Quality Management in Public Health Facilities

An Implementation Handbook

NATIONAL RURAL HEALTH MISSION
राष्ट्रीय ग्रामीण स्वास्थ्य मिशन

NHSRC

Quality Management in Public Health Facilities

An Implementation Handbook

National Health Systems Resource Centre
Technical Support Institution with National Rural Health Mission
Ministry of Health & Family Welfare
Government of India

DISCLAIMER

For reference to ISO 9001:2008 standards, original publication of Bureau of Indian Standards (BIS) is required to be referred to.

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Abbreviations

A&E	Accident and Emergency
Addl. MR	Additional Medical Representative
AERB	Atomic Energy Regulatory Board
ALOS	Average Length of Stay
AMC	Annual Maintenance Contract
ANC	Antenatal Care
ANM	Auxiliary Nurse Midwife
BCC	Behaviour Change Communication
BCG	Bacillus Calmette-Guérin
BHT	Bed Head Ticket
BIS	Bureau of Indian Standards
BMW	Bio Medical Waste
BOR	Bed Occupancy Rate
BP	Blood Pressure
BPL	Below Poverty Line
BTR	Bed Turnover Rate
CDMO	Chief District Medical Officer
CHC	Community Health Centre
CMC	Christian Medical College
CMC	Continuous Maintenance
CMHO	Chief Medical Health Officer
CMO	Chief Medical Officer
COM	Complying
CQI	Continuous Quality Improvement
CSSD	Central Sterile Supply Department
CT SCAN	Computed Tomography
DCI	Document Control In Charge
DDHS	Deputy Director Health Services
DG	Digital
DMN	Document Modification Note
DMS	Deputy Medical Superintendent
DYMR	Deputy Management Representative
EMOC	Emergency Obstetric Care
EPBAX	Electronic Private Branch Automatic Exchange
ESS	Employee Satisfaction Survey
FFH	Family Friendly Hospital
FGD	Focus Group Discussion

FIFO	First In First Out
FIR	First Information Report
FRU	First Referral Unit
HMIS	Hospital Management Information System
HOD	Head of the Department
HR	Human Resource
ICU	Intensive Care Unit
IEC	Information, Education and Communication
IPD	In-Patient Department
IPHS	Indian Public Health Standards
IQA	Internal Quality Auditor
ISO	International Organisation of Standardisation
IUD	Intra Uterine Device
IUGR	Intrauterine Growth Restriction
IV	Intravenous
JCAHO	Joint Commission on Accreditation of Healthcare Organisation
JSY	Janani Suraksha Yojana
KPI	Key Performance Indicator
KRA	Key Result Access
LAMA	Laboratory Asset Management Assessment
LAN	Local Area Network
LBW	Low Birth Weight
LCD	Liquid Crystal Display
LSCS	Lower Segment Caesarian Section
MD	Mission Director
MMD	Measuring and Monitoring Devices
MO	Medical Officer
MOI/c	Medical Officer Incharge
MR	Management Representative
MRM	Management Review Meeting
MTP	Medical Termination of Pregnancy
NABH	National Accreditation Board of Hospitals and Healthcare
NABL	National Accreditation Board of Laboratories
NACO	National AIDS Control Organisation
NC	Non-Conformity
NGO	Non-Government Organisation
NHSRC	National Health Systems Resource Centre
NICU	Neonatal Intensive Care Unit
NOK	Next of Kin
NRHM	National Rural Health Mission

NSSO	National Sample Survey Organisation
NSV	No Scalpel Vasectomy
OBG	Obstetrics and Gynaecology
OHP	One Head Projector
OPD	Out-Patient Department
OPV	Oral Polio Vaccine
OT	Operation Theatre
PCPNDT	Pre-Conception and Pre-Natal Diagnostic Techniques
PDCA	Plan Do Check Act
PERT	Programme Evaluation and Review Technique
PGI	Post Graduate Institute
PHC	Primary Health Centre
PNDT	Pre-Natal Diagnostic Techniques
PO	Purchase Order
PPH	Primary Postpartum Haemorrhage
PPS	Patient Perception Survey
PSS	Patient Satisfaction Survey
PTR	Patient Termination Record
QMS	Quality Management System
RCH	Reproductive and Child Health
RKS	Rogi Kalyan Samiti
RMO	Resident Medical Officer
RTI	Respiratory Tract Infection
SBA	Small Business Administration
SGA	Small Group Activity
SMART	Specific, Measurable, Achievable, Realistic, Time
SOP	Standard Operating Procedures
SPC	Statistical Process Control
SSI	Surgical Sit Injection
STG	Standard Treatment Guidelines
STP	Standard Treatment Protocol
SWOT	Strength Weaken Opportunity Threat
TOR	Terms of Reference
TQM	Total Quality Management
TSSU	Theatre Sterile Supply Unit
USG	Ultra Sonography
UT	Union Territory
UNICEF	The United Nations Children Fund
USA	United States of America
UTI	Urinary Tract Infection
WHO	World Health Organization

