ISO 9001 and its Implementation for Research Institute

Dr.D. Thirugnana Murthy,

Management Representative,

Head, Electronics and Instrumentation Division,

IGCAR, Kalpakkam

dtm@igcar.gov.in

The ISO 9000 : Family of QMS standards is designed to help organizations ensure that they meet the needs of customers and other stakeholders while meeting statutory and regulatory requirements related to a product.

ISO 14000 : Family of standards related to Environmental Management that exists to help organizations

(a) minimize how their operations (processes, etc.) negatively affect the environment

(b) comply with applicable laws, regulations, and other environmentally oriented requirements, and

(c) continually improve.

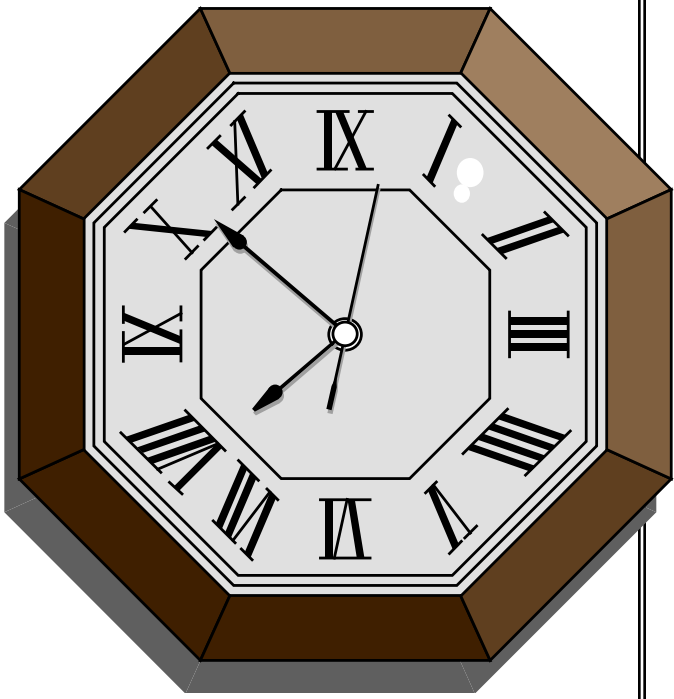
OHSAS 18001: (officially "BS OHSAS 18001:2007") is an standard for occupational health and safety management systems. It helps all kinds of organizations put in place demonstrably sound occupational health and safety performance.

Background to the new standards

- ISO protocol requires that all standards be reviewed every five year to account for lessons learnt/ feedback received during the application of the standard.

History of Changes

1st Edition	1987
2nd Edition	1994
3rd Edition	2000
4th Edition	2008



Evolution of ISO 9000 standards

- **Continually being revised by standing technical committees and advisory groups, who receive feedback from those professionals who are implementing the standard.**
- **ISO 9001:1987 *Model for quality assurance in design, development, production, installation, and servicing* was for companies and organizations whose activities included the creation of new products.**
- ***ISO 9001:2000* replaced all three former standards, *ISO 9001*, *ISO 9002* and *ISO 9003*. Radical change by placing the concept of process management front and center. It also demanded involvement by upper executives in order to integrate quality into the business system. Another goal was to improve effectiveness via process performance metrics. Expectations of continual process improvement and tracking customer satisfaction were made explicit.**

- **ISO 9001:2008 in essence re-narrates ISO 9001:2000. The 2008 version only introduced clarifications to the existing requirements of ISO 9001:2000 and some changes intended to improve consistency.**
- **Since 2012, the current standard has been under revision. A next version is expected to be published in the end of 2015.**
- **With the revision the scope of the standard will not change. An essential change, however, will affect the structure. The new ISO 9001:2015 will follow the high-level structure. This, and the uniform use of core texts and terms, will enable an identical structure for all management systems.**
- **The process-oriented approach is maintained within the standard and includes topics such as risk management, change management and knowledge management.**

ISO

Quality Management System (QMS) requirements

- Creating Awareness
- Documentation
- Audit for Compliance

Relevant Family of Standards

ISO 9000 – It describes fundamentals of quality management systems and specifies the terminology for quality management systems.

