CHAPTER 4

Development of decision support system for ISO 9001:2000 based innovation integrated quality system standard

4.0 Introduction

Today most of the organizations of varied types and sizes situated all over the world have installed ISO 9000 series standards based quality systems (QSs). It is a fact, that this trend has created QS consciousness among practitioners and theorists. However there has been an appraisal over the real benefits of implementing ISO 9000 series QS standards in organizations. In literature, majority of the papers reports the favorable outcome of implementing ISO 9000 series QS standards. However a sizable number of articles like Seddon (1997), Dick (2000) etc., point out the drawbacks of implementing ISO 9000 series in organization. Even ISO itself has revised ISO 9000 series standards twice. These developments indicate that although ISO 9000 series standards facilitate QS installation, they require fine tuning to adapt itself to additional requirements. In this line, the emanation of QS 9000 standard can be considered. This standard has been developed by considering ISO 9001:94 as a basis and additions have been made to meet the specific requirements of automobile industry. In this context, as part of this doctoral work the contents of ISO 9001:2000 were studied with the purpose of identifying any stipulations for infusing innovation in organizations. As the study indicated the absence of any such stipulations, it was decided to make additions to the ISO 9001:2000 standard. Addition of new features dealing with IM to the existing ISO 9001:2000 standard, makes it easy for the organizations which have implemented ISO9001: 2000 standard to evolve innovations through innovative QS without affecting the existing system. In order to fulfill this requirement, one module of this doctoral work, which have been reported in this chapter, has been carried out. To begin with the
principles of IM have been incorporated into ISO 9001:2000 standard by adding carefully the various terminology's of IM. Accordingly a standard called ISO 9001:2000 based innovation integrated QS standard has been designed. A batch consisting of three undergraduates mechanical engineering students were provided with this standard. These students approached a foundry to examine its implementation. As the knowledge on IM and its importance in QS was totally absent in that company, the students could not collect any data on the above proposed standard. This situation indicated that, more than the implementation of the above standard, the companies require a DSS to examine their preparedness in implementing ISO 9001:2000 based QS model. In order to fulfill this requirement, a DSS has been developed. The details of this module of the doctoral work are presented in this chapter.

4.1 ISO 9001:2000 based innovation integrated quality system standard

In this section, the ISO 9001:2000 based innovation integrated QS standard has been presented. This standard has been designed by incorporating the terminologies of IM principles in appropriate position of ISO 9001:2000 standard. Such terminologies are shown using italicised letters.

1.0 Scope

1.1 General

This proposed standard specifies requirements for a innovation integrated quality management system where an organization

a) Needs to demonstrate its ability to consistently provide innovative product quality that delights the customer and applicable regulatory requirements, and

b) Aims to enhance customer delight through the effective application of the system, including processes for continual improvement of the system and the assurance of delight the customer and applicable regulatory requirements.
1.2 Applications

All requirements of this proposed standard are generic and are intended to be applicable to all organization regardless of type, size and product provided. Where any requirement(s) of this proposed standard cannot be applied due to the nature of an organization and its product, this can be revised for exclusion. Where exclusions are made, claims of conformity to this proposed standard are not acceptable unless these exclusions are limited to requirements within clause 7, and such exclusions do not affect the organizations ability, or responsibility, to provide product that delights the customer and meets the applicable regulatory requirements.

2.0 Normative reference

The following normative document contains provisions, which through reference in this text, constitute provisions for this proposed standard. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this proposed standard are encouraged to investigate the possibility of applying the most recent edition of the normative document indicated below. For undated references, the latest edition of the normative document referred to applies.

3.0 Terms and definitions

For the purposes of this proposed standard, the terms and definitions given in ISO 9000:2000 apply. The proposed standard has been designed based on the process of attaining innovative quality, which has been pictorially depicted in Figure 4.1. Throughout the text of this proposed standard, whenever the term “product” occurs, it can also mean “service”. Besides the following definitions are added.

3.1 Innovative Quality:

The performance and contribution of an organization that leads to the delight of the customers by providing innovative solutions.
3.2 Delight of customers:

Offering solutions to the customers which shall be more than their expectation/s and requirement/s.