Glossary

Action plan	Specific actions that respond to short- and longer-term strategic objectives
Alignment	The consistency of plans, processes, information, resource decisions, actions, results and analysis to support key organisation-wide goals.
Analysis	An examination of facts and data to provide a basis for effective decision (s).
Approach	It includes the appropriateness of the methods to the Item requirements and to the organisation's operating environment, as well as how effectively the methods are used.
Audit	Evidence gathering process to evaluate how well audit criteria are met
Benchmarks	The processes and results that represent best practices and performance for similar activities, inside or outside an organisation.
Capability, workforce	See "workforce capability."
Capacity, workforce	See "workforce capacity."
Collaborators	Those organisations or individuals who cooperate with the main/leading organisation to support a particular activity or event or who cooperate on an intermittent basis when short-term goals are aligned.
Conformity	The fulfilment of a requirement.
Control plan*	Documented description of the systems and processes required for controlling product.
Core competencies	These are the organisation's areas of greatest expertise and are those strategically important capabilities that are central to fulfilling your mission or provide an advantage in your marketplace or service environment.
Correction	Any action taken to eliminate a non- conformity
Corrective action	Action to eliminate the cause of a detected non-conformity or other undesirable situation.

Customer	The actual and potential users of organisation's services or programs (referred to as "health care services" in the Health Care Criteria).
Customer engagement	Patients' and/or stakeholders' investment in the commitment to organisation and health care service offerings.
Customer satisfaction	Customer's perception of the degree to which the customers' requirements have been fulfilled.
Cycle time	The time required to fulfil commitments or to complete tasks.
Defect	The non-fulfilment of a requirement, related to an intended or specified use.
Document	Information and its supporting medium.
Effectiveness	Extent to which planned activities are realized and planned results achieved.
Efficiency	Relationship between the results achieved and the resources used.
Empowerment	Giving people the authority and responsibility to make decisions and take appropriate actions.
Engagement, customer	See "customer engagement."
Engagement, workforce	See "workforce engagement."
Error Proofing	Use of product and manufacturing process design and development features to prevent manufacture of nonconforming products
Ethical behaviour	It refers to actions of an organisation to ensure that all its decisions, actions, and stakeholder interactions conform to the organisation's moral and professional principles.
Goals	Future condition or performance level that one intends to attain.
Governance	The system of management and controls exercised in the stewardship of the organisation.
Health care services	Services delivered by the organisation that involves professional clinical/medical judgment, including those delivered to patients and those delivered to the community.
High-performance work	Work processes used to systematically pursue ever-higher levels of overall organisational achievements.

How	Systems and processes that an organisation uses to accomplish its mission requirements.
Innovation	Process of making meaningful changes to improve health care services, processes, or organisational effectiveness and to create new value for stakeholders
Integration	The harmonisation of plans, processes, information, resource decisions, actions, resultsand analyses to support key organisation-wide goals.
Internal audit	Audit carried by in house authorities to evaluate the compliance of implemented Quality Management Set up.
Key	The major or most important elements or factors, those that are critical to achieving intended outcome.
Key Performance Indicator (KPI)	Metric or measure used to quantify and evaluate progress made relative to the objectives wished to achieve.
Knowledge assets	They are the accumulated intellectual resources of the organisation.
Laboratory*	Facility for inspection, test or calibration that may include, but is not limited to, chemical, metallurgical, dimensional, physical, electrical, reliability testing.
Leadership system	Process of exercising the leadership formally and informally, throughout the organisation.
Learning	The new knowledge or skills acquired through evaluation, study, experience, and innovation.
Measures and indicators	Numerical information that quantifies input, output, and performance dimensions of processes, programs, projects, services, and the overall organisation outcomes.
Mission	The overall function of an organisation. It may define patients, stakeholders, or markets served; distinctive or core competencies; or technologies used.
Non-conformity	The non-fulfilment of a requirement.
Partners	Key organisations or individuals who are working in concert with the main or leading organisation to achieve a common goal or to improve performance.
Patient	The person receiving health care services including preventive, promotional, acute, chronic,rehabilitative care and all other services in the continuum of care.