ISO 9001 – It specifies requirements for a quality management system where an organization needs to demonstrate its ability to provide products that fulfil customer and applicable regulatory requirements and aims to enhance customer satisfaction.

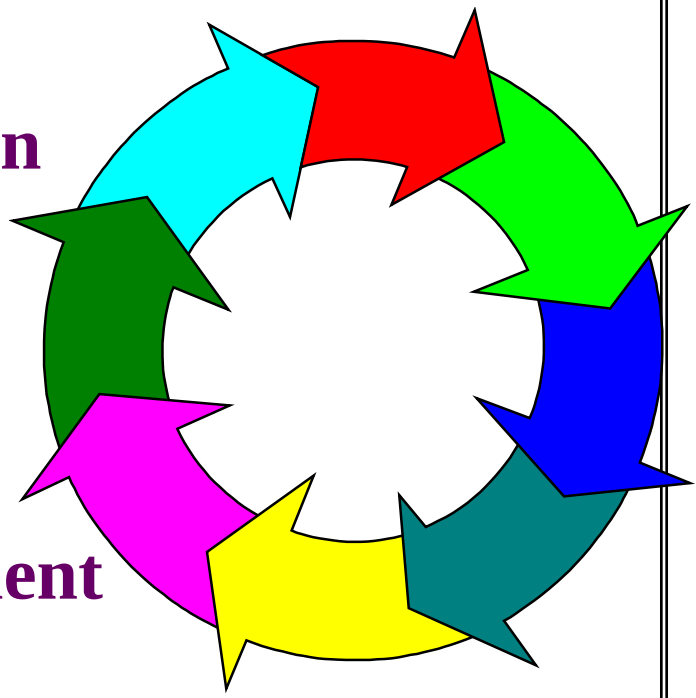
ISO 9004 – It provides guidelines that consider both the effectiveness and efficiency of the Quality Management System. It is intended as a guide for organizations that want to further expand and improve their quality systems after implementing ISO 9001.

ISO 9004 - is not a specification and may not be used for registration or certification assessment.

ISO 19011 – It provides guidance on auditing quality and environmental management systems .

Eight Quality Management Principles

on which new standards ISO 9001 & 9004 are based



- **Customer-focused organisation**
- **Leadership**
- **Involvement of people**
- **Process Approach**
- **System approach to management**
- **Continual improvement**
- **Factual approach to decision making**
- **Mutually beneficial supplier relationship**

Process-based structure of ISO 9001:2008

- Quality Management System (Clause 4)
  - General and documentation requirements
- Management responsibility (Clause 5)
  - Commitment, Customer focus, Policy, Planning, Responsibility, authority & communication, Review..
- Resource Management (Clause 6)
  - “Human resources”, Infrastructure, Work environment
- Product realization (Clause 7)
  - Planning, Customer, Design & development, Purchasing, “Operations”, Calibration
- Measurement, analysis and improvement (Clause 8)
  - Customer satisfaction, Audit, Process/product control, Non-conforming product, Data analysis, Improvement

Activities

1. Awareness Programmes for HODs and above
2. Awareness Programs for scientists, engineers and technical personnel – 8 Batches
3. Documentation programmes – 2 Batches
4. Internal Auditors Training
5. Preparation of DQMs
6. Preparation of AQM
7. Adequacy audit of DQMs – 2 rounds
8. DQMs revised with the comments

Management Review Committee

Chairman & Members

T.Jayanthi – Convenor, Quality Objective & Monitoring

Dr.K.Sankaran – Convenor, Audit Findings & Corrective Action

Dr.D.Thirugnanamurthy – Management Representative

IGCAR Internal Auditors

MHD	K. Velusamy
CD	T.Jayanthi ,K.Kuriakose
PMS	T Ezhilarasi
RSD	R.Baskaran, R.Mathiyarasu
MCD	K. Sankaran, V.Chandramouli
NDED	C.K.Mukopadhyaya, A.Joseph
EID,RTSD	B.Ramswamy Pillai, R.Ramakrishnan
CSTD	M.G. Pujar, Girija Suresh
Hospital	Dr. M.Jayashree, Dr. P. Bhattacharjee
SED	K.K.Satpathy
MTD	A. Moitra, Utpal Bohra, G.Srinivasan
MMD	K.Laha, BK Choudhary, Isaac Samuel
QAD	P Jagannathan, M.Menaka