3.3 Innovative solutions:

A solution, which has never surfaced in any form in any forum that, has been generated by ideation process.

4.0 Quality management system

4.1 General requirements:

The organization shall establish, document, implement and maintain an innovation integrated quality management system, which should facilitate in bringing out innovation through appropriate techniques and continually improve its effectiveness in accordance with the requirements of this standard and Innovation management principles.

The organization shall

a) Identify the innovative processes and methodologies needed for the continuous innovation through the innovation integrated quality management system and their
application throughout the organization,
b) Determine the sequence and interaction of these innovative processes and innovation enabling methodologies.
c) Determine criteria and methods needed to ensure that both the operation and control of these processes and innovation enabling methodologies are effective,
d) Ensure the availability of resources and information necessary to support the operation and monitoring of these innovative processes and methodologies,
e) Monitor, measure and analyze these processes and methodologies.
f) Implement actions necessary to achieve planned results.

4.2 Documentation Requirements

4.2.1 General

The innovation integrated quality management system documentation shall include

a) Documented statements of a quality policy integrated with innovation management techniques and quality objectives and expected innovation,
b) A quality manual impregnated innovation management principles,
c) Documented procedure required by this proposed standard,
d) Documents needed by the organization to ensure the effective planning, operation and control of its processes and innovation methodologies, and
e) Records required by the proposed standard with innovation management principles.

4.2.2 Quality Manual

The organization shall establish and maintain an innovation integrated quality manual that includes

a) The scope of the innovation integrated quality management system, including details of and justification for any exclusions and the method of creating innovations,
b) The documented procedures established for the innovation integrated quality management system, is reference to them and innovation techniques,
c) A description of the interaction between the processes of the innovation integrated quality management system.

4.2.3 Control of documents

Documents required by the innovation integrated quality management system shall be controlled. Records are special type of document and shall be controlled according to the requirements given in 4.2.4.

A documented procedure shall be established to define the controls needed

a) To approve documents for adequacy prior to issue,

b) To review and update as necessary and re-approve documents,

c) To ensure that changes and the current revision status of documents are identified,

d) To ensure that relevant versions of applicable documents are available at points of use.

e) To ensure that documents remain legible, readily identifiable and facilitate in applying innovation management principles,

f) To ensure that documents of external origin are identified and their distribution is Controlled, and

g) To prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose.

4.2.4 Control of records

Records shall be established and maintained to provide evidence of conformity to requirements and of the effective operation of the innovation integrated quality management system. Records shall remain legible, readily identifiable, retrievable and facilitate in applying innovation management principles. A documented procedure shall be established to define the controls needed for the identification, storage, protection, retrieval, retention time and disposition of records.
5.0 Management responsibility

5.1 Management commitment

Top management shall provide evidence of its commitment to the development and implementation of the innovation integrated quality management system and a culture to create creativity and continually improving its effectiveness by

a) Communication to the organization the importance of meeting customer as well as statutory and regulatory requirements,

b) Establishing the quality policy which ensures the importance of creating innovation at all levels,

c) Ensuring that quality objectives brings out innovative concepts,

d) Conducting management reviews which ensures that innovative concepts are implemented, and

e) Ensuring the availability of adequate resources which are needed for continuous innovation.

5.2 Customer focus

Top management shall ensure that customer requirement are determined and are met with the aim of enhancing customer delight.

5.3 Innovative Quality Policy:

Top management shall ensure that the innovative quality policy

a) Is appropriate to the purpose of the organization,

b) Includes a commitment to comply with requirement and continually improve the continuous innovation by innovation management techniques through the innovation integrated quality management system,

c) Provides a frame work for establishing and reviewing innovative quality objectives,

d) Is communicated and understood within the organization, and

e) Is reviewed for continuing suitability.
5.4 Planning

5.4.1 Quality objectives

Top management shall ensure that innovative quality objectives, including those needed to meet the requirements for product are established at relevant functions and levels within the organization. The innovative quality objectives shall be measurable and consistent with the innovative quality policy.

5.4.2 Quality management system planning

Top management shall ensure that

a) The planning of the innovation integrated quality management system is carried out in order to meet the requirements given in 4.1, as well as the innovative quality objectives, and

b) The integrity of the innovation integrated quality management system is maintained when changes to the innovation integrated quality management systems are planned and implemented.