Performance	Outputs and outcomes obtained from processes, health care services, and patients and stakeholders that permit evaluation and comparison relative to goals, standards, past results, and other organisations.
Performance excellence	Integrated approach to organisational performance management resulting in delivery of ever-improving value to patients and stakeholders, contributing to improved health care quality and organisational sustainability, improvement of overall organisational effectiveness and capabilities as a health care provider and organisational and personal learning.
Performance Projections	Estimates of future performance.
Predictive maintenance*	Activities based on process data aimed at the avoidance of maintenance problems by prediction of likely failure modes.
Preventive action	Action to eliminate the cause of a potential non-conformity or other undesirable potential situation
Preventive maintenance*	Planned action to eliminate causes of equipment failure and unscheduled interruptions to production, as an output of the manufacturing process design.
Process	Set of activities with the purpose of producing a health care service for patients and stakeholders within or outside the organisation. In the Baldrige Scoring System, process achievement level is assessed.
Productivity	The term “productivity” refers to measures of the efficiency of resource use.
Purpose	The fundamental reason of existence of an organisation.
Quality	Degree to which a set of inherent characteristics fulfils the requirements.
Quality assurance	Part of quality Management, focussed in providing confidence that quality requirements will be fulfilled.
Quality control	Part of Quality Management, focussed on fulfilling quality requirements.
Quality Improvement	Part of Quality Management, focussed on increasing the ability to fulfil quality requirements.
Quality management	Co-ordinated activities to direct and control an organisation with regard quality.
Quality manual	Document specifying the Quality Management System of an organisation.
Quality objective	Something sought or aimed for, related to quality.

Quality plan	Document specifying which procedures and associated resources shall be applied by whom and when, to a specific project, product, process or contract.
Quality policy	Overall intentions and direction of an organisation related to quality, as formally expressed by top management.
Record	Document stating results achieved or providing evidence of activities performed.
Results	The outputs and outcomes achieved by an organisation and evaluated on the basis of current performance; performance relative to appropriate comparisons; the rate, breadth, and importance of performance improvements; and the relationship of results measures to key organisational performance requirements.
Segments	It's the part of an organisation's overall patient, stakeholder, market, health care service, or workforce base.
Stakeholders	Are the marketplace benefits that exert a decisive influence on an organisation's likelihood of future success.
Strategic challenges	Those pressures that exert a decisive influence on an organisation's likelihood of future success.
Strategic objectives	They are the organisation's articulated aims or responses to address major change or improvement, competitiveness or social issues, and health care advantages.
Sustainability	It's the organisation's ability to address current organisational needs and to have the agilityand strategic management to prepare successfully for future organisational, market, and operating environment.
Systematic	The approaches that are well ordered, repeatable, and use data and information making learning possible.
Top management	Person or group of people who directs and an organisation, at the highest level
Trends	The numerical information that shows the direction and rate of change for an organisation'sresults. Trends provide a time sequence of organisational performance. Examples of trends called for by the Health Care Criteria include data related to health care outcomes and other health care service performance; patient, stakeholder, and workforce satisfaction and dissatisfaction results
Validation	A process which confirms the requirements which define an intended use or application have been met.

Value	The perceived worth of a product, process, asset, or function relative to cost and to possible alternatives.
Values	The guiding principles and behaviours that embody how the organisation and its people are expected to operate. Values reflect and reinforce the desired culture of an organisation. Examples of values might include demonstrating integrity and fairness in all interactions, exceeding patient and stakeholder expectations, valuing individuals and diversity, protecting the environment, and striving forperformance excellence every day.
Vision	The desired future state of organisation describing where the organisation is headed, what it intends to be, or how it wishes to be perceived in the future.
Voice of the customer	The process of capturing patient- and stakeholder-related information which may include gathering and integrating various types of customer data, such as survey data, focus group findings, and complaint data, that affect patients' and stakeholders' relationship and engagement decisions.
Work force	All those people actively involved in accomplishing the work of the organisation, including paid employees, independent practitioners not paid by the organisation, volunteers, and health team leaders, supervisors, and managers at all levels.
Work force capability	The organisations' ability to accomplish its work processes through the knowledge, skills, abilities, and competencies of its people
Work force capacity	The organisations' ability to ensure sufficient staffing levels to accomplish its work processes and successfully deliver health care services to patients and stakeholders, including the ability to meet varying demand levels.
Work system	Refers to the process of accomplishment of work in the organisation. It involves workforce, key suppliers and partners, your contractors, collaborators, and other components of the supply chain needed to produce and deliver health care services and your business and support processes
Workforce engagement	The extent of workforce commitment, both emotional and intellectual, to accomplish the mission and vision of the organisation.
Work process	They are the most important internal value creation processes and might include health care service design and delivery, patient support, supply chain management, etc.