Facilities Covered

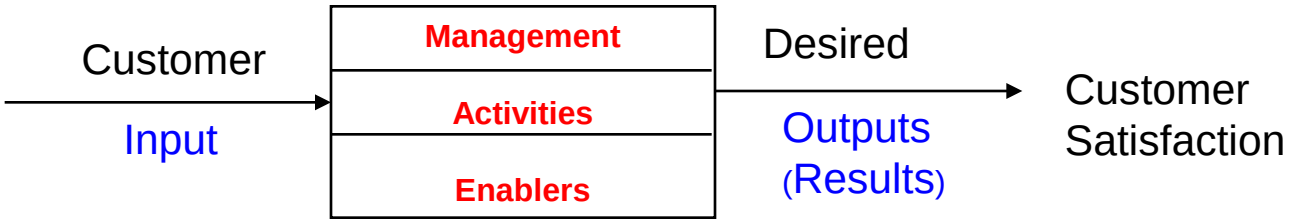
- Mechanical testing and Materials Technology, Non-destructive evaluation, Corrosion testing, Materials characterisation (MMG)
- Hardware and software design (EIG)
- Quality assurance (QAD)
- Component testing (RDG)
- Chemical characterisation (CG)
- Health and engineering safety (SG)
- Medical testing (Hospital)
- **Fast Breeder Test Reactor**
- **Central Workshop**

IGCAR Working Group Members

SED	J.Harvey
MTD	A. Moitra
MMD	M.D.Mathew
QAD	G.Ramesh
NDED	A.Joseph
SML	K. Velusamy
CD	T.Jayanthi
PMS	T. Ezhilarasi
RSD	R. Baskaran
MCD	K. Sankaran
EID	B.Ramaswamy Pillai
CSTD	N.Parvathavarthini
Hospital	Dr. P. Bhattacharjee
RTSD	R.Ramakrishnan

The Process Approach

Basic Process Model



An activity using resources, and managed in order to enable the transformation of inputs into outputs, can be considered as a **process.**

The application of a system of processes within an organization, together with the identification and interactions of these processes, and their management, can be referred to as the '**process approach'**.

This approach in QMS emphasizes the importance of :

Understanding and meeting requirements.

The need to consider processes in terms of added value.

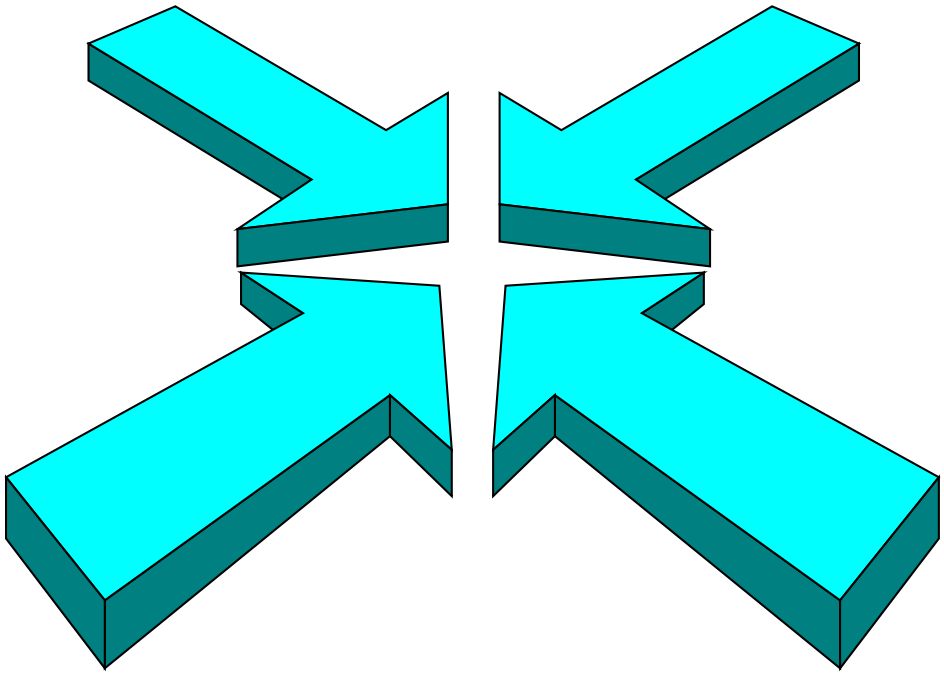
Obtaining results of process performance and effectiveness, and

Continual improvement of processes based on objective measurement.