5.5 Responsibility, authority and communication

5.5.1 Responsibility and authority

Top management shall ensure that responsibilities and authorities are defined and communicated within the organization

5.5.2 Management representative

Top management shall appoint a member of management who, irrespective of other responsibilities shall have responsibility and authority that includes

a) Ensuring that processes needed for the innovation integrated quality management system are established, implemented and maintained,

b) Reporting to top management on the performance of the innovation integrated quality management system and any need for further innovation,

c) Ensuring the promotion of awareness of customer requirements and the importance of Innovation throughout the organization.
5.5.3 Internal communication

Top management shall ensure that appropriate communication processes are established within the organization and that communication takes place regarding the effectiveness of the innovation integrated quality management system.

5.6 Management review

5.6.1 General

Top management shall review the organization’s innovation integrated quality management system at planned intervals to ensure its continuing suitability, adequacy and effectiveness. This review shall include assessing opportunities for continuous innovation and the need for changes to the innovation integrated quality management system including the quality policy and quality objectives. Records for management review shall be maintained.

5.6.2 Review input

The input to management review shall include information on

a) Results of audits,
b) Customer feedback,
c) Innovations created,
d) Recommendation for further innovation,
e) Process performance and product conformity,
f) Status of preventive and corrective actions,
g) Follow-up actions from previous management reviews, and
h) Changes that could affect the innovation integrated quality management system.

5.6.3 Review output

The output from the management review shall include any decisions and actions related to

a) Improvement of the effectiveness of the innovation integrated quality management system and its processes with building innovation.

b) Innovation of product related to customer requirements, and
c) Resource needed to support continuous innovation.

6.0 Resource management

6.1 Provisions of resources

The organization shall determine and provide the resource needed for continuous innovation.

a) To implement and maintain the innovation integrated quality management system and continually improve its effectiveness, and

b) To enhance customer delight by meeting customer requirements.

6.2 Human resources

6.2.1 General

Personnel performing work affecting product quality shall be competent on the basis of appropriate education, training skills and experience. Organization need to consider the type of dedicated employees that can most effectively drive innovation.

6.2.2 Competence awareness and training

The organization shall

a) Determine the necessary competence and creative ability for personnel performing work affecting product quality,

b) Provide training in new idea generation techniques or take necessary other actions to satisfy these needs,

c) Evaluate the effectiveness of the actions taken and new idea generated,

d) Ensure that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievements of the innovative quality objectives and expect that innovation is part of creative problem solving technique,.

e) Maintain appropriate records of education, training, skills, experience and capability of creativity,

f) Specify efforts to promote creativity and innovation,
6.3 Infrastructure

The organization shall determine, provide and maintain the infrastructure needed to achieve conformity to product requirements and innovation. Infrastructure includes, as applicable

a) Building, workspace and associated utilities,

b) Process equipment (both hardware and software), and

c) Supporting services (such as transport and communication).

6.4 Work environment

The organization shall determine and manage the work environment needed to achieve conformity to product requirements and the required critical parameters are

a) Freedom to the employees to think and act according to their own ideas,

b) Encouragement of risk taking.

6.4.1 Organization culture

a) Constantly guides organization members to strive for innovation,

b) Climate that is conducive to creativity.

7.0 Product realization

7.1 Planning of product realization

The organization shall plan and develop the innovative processes and methodologies needed for new product realization. Planning of new product realization shall be consistent with the requirements of the other processes and innovative methodologies needed for the innovative quality management system. In planning new product realization, the organization shall determine the following, as the appropriate

a) Innovative quality objectives and requirements for the new product,

b) The need to establish new processes and innovative methodologies, documents, and provide resources specific to the new product,

c) Required verification, validation, monitoring, inspection and test activities specific
to the new product and the criteria for product acceptance,

d) Records needed to provide evidence that the innovative processes and resulting new product meet requirements,

The output of this planning shall be in a form suitable for the organization's method of operations.