* Source:ISO/TS 16949:2002

Introduction

This handbook is best used as a training manual for healthcare functionaries and hospital management to assist them in developing strong management practices for effective and efficient healthcare services to the community through public health facilities.

The National Rural Health Mission (NRHM) thrust is on strengthening public health systems. Considerable investment is being made under NRHM in to improve health infrastructure and human resources. By investing a bit more in a Quality Management System (QMS), the department would be ensuring outcomes in return for these investments. The experience of the public health sector has been that there is no appreciable increase in patient satisfaction, or in health outcomes. The main reasons for this have been the lack of a systems approach - as one or the other essential component of the system is missing, or there is a lack of motivation and leadership. Putting a QMS in place is likely to ensure that these constraints are addressed in parallel to the major additional investments being made.

Definition of quality standards, in terms of services to be delivered and investments in inputs, is adequately defined by the Indian Public Health Standards (IPHS). The IPHS defines the minimum infrastructure, human resources, equipment and supplies that should be in place for a given health facility type. These are transparent standards and the public health facility is committed to reaching these standards. However, both in infrastructure and in human resources, the system has to face severe constraints and it would take time and sustained effort at the state and district levels to reach the IPHS. But in the meantime whatever service is being provided and whatever inputs are available should be of quality. Improved public and provider satisfaction and the improved effectiveness of care, depends a lot on soft factors - for example, the behaviour of the staff towards patients, the establishment of a system of regular clinical audits etc. which are not contingent upon inputs, but which are nevertheless of great importance to public satisfaction. These become easier if a QMS is in place. Even if all the infrastructure and human resource is in place, these “soft factors” would need to be addressed and some of them could be much harder than getting the infrastructure required.

Under the Reproductive and Child Health (RCH) programme, quality assurance committees have been set up in many states. A quality check protocol has been

developed. This is in the form of a check list that identifies the gaps in service delivery and in some of the processes leading up to it. It then segregates the gaps into three levels - what can be managed within the facility, what needs district support to manage and what needs state level intervention to manage.

This process could seamlessly flow into a QMS which would use the check list findings as one of the inputs to identify the gaps that need to be corrected. What the QMS would do, is that by introducing the documentation needed, it would make visible the process planned to correct the gap - not as a one-time effort (e.g. toilets cleaned out, once they are found to be dirty), but as a system in place, and the evidence that the gap is being addressed in a sustainable way. (e.g., well drafted outsourcing contract, well managed by a contract management group ensuring that toilets are always kept clean).