Process approach

Description of:

- **Processes**
- **Responsibilities**
- **Interfaces**
- **Inter-relations**
- **Measures**



General Requirements

Organisation shall establish, document, implement, maintain and continually improve QMS

Documentation requirements

Quality policy and quality objectives and quality manual;

Control of documents, Control of records, Internal audit, Control of nonconforming product, Corrective and Preventive action

General

Documentation requirements

"Document" defined as information and its supporting medium;

Medium can be paper, magnetic, electronic or optical computer disc, photograph or master sample or combination thereof.

Quality Manual

Shall include:

- **Scope of Quality management System (including details of justification for any exclusions);**
- **Description of interaction between the processes of the QMS;**
- **Documented procedures or reference thereto.**

Management responsibility

- Management commitment
- Customer focus
- Quality Policy
- Planning
- Responsibility, authority and communication
- Management review

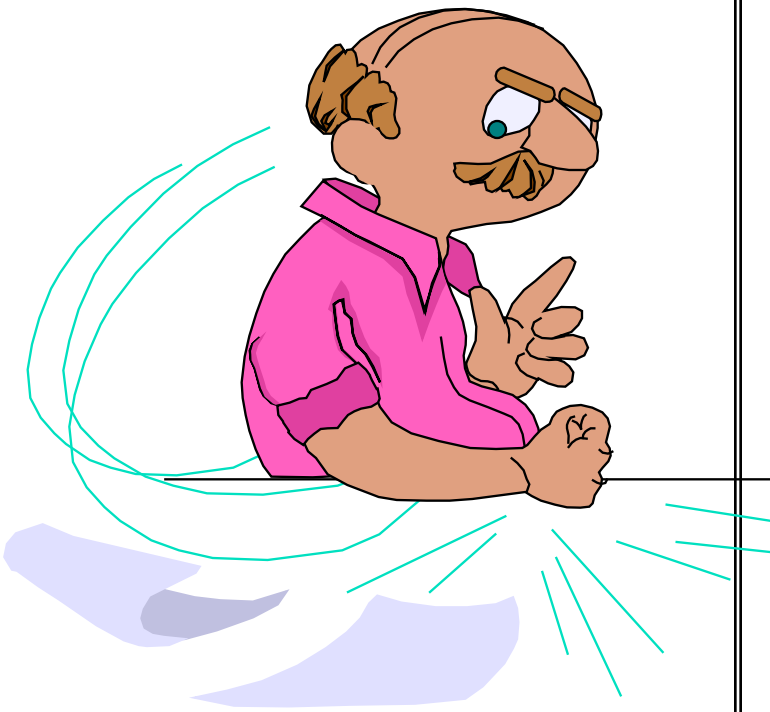
Resource management

Provision of resources

Human resource

Infrastructure

Work environment



Human Resources

- Personnel performing work affecting product quality shall be competent;
- Competence based on appropriate:
  1. Education
  2. Training
  3. Skills
  4. Experience

Control of Measuring and Monitoring Devices

Where applicable, measuring and monitoring devices shall :

a) Be calibrated and adjusted periodically or prior to use, against devices traceable to international or national standards; where no such standards exist, the basis used for calibration shall be recorded.
b) Be safeguard from adjustments that would invalidate the calibration.
c) Be protected from damage and deterioration during handling, maintenance and storage.
d) Have the results of their calibration recorded.
e) Have the validity of previous results re-assessed if they are subsequently found to be out of calibration, and corrective action taken.
Software used for measuring and monitoring of specified requirements shall be validated prior to use.