7.2 Customer - related processes

7.2.1 Determination of requirements related to the product

The organization shall determine

a) Requirements specified by the customer, including the requirements for delivery and post-delivery activities,

b) Requirements not stated by the customer but necessary for specified or intended use, where known and the possible innovations,

c) Statutory and regulatory requirements related to the product, and

d) Any additional requirements determined by the organization.

7.2.2 Review of requirements related to the product

The organization shall review the requirements related to the product. This review shall be conducted prior to the organization commitment to supply a product to the customer (e.g. submission of tenders, acceptance of contracts or orders, acceptance of changes to contracts or orders) and shall ensure that

a) Product requirements are defined,

b) Contract or order requirements differing from those previously expressed are resolved and

c) The organization has innovative methodologies to meet the defined requirements.

Records of the results of the review and actions arising from the review shall be maintained. Where the customer provides no documented statement of requirement, the customer requirements shall be confirmed by the organization before acceptance. Where product requirements are changed, the organization shall ensure that relevant documents are amended and that relevant personnel are made aware of changed requirements.
7.2.3 Customer communication

The organization shall determine and implement effective arrangements for communicating with customers in relation to

a) Product information,
b) Enquiries, contracts or order handling including amendments, and
c) Customer feedback, including customer complaints.

7.3 Design and development

7.3.1 Design and development planning

The organization shall plan and control the design and development of products. During the design and development planning the organization shall determine

a) The design and development stages,
b) The review, verification and validation that are appropriate to each design and development stage, and
c) The responsibilities and authorities for design and development.
d) The nature and level of innovation to be incorporated during each design and development stage.

The organization shall manage the interfaces between different groups involved in design and development to ensure effective communication and clear assignment of responsibilities which will facilitate in integrating innovation during design and development stages. Planning output shall be updated as appropriate as the design and development progresses.

7.3.2 Design and development inputs

Inputs relating to product requirements and innovations shall be determined and records maintained. These inputs shall include

a) Functional and performance requirements,
b) Applicable statutory and regulatory requirements,
c) Where applicable, information derived from previous similar designs, and
d) Other requirements essential for design and development and for evolving innovative products.

These inputs shall be reviewed for adequacy. Requirements shall be complete unambiguous and not in conflict with each other.

7.3.3 Design and development outputs

The outputs of design and development shall be provided in a form that enables verification against the design and development input and shall be approved prior to release.

Design and development outputs shall

a) Meet the input requirement for design and development,
b) Provide appropriate information for purchasing, production and service provision,
c) Contain or reference product acceptance criteria, and
d) Specify the characteristics of the product that are essential for its safe and proper use,
e) Impart innovative features on the product.

7.3.4 Design and development review

At suitable stages, systematic reviews of design and development shall be performed in accordance with planned arrangements.

a) To evaluate the ability of the results of design and development to meet requirements and incorporate innovative features, and
b) To identify any problems and propose necessary actions associated with the innovative features and requirements.

Participants in such reviews shall include representatives of function who should have the flair for providing innovative solutions and concerned with the design and development stages being reviewed. Records of the results of the reviews and any necessary actions shall be maintained.
7.3.5 Design and development verification

Verification shall be performed in accordance with planned arrangements to ensure that the design and development outputs have met the design and development input requirements and innovative features. Records of the results of the verification and any necessary actions shall be maintained.

7.3.6 Design and development validation

Design and development validation shall be performed in accordance with the planned arrangements to ensure that the resulting product is capable of meeting the requirements for the specified application or intended use, where known. Wherever practicable, validation shall be completed with regard to the design and development requirements coupled with innovative features prior to the delivery or implementation of the product. Records of the results of the validation and any necessary actions shall be maintained.

7.3.7 Control of design and development changes

Design and development changes shall be identified and records maintained. The changes shall be reviewed, verified and validated, as appropriate, and approved before implementation. The review of design and development changes shall include evaluation of the effect of the changes and incorporation of innovative characteristics on constituent parts and products already delivered and the records of the results of the reviews of changes, innovative characteristics and any necessary actions shall be maintained.