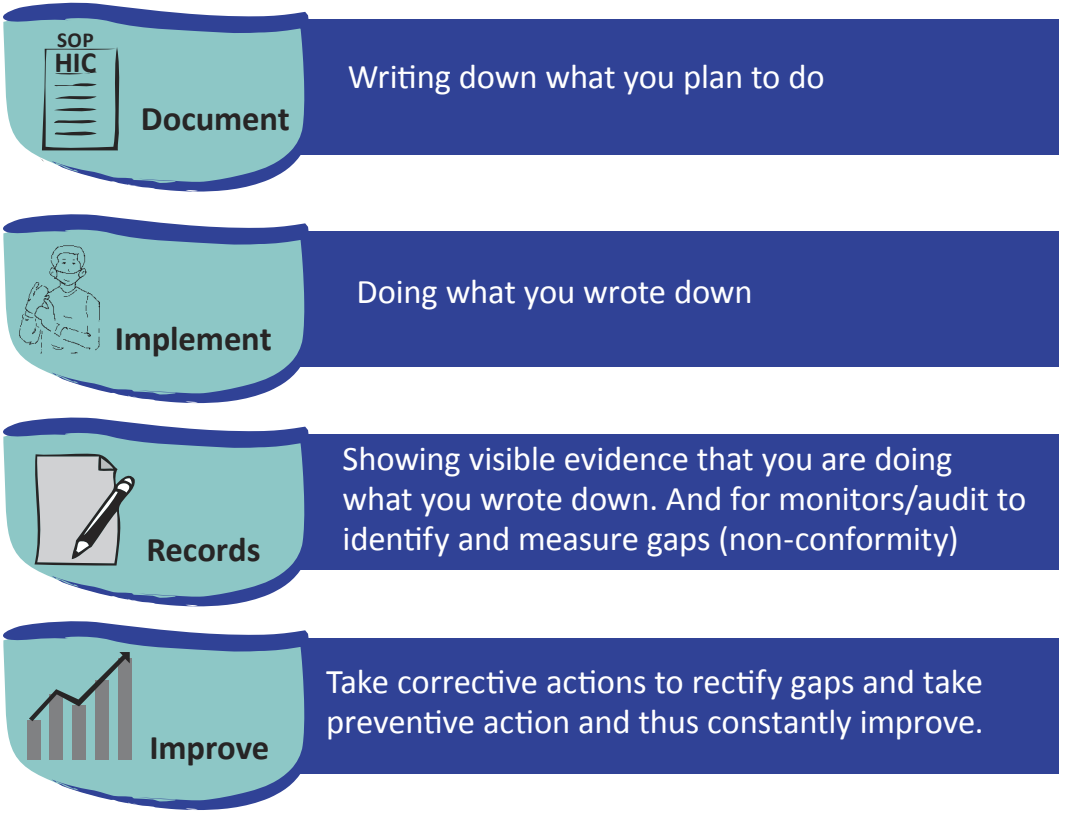
The contents of this manual shall guide a public healthcare facility to understand the principles of QMS, which may lead them to a formal certification against a formal system such as ISO 9001 standards. It will also help them to understand specific IPHS requirements for aligning core healthcare processes and support processes for enhancing patients' satisfaction for the health services provided, through public healthcare facilities.

- The accrediting agency which does the Quality Audit and certification should have no links with the management and should have no links with consulting firms that provide management consultancy or consultancy in any form to that hospital. Not doing so, undermines the external nature of this process.
- The process should be affordable.
- The standards should be transparent – made known to the hospital owners before the process starts – unless it is an owner defined standard.
- It should be feasible for different levels of inputs and different service packages. All public hospitals cannot provide the same service packages but they can have quality in what they provide. This must be respected and built upon. A fair proportion of hospitals which make the effort should be able to get the certification within a reasonable period of time.

These guidelines are generic in nature and would have to be customised for public health facilities. This would empower the healthcare personnel in public healthcare delivery system to implement and maintain a QMS and continually improve its effectiveness.

It has been the concerted effort of the Quality Improvement Division of National Health System Resource Centre (NHSRC) team to keep the style of the handbook simple at the best, so that staff at all level understand, comprehend and apply the principles of QMS at their work place. The chapters have been arranged in such a way that as you proceed with reading sequentially, the concept of QMS gets demystified and clarity is attained for implementation. At the same time, we have also kept in mind that this book functions as a help book - whenever, the reader intends to cross-check a quality related topic. The reader is also walked through the relevant clauses of ISO 9001 standards in the boxes juxtaposed to the main narrative. Also mirrored are the explanations describing what a particular clause means in a hospital setting. Since these ISO standards have international recognition, they have been quoted verbatim (of course after obtaining permission from the competent bodies).

The core process of a QMS consists of constant "Process Management" which has the following steps:



QMS provides scope for an *external* process of certification and accreditation so that the achievement of quality is independently assessed and declared. This is in addition to periodic internal quality audit processes.

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CHAPTER 1

Why this handbook?

Chapter 1

Why this handbook?

The purpose of this handbook is to empower all personnel working in the Public Health System to implement a formal system of Quality Management System (QMS) at their work place, so that health facilities not only provide a range of services which are supposed to have been provided, but also ensure that the services meet a minimum standard of quality. The book provides guidelines to small and medium size healthcare units – ranging from primary health centres, to district level hospitals – for successfully implementing a QMS. The book is meant to enable healthcare personnel – be it lab technicians, nurses or doctors – to be consistent and work towards continual improvement, to get the best out of available resources and platforms provided by ISO 9001:2008, whose standards have been used to leverage this.