Measurement and Monitoring

Customer Satisfaction

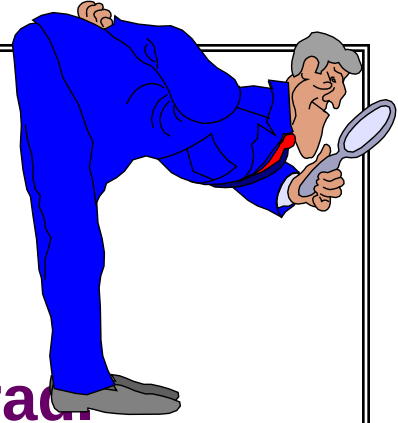
The organization shall monitor information on customer satisfaction and/or dissatisfaction as one of the measurements of performance of the quality management system. The methodologies for obtaining and using this information shall be determined.

The important point here is that :

a) It is the organizations responsibility to determine the methods to be employed.

- Whatever method is employed, it must be meaningful.

Internal Audit



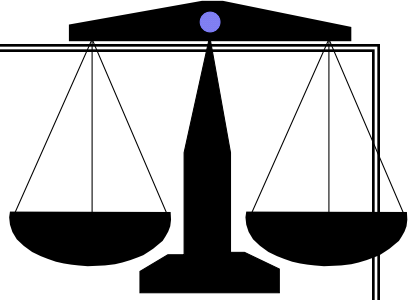
Audits to assess :

a) Conforms to the requirements of this Standarad.

b) Has been effectively implemented and maintained.

The organization shall plan the audit program taking into consideration, the status and importance of the activities and areas to be audited as well as the results of previous audits. The audit scope, frequency and methodologies shall be defined. Personnel other than those who perform the activity being audited shall conduct audits.

Follow – up actions shall include the verification of the implementation of the corrective action, and the reporting of verification results.



Measurement and Monitoring of Product

The organization shall measure and monitor the characteristics of the product to verify that requirements for the product are met. This shall be carried out at appropriate stages of the product realization process.

Evidence of conformity with the acceptance criteria used shall be documented. Records shall indicate the authority responsible for release of product.

Product release and service delivery shall not proceed until all the specified activities have been satisfactorily completed, unless otherwise approved by the customer.

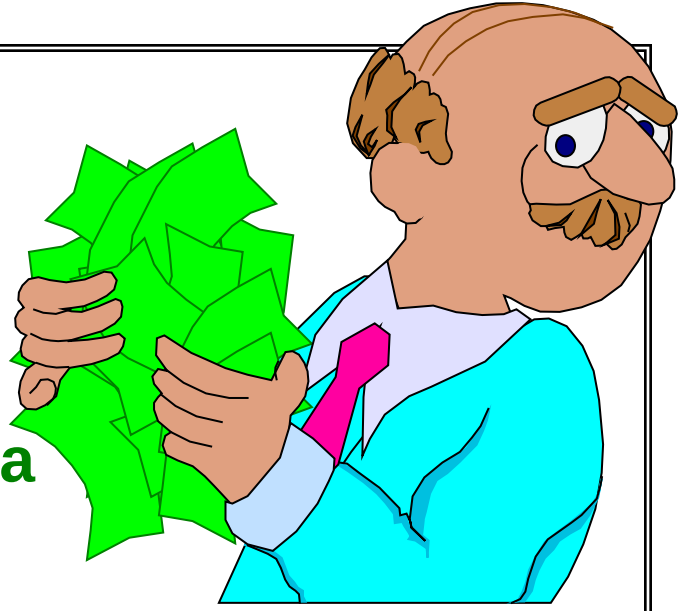
Control of Nonconformity Product

The organization shall ensure that product which does not conform to requirements is identified and controlled to prevent unintended use or delivery. These activities shall be defined in a documented procedure.

When nonconformity product is detected after delivery or use has started, the organization shall take appropriate action regarding the consequences of the nonconformity.

It will often be required that the proposed rectification of nonconforming product be reported for concession to the customer, the end-user, regulatory body or other body.

Analysis of Data



The organization shall analyse this data to provide information on :

a) Customer satisfaction and/or dissatisfaction

b) Conformance to customer requirements

c) Characteristics of processes, product and their trends

d) Suppliers

Improvement

Continual Improvement

The organization shall plan and manage the processes necessary for the continual improvement of the quality management system.

The organization shall facilitate the continual improvement of the quality management system through the use of the quality policy, objectives, audit results, analysis of data, corrective and preventive action and management review.