7.4 Purchasing

7.4.1 Purchasing process

The organization shall ensure that purchased product conforms to specified purchase requirements and facilitates in evolving innovative products. The type and extent of control applied to the supplier and the purchased product shall be dependent upon the effect of the purchased product and the incorporation of innovative characteristics on subsequent product realization or the final product.
The organization shall evaluate and select suppliers based on their ability to supply product in accordance with the product innovation and organization’s requirements. Criteria for selection and evaluation and re-evaluation shall be established from the point of innovative characteristics. Records of the results of evaluations and any necessary actions arising from the evaluation shall be maintained.

7.4.2 Purchasing information

Purchasing information shall describe the product to be purchased, including where appropriate

a) Requirements for approval of products, procedures, processes and equipment,
b) Requirement for qualification of personnel, and
c) Innovative quality management system requirements.

The organization shall ensure the adequacy of specified purchase requirements prior to their communication to the supplier.

7.4.3 Verification of purchased product

The organization shall establish and implement the inspection or other activities necessary for ensuring that purchased product meets specified purchased requirements. Where the organization or its customer intends to perform verification at the supplier’s premises, the organization shall state the intended verification arrangements and method of product release in the purchasing information.

7.5 Production and service provision

7.5.1 Control of production and service provision

The organization shall plan and carry out production and service provision under controlled conditions. Controlled conditions shall include, as applicable

a) The availability of new ideas that describes the characteristics of the new product,
b) The availability of work instructions to produce the innovative product,
c) The use of suitable equipment,
d) The availability and use of monitoring and measuring devices,
7.5.2 Validation of processes for production and service provision

The organization shall validate any processes for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement. This includes any processes where deficiencies become apparent only after the product is in use or the service has been delivered. Validation shall demonstrate the ability of these processes to achieve planned results. The organization shall establish arrangements for these processes including, as applicable

a) Defined criteria for review and approval of the processes,
b) Approval of equipment and qualification of personnel,
c) Use of innovative methodologies and procedures,
d) Requirements for records (see 4.2.4), and
e) Revalidation.

7.5.3 Identification and traceability

Where appropriate, the organization shall identify the product by suitable means throughout product realization. The organization shall identify the product status with respect to monitoring and measurement requirements. Where traceability is a requirement, the organization shall control and record the unique identification of the product (see 4.2.4)

NOTE: In some industry sectors, configuration management is a means by which identification and traceability is maintained.

7.5.4 Customer property

The organization shall exercise care with customer property while it is under the organization's control or being used by the organization. The organization shall identify, verify, protect and safeguard customer property provided for use or incorporation into the product. If any
customer property is lost, damaged or otherwise found to be unsuitable for use, this shall be reported to the customer and records maintained (see 4.2.4).

NOTE: Customer property can include intellectual property.

7.5.5 Preservation of product

The organization shall preserve the conformity of product during processing and delivery to the intended destination. This preservation shall include identification, handling, packaging, storage and protection. Preservation shall also apply to the constituent parts of a product.

7.6 Control of monitoring and measuring devices

The organization shall determine the monitoring and measurement to be undertaken and the monitoring and measuring devices needed to provide evidence of conformity of product to determined requirements and innovative features incorporated in the product. (See 7.2.1). The organization shall establish processes to ensure that monitoring and measurement can be carried out in a manner that is consistent with the monitoring and measurement of innovation requirements. Where necessary to ensure valid results, measuring equipment shall

a) Be calibrated or verified at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards; where no such standards exist, the basis used for calibration or verification shall be recorded;

b) Be adjusted or re-adjusted as necessary;

c) Be identified to enable the calibration status to be determined;

d) Be safeguarded from adjustments that would invalidate the measurement result;

e) Be protected from damage and deterioration during handling, maintenance and storage.

In addition, the organization shall assess and record the validity of the previous measuring results when the equipment is found not to conform to requirements. The organization shall take appropriate action on the equipment and any product affected. Records of the results of calibration and verification shall be maintained (see 4.2.4). When used in the monitoring and
measurement of specified requirements, the ability of computer software to satisfy the intended application shall be confirmed. This shall be undertaken prior to initial use and reconfirmed as necessary.

8.0 Measurement, analysis and improvement

8.1 General

The organization shall plan and implement the monitoring, measurement, analysis and innovative processes needed

a) To demonstrate conformity of the product,

b) To ensure conformity of the innovation integrated quality management system, and

c) To continually improve the effectiveness of the innovation integrated quality management system.