Advantages of having a formal system of Quality Management System

- Assured level of healthcare
- Enhancing patient satisfaction
- Optimum utilisation of resources
- Employee empowerment
- Enhancing equity & eliminating gender bias

All healthcare facilities follow some management procedures and instructions for delivery of their services to patients. Most have evolved over years and aspire to be good. However, such processes become stagnant and at times, function as impediments in the smooth functioning of the organisation. There is a requirement of looking at the processes within the hospitals in order to deliver the expected level of hospital care which is consistent, irrespective of the socio-economic status, caste and religion of service providers and as well as of patients.

In the absence of QMS, the problems of wasteful exercises, re-work and patient dissatisfaction precipitate.

A formal QMS in place, assesses the adequacy of hospital processes, identifies the gaps after analysing their root cause, and takes action to eliminate such causes and help in future planning.

The Indian Public Health Standards (IPHS) and its relationship to QMS at Public Health Facilities:

What is IPHS?

With the launch of the National Rural Health Mission (NRHM), the Government of India entered into an era of financing states to strengthen their public health systems. One key element of this strengthening has been the laying down of a minimum level of service guarantees that each facility type would provide, and their norms. To provide a quality dimension to these norms, it created the Indian Public Health Standards (IPHS), which specifies the minimum infrastructure norms that the government aims to provide in terms of physical infrastructure, human resources and skills, equipment, supplies and services. The IPHS also specifies the services that each facility should provide. The IPHS drives forward rationalisation of infrastructure and human resources at a facility, which is essential to ensure quality of services at the health facility. The IPHS also represents a policy commitment to provide the financial resources required for the facility to function with adequate infrastructure, human resources and supplies.

What is Quality?

The word 'quality' has different connotations for different people. ISO 8402-1986 standards defines quality as *'the totality of features and characteristics of a product or service that bears its ability to satisfy stated or implied needs.*

The Joint Commission on Accreditation of Healthcare Organisation (JCAHO) (USA) defines quality of health services as *"the degree to which health services for individuals and population increases the likelihood of the desired health outcomes and are consistent with current professional knowledge."*

Objectives of this Handbook

On completing study of this handbook, the reader should have the knowledge and skills needed to:

- explain what a QMS is, what its essential components are, and why it is needed for the public health system.
- Define core processes of patient care and how to identify gaps and maintain quality in these.
- Know what documents are essential to maintain quality in a hospital setting and how to put it in place. (documentation requirements)
- Know how to define management responsibilities and how to measure performance against these responsibilities.
- Define core processes of Resource Management especially human resources and infrastructure management, procurement and logistics and how to identify the gaps and maintain quality in this.
- Learn how processes are mapped, gaps and their causes are identified and measures for improvement are taken.
- Know the relevant ISO 9001 systems clauses and its application to a healthcare/hospital setting.

Need for Quality in the Public Health System

Traditionally, the quality of health services provided by the Public Health System has been associated with sub-optimal satisfaction. Until a few years ago, most people in healthcare were convinced that higher quality is linked to higher costs. If people wanted better healthcare, they would be spending more. Better quality was equated with new technologies, new medicines and more staff. However, this is not always so. Good clinical skills and patient care, regard for patient safety and their rights, and efforts to make their stay comfortable is often possible with optimum inputs.

The introduction of a QMS ensures minimisation of medical errors and helps in enhancing patient/service seeker's safety. Eliminating service delivery time lags and inefficiencies also increases patient-handling capacity and flow, which decreases wait times and potentially harmful delays in care. The result is a safer, more efficient, cost-effective system with better satisfied patients and healthcare service providers.

Market forces, such as medical tourism and insurance and maximisation of profits have accelerated the demand for quality in healthcare services in the private sector. However, in the Public Health facility, the need for quality is driven by the commitment of the government to provide universal access to quality care. Health equity requires that even the poor have access not just to any healthcare facility, but healthcare which conforms to a basic minimum standard of quality.