Corrective Action

The **documented procedure** for corrective action shall define the requirements for :

a) Identifying nonconformities (including customer complaints)

b) Determining the causes of nonconformity

c) Evaluating the need for actions to ensure that non-conformities do not recur

d) Determining and implementing the corrective action needed

e) Recording results of action taken

f) Reviewing of corrective action taken

Preventive Action

The documented procedure for preventive action shall define requirements for :

a) Identifying potential non-conformities and their causes

b) Determining and ensuring the implementation of preventive action needed

c) Recording results of action taken

d) Reviewing of preventive action taken

Steps Involved

Appointing MR

Quality Policy – Cards

Identifying Inclusions & Exclusions

Awareness Programmes for HODs and above

Awareness Programs for scientists, engineers and technical personnel

Documentation programmes

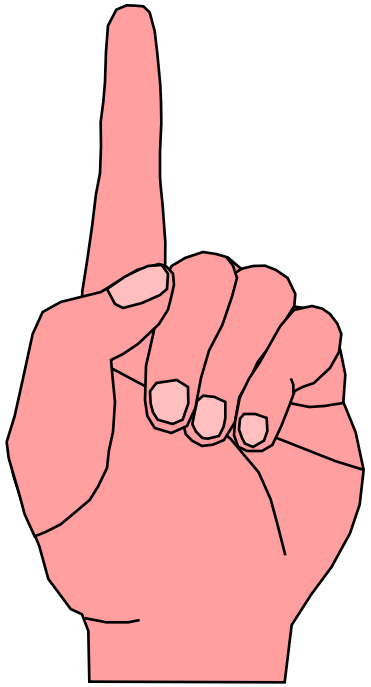
Internal Auditors Training

Preparation of DQMs

Preparation of AQM

Adequacy audit of DQMs

DQMs revised with the comments



Certification

Awarded to

INDIRA GANDHI CENTRE FOR ATOMIC RESEARCH

KALPAKKAM – 603 102, TAMILNADU, INDIA.

FOR ALL LABORATORIES LISTED IN ANNEXURE AND LOCATED AT:
1. INDIRA GANDHI CENTRE FOR ATOMIC RESEARCH, KALPAKKAM.
2. DAE HOSPITAL, DAE TOWNSHIP, KALPAKKAM.

BVQI certify that the Management System of the above organisation has been audited and found to be in accordance with the requirements of the standards detailed below

STANDARD

ISO 9001:2000

SCOPE OF SUPPLY

LISTED IN ANNEXURE

Original Approval Date: **08 March 2006**

Subject to the continued satisfactory operation of the organisation's Management System, this certificate is valid until: **08 March 2009**
To check this certificate validity please call : +91 22 56956300
Further clarifications regarding the scope of this certificate and the applicability of the Management System requirements may be obtained by consulting the organisation.

Date: **25 March 2006**

Certificate Number: **185932**

Ryszard Kaszuba
Chief Executive

NABCB

QM003

MANAGING/ISSUING OFFICE: BVQI (India) Pvt. Ltd., "MARWAH CENTRE" 6th Floor, Opp. Amra Industrial Estate, Krishanlal Marwah Marg, Off Saki Vihar Road, Andheri (East), Mumbai – 400 072, India.

Certification

Awarded to

INDIRA GANDHI CENTRE FOR ATOMIC RESEARCH

BVQI has issued this appendix to the Certificate Awarded to the above named organisation.

Sr. No.	Division	Scope Of Supply
1.	Mechanical Metallurgy Division	Materials Development and Evaluation of Mechanical Properties.
2.	Materials Technology Division	Research & Development in Materials Mechanics, Welding, Hard facing and Metal Forming.
3.	Non-Destructive Evaluation Division	Development of Non-Destructive Evaluation Procedures.
4.	Corrosion Science & Technology Division	Research & Development on Materials Corrosion.
5.	Physical Metallurgy Section	Research & Development In Physical Metallurgy of Advanced Materials and Processes.
6.	Electronics & Instrumentation Division	Design & Development of Electronic Instrumentation and Control Systems.
7.	Computer Division	Management of Computing & Data Communication Facilities.
8.	Quality Assurance Division	Quality Assurance Services for DAE Projects.
9.	Structural Mechanics Laboratory	Validation of Structural Design for Fast Reactor Components.
10.	Chemistry Group	Chemical Characterization of Non-Radioactive Materials.
11.	Radiological Safety Division	Radiation Safety Services and Research & Development in Radiation Physics.
12.	Safety Engineering Division	Fast Reactor Safety Studies and Industrial Safety Surveillance & Training.
13.	DAE Hospital Laboratories	Laboratory & Diagnostic Testing Services for Beneficiaries.
Except for Sr. No. 13, all other Divisions are located at IGCAR, Kalpakkam. The DAE Hospital Laboratories are located in the DAE Township, Kalpakkam.		