This shall include determination of applicable methods, including statistical techniques, and the extent of their use.

8.2 Monitoring and measurement

8.2.1 Customer delight

As one of the measurements of the performance of the innovation integrated quality management system, the organization shall monitor information relating to customer perception and delight as to whether the organization has met to achieve the same. The innovative methods for obtaining and using this information shall be determined.

8.2.2 Internal audit

The organization shall conduct internal audits at planned intervals to determine whether the innovation integrated quality management system

a) Conforms to the planned arrangements (see 7.1), to the requirements of this proposed standard and to the innovation integrated quality management system requirements established by the organization, and

b) Is effectively implemented and maintained.
An audit programme shall be planned, taking into consideration the status and importance of the processes and areas to be audited, as well as the results of previous audits. The audit criteria, scope, frequency and methods shall be defined. Selection of auditors and conduct of audits shall ensure objectivity and impartiality of the audit process. Auditors shall not audit their own work. The responsibilities and requirements for planning and conducting audits, and for reporting results and maintaining records (see 4.2.4) shall be defined in a documented procedure. The management responsible for the area being audited shall ensure that actions are taken without undue delay to eliminate detected nonconformities and their causes and innovative techniques. Follow-up Activities shall include the verification of the actions taken and the reporting of verification results (see 8.5.2).

8.2.3 Monitoring and measurement processes

The organization shall apply suitable innovative methods for monitoring and, where applicable, measurement of the innovation integrated quality management system processes. These methods shall demonstrate the ability of the innovative processes to achieve planned results. When planned results are not achieved, correction and corrective action shall be taken, as appropriate, to ensure conformity of the product and to check out the innovative features.

8.2.4 Monitoring and measurement of product

The organization shall monitor and measure the characteristics of the new product to verify that new product requirements have been met. This shall be carried out at appropriate stages of the product realization process in accordance with planned arrangements (see 7.1). Evidence of conformity with the acceptance criteria shall be maintained. Records shall indicate the person(s) authorizing release of new product (see 4.2.4). Product release and service delivery shall not proceed until planned arrangements (see 7.1) have been satisfactorily completed, unless otherwise approved by a relevant authority and, where applicable, by the customer.
8.3 Control of nonconforming product

The organization shall ensure that product which does not conform to product requirements is identified and controlled to prevent its unintended use or delivery. The controls and related responsibilities and authorities for dealing with nonconforming product shall be defined in a documented procedure. The organization shall deal with nonconforming product by one or more of the following ways:

a) By taking action to eliminate the detected nonconformity;

b) By authorizing its use, release or acceptance under concession by relevant authority and where applicable, by the customer;

c) By taking action to preclude its original intended use or application;

d) Any arrangement made for additional innovative features as per the design.

Records of the nature of nonconformities and any subsequent actions taken, including concessions obtained, shall be maintained (see 4.2.4). When nonconforming product is corrected it shall be subject to re-verification to demonstrate conformity to the requirements. When nonconforming product is detected after delivery or use has started the organization shall take action appropriate to the effects, or potential effects, of the nonconformity.

8.4 Analysis of data

The organization shall determine, collect and analyze appropriate data to demonstrate the suitability and effectiveness of the innovation integrated quality management system and to evaluate where continual improvement and innovation of the effectiveness of the innovation integrated quality management system can be made. This shall include data generated as a result of monitoring and measurement and from other relevant sources.

The analysis of data shall provide information relating to

a) A customer delight,

b) Conformity to new product requirements.

c) Characteristics and trends of innovative processes and new products including opportunities for preventive action, and
d) Suppliers' ability to meet the innovative requirements.

8.5 Improvement

8.5.1 Continual improvement

The organization shall continually develop the new methodologies for innovative effectiveness of the *innovation integrated* quality management system through the use of quality policy, quality objectives, audits results, analysis of data corrective and preventive actions and management review and develop the new methodologies for continuous innovation.

8.5.2 Corrective action

The organization shall continually take action to eliminate the cause of nonconformities in order to prevent recurrence. Corrective actions shall be appropriate to the effects of the nonconformities encountered.