Quality has the following perspectives in a healthcare facility environment, which are described below:

Patient's Perspective:

- Effective treatment without delay
- Availability of service, medicines and diagnostics
- Short waiting time for OPD registration, consultation, admissions and diagnostic procedures
- Clean beds and surroundings
- Comfortable stay, supportive and friendly environment
- Reduced errors and patient safety
- Affordable care
- Availability of important information and display Citizen's Charter
- Safety, security and dignity

Service Provider's Perspective:

- Technical competence
- Reduced delay in service delivery
- Positive and innovation promoting working environment
- Work systems including allocation of responsibilities and authorities
- Support services including upkeep of equipment essential for care
- Availability of medicines, furniture, linen and equipment
- Satisfaction, well-being and motivation

States' Perspective:

- Staff has knowledge and skill to manage hospital services
- Better access and optimum output
- Satisfied patients
- Satisfied customers
- Optimum utilisation of resource
- Avoidance of wastage
- Meeting performance indicators
- Meeting National and State health programme goals/objectives

Developing Quality Management Structure in Hospitals

The main enablers for developing a QMS for public hospitals are:

Policy Framework: A broad and enabling policy framework, which supports such QMS initiative, with focus on the most critical areas of performance in our socio-economic context, which also takes into the account, the requirements of professional and statutory bodies to the benefit of the users of health facilities.

Accreditation Strategy: A strategy of accreditation to ensure that areas of critical importance to the delivery of quality health services are evaluated by appropriate methods that are objective, valid, reliable and replicable.

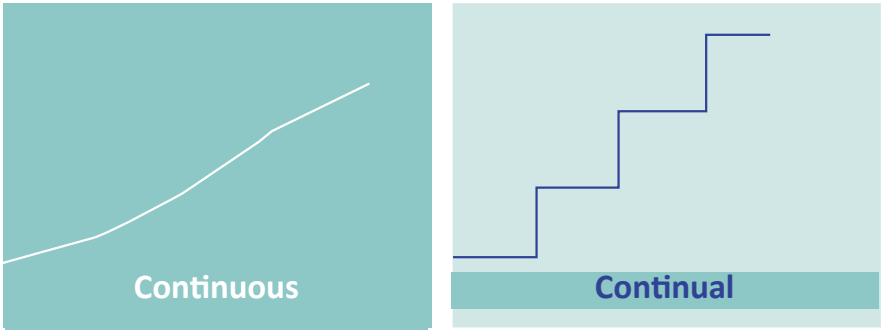
Process of Assessment: The process of internal and external assessment should have significant benefits for healthcare institutions and its users in terms of identifying the gaps in the existing system and planning action to fill those gaps.

Standards of Care: Standards of excellence should assure the public of ethical, humane, equitable, rational and competent care.

Continual Improvement: Accreditation should have its focus on continuous improvement in the organisational and clinical performance of health services and not just in the achievement of a certificate or award or merely by assuring compliance with the minimum acceptable standards.

The point to be noted here is that in the continuous process, the efforts are on-going without any time/phase being allocated for consolidation, whereas in the continual process, you improve a notch, sustain the improvement and then go to next stage, sustain and again improve and so on. Continual improvement is defined as a recurring activity to increase the ability to fulfill requirements.

This is graphically presented below:



Model questions and review of ISO 9001:2008

1. Please visit your hospital critically and identify three problem areas in your hospital. (Please mention name of the department and short statement of the problem, which were noticed).
2. Identify three improvements in your hospital, which are expected to happen after implementation of the Quality Management System.
3. Describe your understanding of 'continual improvement'. How does it differ from 'continuous improvement'?

CHAPTER 2

Implementation of Quality Programme at Public Health Facility

Chapter 2

Implementation of Quality Programme at Public Health Facility

1. Sensitisation of stakeholders

Doctors, nurses, paramedical staff, administrative staff, class IV staff, patients, visitors, community, out-sourced service providers, suppliers, district administration, members of Rogi Kalyan Samiti (RKS)

- Sensitisation workshop
- Formal training
- Information Education Communication (IEC) Strategy
- Appropriate Behaviour Change Communication (BCC) strategy

2. Constituting Quality Committee

- Appointment of MR, DCI, Training Incharge, IQA Incharge and Addl. MR
- Facility In-charge – Civil Surgeon, Medical Superintendent, MO I/C
- In-charge of Key Departments/Services (Dietician, Security Services, Central Strike Supply Department (CSSD), etc.)
- Matron + one nurse/Auxiliary Nurse Midwife (ANM)
- Pharmacist
- Representative(s) of class IV staff

3. Defining quality objectives

Health facility needs to fix Specific, Measurable, Achievable, Realistic, Time bound (SMART) quality objectives

Setting the time-frame – Developing activity chart/ (Programme, Evaluation Review Technique (PERT) chart for the implementation of QMS

4. Expected improvement in the first year

Please define measurable and objective parameters which are stretched and likely to be achieved at the end of one year. This may emanate from the Quality objectives. It could also be simple, such as accreditation of the hospital as a 'Family Friendly Hospital' (FFH).