Certificate Number: **185932**

MANAGING/ISSUING OFFICE: BVQI (India) Pvt. Ltd., "MARWAH CENTRE" 6th Floor, Opp. Amra Industrial Estate, Krishanlal Marwah Marg, Off Saki Vihar Road, Andheri (East), Mumbai – 400 072, India.

BUREAU VERITAS
Certification

Certification

Awarded to

INDIRA GANDHI CENTRE FOR ATOMIC RESEARCH

Kalpakkam – 603 102, Tamilnadu, India.

FOR ALL LABORATORIES LISTED IN ANNEXURE AND LOCATED AT

1. **Indira Gandhi Centre for Atomic Research, Kalpakkam.**
2. **DAE Hospital, DAE Township, Kalpakkam.**

Bureau Veritas Certification (India) Private Limited certify that the Management System of the above organisation has been audited and found to be in accordance with the requirements of the standard detailed below

STANDARD

ISO 9001:2008

SCOPE OF SUPPLY

LISTED IN ANNEXURE.

PERMITTED EXCLUSION(S)

7.3 – Design and development for all departments except for Electronics and Instrumentation.

Original Approval Date: **08 March 2006**

Subject to the continued satisfactory operation of the organisation's Management System, this certificate is valid until: **07 March 2012**

To check this certificate validity please call: +91 22 6695 6300

Further clarifications regarding the scope of this certificate and the applicability of the Management System requirements may be obtained by consulting the organisation.

Certificate Number: **IND96197** *Date:* **14 April 2009**

R. K. SHARMA
Director

NABCB
QM 003

Certification / Managing Office Address: "Marwah Centre" 6th Floor, Krishanlal Marwah Marg, Opp. Ansa Industrial Estate, Off Saki Vihar Road, Andheri (East), Mumbai – 400 072, India.

BUREAU VERITAS
Certification

Certification

Awarded to

INDIRA GANDHI CENTRE FOR ATOMIC RESEARCH

Kalpakkam – 603 102, Tamilnadu, India.

FOR ALL LABORATORIES LISTED IN ANNEXURE AND LOCATED AT

1. **Indira Gandhi Centre for Atomic Research, Kalpakkam.**
2. **DAE Hospital, DAE Township, Kalpakkam.**

Bureau Veritas Certification (India) Private Limited has issued this Annexure to the Certificate Awarded to the above named organisation.

ANNEXURE

S. NO.	DIVISION	SCOPE OF SUPPLY
1	Mechanical Metallurgy Division	Materials Development and Evaluation of Mechanical Properties.
2	Materials Technology Division	Research & Development in Materials Mechanics, Welding, Hard facing and Metal Forming.
3	Non-Destructive Evaluation Division	Development of Non-Destructive Evaluation Procedures.
4	Corrosion Science & Technology Division	Research & Development on Materials Corrosion.
5	Physical Metallurgy Section	Research & Development in Physical Metallurgy of Advanced Materials and Processes.
6	Electronics & Instrumentation Division	Design & Development of Electronic Instrumentation and Control Systems.
7	Computer Division	Management of Computing & Data Communication Facilities.
8	Quality Assurance Division	Quality Assurance Services for DAE Projects.

Certificate Number: **IND96197** *Date:* **14 April 2009**

R. K. SHARMA
Director

Certification / Managing Office Address: "Marwah Centre" 6th Floor, Krishanlal Marwah Marg, Opp. Ansa Industrial Estate, Off Saki Vihar Road, Andheri (East), Mumbai – 400 072, India.

