. Master document controlled list shall be available with the earmarked controlling person of the department, for use as master reference during the audits in the functional areas.

**Contract Reviews**

Contract reviews concern two major aspects i.e. pre-award and post-award stages. The pre-award reviews need to be carried out through the marketing/sales personnel who have direct contact with the customers. This involves negotiating and finalising the tender specification requirements with the customers so that there is no dispute at the time of execution of contracts. The post-award reviews shall be carried out by the design/production personnel to ensure that the manufactured product (s) meet the customers specification requirements. Any major departure from the specifications shall be settled with the customers through marketing/sales. Records of the delibrations both for pre-award and post-award contract reviews shall be maintained by the marketing/sales and design/production personnel respectively.

**Design Reviews**

All available not-in-use designs before their use any time towards production, shall be re-validated by way of a prototype or a pilot trial or a model study on computer to ensure that the designs can be re-applied without any problem. The minimum not-in-use period of old designs after which revalidation is required, shall also be defined. The new designs whenever developed, shall have also a similar approach for verification before introducing it for mass production.

Design personnel shall invariably involve production personnel to seek their acceptance of the new designs developed. Quality plans shall also be issued by them in advance about the specific requirements regarding manufacturing, testing inspection, packing and despatch. All the delibrations and records shall be maintained by the design/quality department.

**Purchased And Stored Items**

Indenting, purchasing and storage procedures must be clearly defined alongwith appropriate delegation of powers. Thrust shall be exercised towards the use of appropriate, approved and proven specifications for all purchased items i.e. raw materials and components. The purchase orders must be complete in all respects, covering appropriate specification requirements, drawings, data sheet etc. alongwith testing, inspection and acceptance requirements as applicable. The parties be evaluated at regular intervals for their adequacy and competence towards regular and consistent supplies. Records of the evaluation, its procedure and a list of the established parties be also maintained. The storage of the items (both for main and department stores) shall be done in a way that each item is tagged for easy identification and traceability. Also, regular health monitoring and upkeep of the critical items be exercised and records maintained.

**Calibration of Instrumentation**

All Instrumentation, affecting the product quality measurements shall be regularly calibrated. A list of such instruments shall be drawn out and its monitoring ensured with regard to calibration as per schedule. Instrumentation other than the ones affecting product quality measurement, shall be over-hauled periodically and marked as 'For indication only'. Calibration certificate where-ever applicable, shall essentially have traceability to the master instrument, reference to national/international standards, accuracy, percentage error and validity period indicated. Status of calibration for instrumentation shall be available with the incharge of the area concerned and un-calibrated instrumentation shall never be employed.

**Manufacturing Operations And corrective/Preventive Actions**

All manufacturing operations shall be carried out as per the specified/documented procedures and work instructions. All toolings, gauges, safety valves, templates and instrumentation used in the manufac-

turing operation/process shall have due calibration before use and their records shall be available for reference and audit checks.

Any deviation in the product quality from specifications, if in the un-acceptable range, shall be analysed, and necessary corrective actions taken. On-line SQC techniques followed by corrective actions shall be employeed as necessary, to ensure quality products. Non-conforming products, shall be dealt with as per the procedures outlined in the documentation. Full identification of the products with customer/manufacturing orders shall be maintained up to the despatch stage. All records of non-conformances and corresponding corrective as well as preventive actions or disposals etc., shall be maintained.

**Internal Audits**

The audits shall be carried out by the qualified internal auditors team of 1-3 persons headed by a lead auditor as per the audit plan issued by the MR in the beginning of each year. The non-conformities/ observations shall be brought out by the team and discussed with the auditee for ensuring time framed compliance of their proposed action plan to overcome the weaknesses.

The audit plan demanding at least one audit in two months for each area, will define the audit team members, the departments to be audited, dates and time for the audit etc. The audit plan indicating the status of audit, closing of non-conformities/observations, and compliance status shall be maintained by MR.

**Quality Systems Effectiveness**

Effectiveness of ISO-9000 shall be ascertained periodically by way of direct/tangible benefits in terms of reduction in customers' complaints, quality based rejections in the production shops and the forced outages of the machines. The indirect benefits are also discernable through increased awareness on quality, understanding of internal customers concept and a cultural change at large. Based on the feedback through these effectiveness indices, relevant corrective actions shall be planned and monitored for further improvements on a continual basis. Records of all these findings, corrective actions and further improvements shall be maintained.

**Record Keeping**

All the quality records in appropriate proformas having format numbers, shall be kept upto date for easy identification and traceability.

Each record format and the record file shall have distinct numbers under a rationalised numbering scheme so as to give a clear identification and traceability.

**Management Reviews And Management Representative (MR)**

Management reviews shall be held periodically to ascertain critical issue to resolve them promptly. Also follow-up of the decision taken by the management shall be monitored as per the time frame committed. 'Management Review Committee', shall comprise senior executives holding key positions, with the chief executive as its chairman and MR as convenor.

MR shall follow-up all the decisions taken and ensure the periodicity of the meetings as well as records of the same.

**External Periodic Audit**

ISO Certification by recognised certifying agencies is subject to periodic audit by the certifying agency. It is mandatory to have such audits carried out at 6 or 9 months intervals. Such audits would assess the effectiveness of quality systems in force and overall awareness of the programme in the areas.

The certifying agencies auditing during their audit, which may normally extend to 2 days, would at random check the operation in all sections together with respective areas managers so as to identify all variations and non-compliance which they call as "Non-Conformities" (NC). At the end of the audit visit all NCs are discussed with the auditee management team and the same have to be corrected within stipulated period duly certified by MR and reported back to certifying agency audit team. Any major non-conformity can even result in withdrawal of the ISO certification whereas minor NCs, not in large numbers, can be permitted to be corrected.

The validity of ISO certificate is for 3 year duration whereafter renewal exercise has to be carried out.

## OTHER GENERAL GUIDELINES

(i) To ensure timely implementation, the systems shall be built up on the operational modes already existing, with minimum changes.

(ii) The systems shall focus on the prevention of errors. Repetition of the same when found, be taken seriously and solution found immediately to resolve them.

(iii) Internal audit team shall check the auditee's areas very rigorously on a regular basis as per scheduled plan drawn out in advance.

(iv) Effectiveness of the system, shall be made a regular agenda item for discussions in the management review meetings. Improvements be clearly broughtout preferably in quantitative terms for analysis and effective remedial measures.

(v) Communication down the line, for the changes to be made, shall be given highest priorty.

(vi) Process and product specifications, shall be drawn up more on practical considerations. To cover the excessive variations, an acceptable norm-range shall be specified to avoid repeated non-conformities. If the parameter particulars are only for guidance/reference, the same shall be mentioned accordingly.

(vii) Full thrust shall be given to the preventive maintenance of the process and other equipments to limit their breakdowns to minimum. The audit feedback shall reflect the status of the preventive maintenance.

(viii) Last but not the least, the management must be committed to its quality policy and offer all support to the activities involved.

## CONCLUSION

Practical and important guidelines have been detailed out in the paper, based on the experience of the author. If the steps and measures as given here are effectively taken care of, it is expected that securing of certification as well as maintaining of the same, would pose no problem. It is also very significant to mention that the success for the project would essentially have the bearing on the commitment from the top management in true spirit. In addition, involvement of all personnel with full sincerity is a must to achieve the results.