A documented procedure shall be established to define requirements for

a) Reviewing nonconformities (including customer complaints),

b) Determining the causes of nonconformities,

c) Evaluating the need for action to ensure that nonconformities do not recur,

d) Generate new ideas by conducting the meeting in each department using innovation management technique.

e) Select the best idea by fixing the criteria.

f) Determining and implementing action needed,

g) Records of the results of action taken, and

h) Reviewing corrective action.

8.5.3 Preventive action

The organization shall determine action to eliminate the causes of potential nonconformities in order to prevent their occurrence. Preventive actions shall be appropriate to the effects of the potential problems.

A documented procedure shall be established to define requirements for

a) Determining potential non-conformities and interactive functions.
b) Evaluating the need for action to prevent occurrence of non-conformities,
c) Determining and implementing action needed,
d) Records of results of action taken,
e) Reviewing preventive action taken,
f) Identification of the relevant people, and
g) Generate new ideas through innovation management techniques.

4.0 Development of DSS

As mentioned under introduction section, a DSS was developed to enable the checking of the preparedness of an organization towards implementing ISO 9001:2000 based innovation integrated QS standard. For this purpose, a questionnaire containing 217 questions has been developed. These questions have been annexed with this thesis under Annexure B. These questions have been developed by referring to the designed innovation integrated ISO 9001:2000 quality system standard. In order to avoid ambiguity in responding, provision for entering only the 'yes' or 'no' type answer has been incorporated. Depending upon the success factors, marks are allotted to each question for which 'yes' answer is fed by the responder. No mark is allotted against the 'no' answers.

The mark distribution against the five clauses are given below:

1. General requirements : 200
2. Management responsibility : 500
3. Resource management : 100
4. Product realization : 100
5. Measurement, analysis and improvement : 100

The rational behind in allotment of marks is as follows. A company in which no management support and commitment exists for implementing ISO 9001:2000 based innovation integrated QS standard would not be able to succeed in installing it. Hence out
of the total of 1000 marks, 500 marks are allotted against the clause titled “Management responsibility”. Next, if a company does not provide adequate resources to implement this standard, then its effectiveness will be minimum. Hence, secondary importance is given to the implementation of elements given under the clause “General requirements”. Hence, a maximum of 200 marks have been allotted against the questions for which ‘yes’ answers are available under this clause. Equal importance has been given to other three clauses and equally 100 marks have been allotted. The organization which scores more than 500 marks is advised to proceed with the implementation of innovation integrated ISO 9001:2000 based quality system. As hinted earlier, an organization which scores less than 500 marks, would not enjoy the “Management responsibility”, and hence should not be allowed to proceed with implementing innovation integrated ISO 9001:2000 based quality system. These details were used to develop the DSS. For developing the DSS, Microsoft Access has been used as back end tool and Visual Basic version 6.0 has been used as front end tool.

4.1 Working methodology

The steps to be followed to use the DSS are as follows:

1. Input the company details.
2. Answer the question by choosing either ‘yes’ or ‘no’.
3. View the score in numerical value and graphical display which portray the preparedness of the company in implementing ISO 9001:2000 based innovation integrated QS.

4.2 Sample Run

The developed DSS is available in the CD attached with this report under the name ‘ISO’. On loading and invoking it, the login screen shown in Figure 4.2 will appear. Against employee ID the letter ‘admin’ has to be entered. The same word has to be entered as password also. After that, the master entry screen shown in Figure 4.3 will
be displayed. Using this screen, the questions developed can be entered. This provision is made to enable the edition of questions at a later point of time, which may be necessitated due to the revision of ISO 9001:2000 standard or its updating. On pressing, test module the questions will start appearing. The first question that appears is shown in Figure 4.4. As shown, the user can respond ‘yes’ or ‘no’. The answer is to be confirmed.