Benefits Derived

- Calibration - Accurate Results, Confidence
- Documentation - Systematic Approach
- Third Party Check - Checking with other labs
- Periodic Auditing
- Confirming to Standards
- Quality Objectives - Continual Improvement
- Personal Interaction

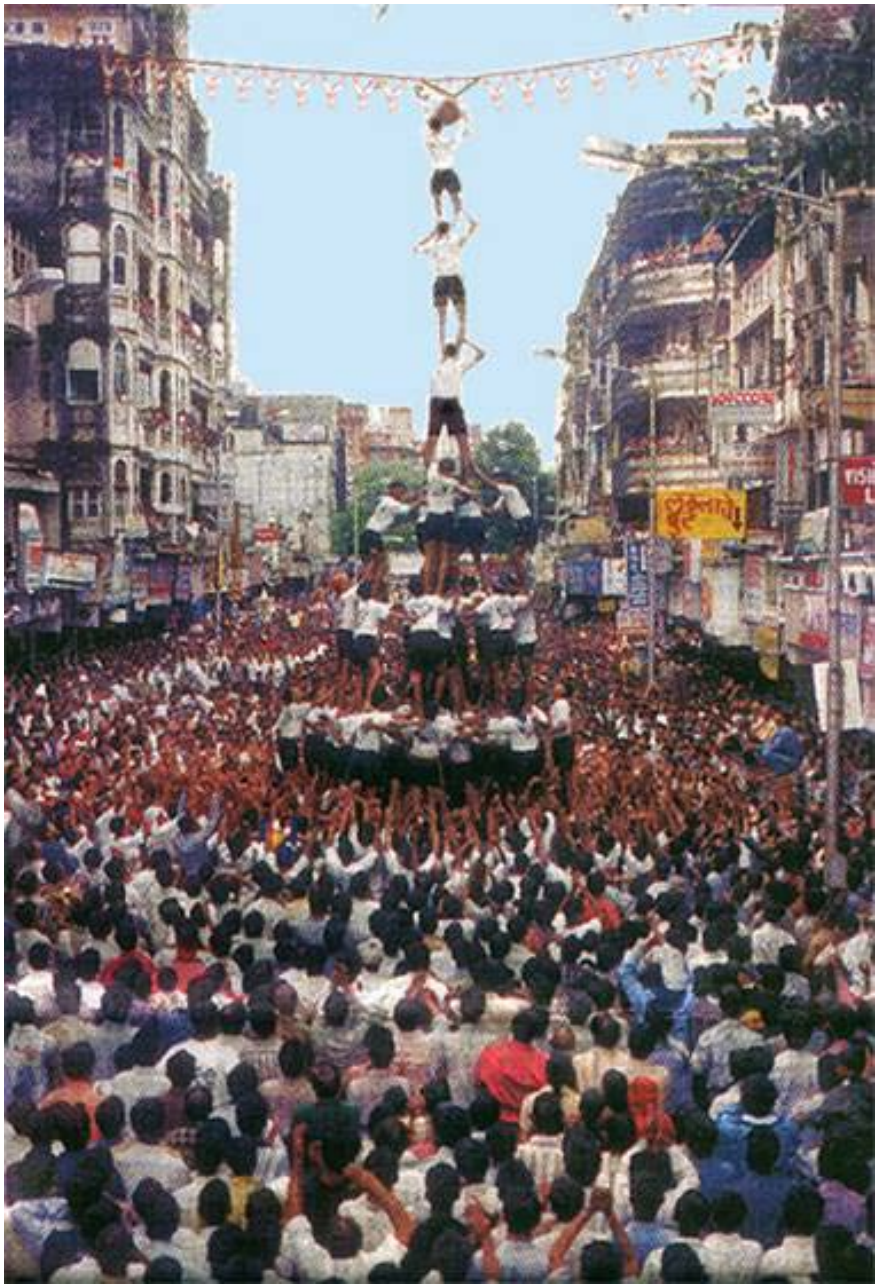
ISO 9001: 2000 for CISF

CISF, Kalpakkam unit Ceritified by Integrated Quality Certification (IQC) on 17.6.2008

IGCAR Certified on March 6, 2006 by BVQI

ISO Team

- **Working Group Members**
- **Auditors**
- **Heads of Divisions**
- **Management**



Thank you