Figure 4.2 Login screen of DSS for ISO 9001:2000 based innovation integrated quality system
Figure 4.3 Master entry for entering questions
Figure 4.4 Screen display of sample question and response
Figure 4.5 Score display for the clause General Requirements
Figure 4.6 Graphical display of marks scored for the clause General Requirements
### Score Display

<table>
<thead>
<tr>
<th>Title</th>
<th>Max Marks</th>
<th>Marked Score</th>
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<tr>
<td>Innovative quality management system</td>
<td>200</td>
<td>160</td>
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<tr>
<td>Management responsibility towards innovative quality</td>
<td>500</td>
<td>220</td>
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<td>Resource management</td>
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<td>Measurement, analysis and improvement</td>
<td>100</td>
<td>0</td>
</tr>
</tbody>
</table>

**Advice:**

Since your organisation possesses less than 50% of the system requirements for attaining innovative quality, it is not advisable to proceed with implementing innovative quality system.

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Figure 4.7 Score display for the clause Management Responsibility
Figure 4.8 Graphical display of marks scored up to the clause Management Responsibility
### Score Display

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<thead>
<tr>
<th>Title</th>
<th>Max Marks</th>
<th>Make Score</th>
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<tbody>
<tr>
<td>Innovative quality management system</td>
<td>200</td>
<td>180</td>
</tr>
<tr>
<td>Management responsibility towards quality</td>
<td>500</td>
<td>730</td>
</tr>
<tr>
<td>Resource management</td>
<td>100</td>
<td>15</td>
</tr>
<tr>
<td>Product recall</td>
<td>100</td>
<td>0</td>
</tr>
<tr>
<td>Measurement, analysis and improvement</td>
<td>100</td>
<td>0</td>
</tr>
</tbody>
</table>

**Advice:** Since your organization possesses less than 50% of the system requirements by obtaining innovative quality, it is not advisable to proceed with implementing innovative quality system.

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**Figure 4.9** Score display up to the clause Resource Management
Figure 4.10 Graphical display of marks scored up to the clause Resource Management
Figure 4.11 Score display up to the clause Product Realization

<table>
<thead>
<tr>
<th>Title</th>
<th>Max Marks</th>
<th>Max Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Innovative quality management system</td>
<td>200</td>
<td>195</td>
</tr>
<tr>
<td>Management responsibility towards innovative quality</td>
<td>500</td>
<td>270</td>
</tr>
<tr>
<td>Resource management</td>
<td>100</td>
<td>15</td>
</tr>
<tr>
<td>Product realization</td>
<td>100</td>
<td>85</td>
</tr>
<tr>
<td>Measurement, analysis and improvement</td>
<td>100</td>
<td>0</td>
</tr>
</tbody>
</table>

Advice:
Since your organization possesses 53% percentage it is advisable to implement innovative quality system with caution.
Figure 4.12 Graphical display of marks scored up to the clause Product Realization
Figure 4.13 Score display up to the clause Measurement, analysis and Improvement
Figure 4.14 Graphical display of marks scored up to the clause Measurement, Analysis and Improvement
to proceed with answering the next questions. If the interaction to be terminated temporarily the user can exit by pressing 'save and exit' button. Meanwhile if the user is curious to know the marks scored so far, the same can be viewed by pressing the button 'view score'. The screen displaying the scores is shown in Figure 4.5. This screen also shows the advice given to the user based upon the marks scored. On pressing the graph button, a screen will appear showing the graphical display of marks scored against each clause in comparison to the maximum marks allotted. Figure 4.6 displays the graph for the clause General Requirements. Figures 4.7 – 4.14 display the score and graph for the remaining clauses. Thus this DSS helps the user to gather knowledge on strengths and weakness of the preparedness of his/her company for successfully implementing innovative ISO 9001:2000 based QS.

5.0. Conclusion

In literature, a number of articles have emerged reporting the benefits of implementing ISO 9001:2000 based QS. However no article has been reported on evolving innovation through the implementation of ISO 9000 based QS standard. On considering enormous time and money that have been spent by companies situated in majority of the parts of the world, it is alarming to note that innovations have not been accompanied by continuous quality improvement enabled by these standards. On considering this situation, a module of the doctoral work reported in this chapter has been carried out in which a model called innovation integrated ISO 9001:2000 based QS standard has been designed. On sensing the fact that today’s companies require thorough expertise to assess their preparedness to implement this model, a DSS has been developed. The contributions made by carrying out this module of the doctoral work will be useful to the companies, which view innovations coupled with quality as weapon to surge ahead in competitive battle.