5. Need of technical assistance

The health facility would have to make an objective assessment, as to whether it needs any external support in its path of quality. If yes, then the quantum of support would have to be defined – self implementation model/ full time 'on-site' support/supportive supervision model. External support could be from the State/District Quality Team, NHSRC either through a consulting organisation or direct umbrella supervision.

6. 'As-Is' study and gap analysis

The first step in the implementation of QMS would be a thorough study of the hospital's infrastructure, and equipment under taken by the health facility while, human resources and processes should be followed at the hospital. For this study, the following documents should be referred to:

- State Government orders
- Guidelines and orders issued by the Government of India
- IPHS
- NRHM/RCH Guidelines
- Standard Treatment Guidelines

- Standard Treatment Protocols
- Essential Drug List
- Recommendations contained in standard medical textbooks
- Recommendations of expert groups
- WHO recommendations

7. Categorisation of gaps

All gaps should be categorised into the following three groups:

- Gaps which can be actioned and closed at the level of Facility In-charge/ Superintendent/Civil Surgeon
- Gaps which require support from other district level functionaries
- Gaps which can be closed after intervention of state level functionaries

8. Action planning

After identification of gaps, the hospital should plan the actions which would be required to be undertaken for closure of gaps. Such action planning should be reviewed periodically.

9. Calibration of equipment

Health facilities use a range of equipment depending upon the size of the hospital. At one end of spectrum, it would be a Blood Pressure (BP) instrument and weighing scale at the level of the sub-centre, to high technology equipment/instruments, such as CT Scan, Echocardiography, Defibrillator, etc. These equipment are required to calibrated, so as to ensure their accuracy.

10. Conformity to relevant rules and regulations

Hospitals/Health facilities are governed by relevant rules and regulations, as applicable to any building, organisation service or industry. In addition, the hospitals services are also guided by rules and

statutes, as relevant to Professional bodies (e.g., Indian Medical Council, Indian Nursing Council, Indian Dental Association), Drugs & Cosmetics Act, etc. The list of Rules & Regulations as applicable to a hospital, are given in Table 2 (on page 47).

11. Developing Standard Operating Procedures (SOP)

After completion of gap-analysis study, each department/ sub-department/process owner is required to develop SOPs, which would imbibe the 'Do's and Don'ts' for the department. The development of SOPs is always through a consultative process.

12. Training and Plan

At most locations, it has been observed that the knowledge and skill required for the implementation of QMS are woefully inadequate at all level of staff. Hence, the training of staff needs to be planned in a systemic way.

Training Plan - The initial activity would be the planning of training for the hospital staff and other stakeholders

Why are SOPs important?

i. They remove subjectivity in decision making.
ii. SOPs provide uniform do's and don'ts, irrespective of change in individual (transfer-out)
iii. SOPs strength on the system.
iv. Errors are minimised.
v. Uniform quality in service/product is maintained.

like RKS members. The development of the training plan should be based on *training needs assessment, which is used* to identify the gaps in knowledge and skill of hospital staff, specially with regard to quality.

The training plan requires the approval of the Management Representative (top Management – Civil Surgeon/Chief District Medical Officer (CDMO)/Chief Medical and Health Officer (CMHO), Medical Superintendent, Deputy Medical Superintendent,), before its implementation. For clinical processes, the faculty who is to impart the training, may be provided by the concerned hospital. However, in the event of non-availability of such faculty in the hospital, the same should be organised from other institutions. Care must be taken to ensure that the training plan covers all the relevant topics related to Total Quality Management (TQM), quality manual, procedures and work instructions. A detailed record of the training i.e., carrying the name and signature of the participants, topics discussed, name and signature of the faculty, the duration of the programme evaluation of the issues for each programme should be maintained. Training should be conducted on the following topics:

- Awareness about QMS
- TQM, improvement initiatives including Small Group Activity (SGA), quality improvement exercise etc.
- Internal Auditors Training for QMS for selected personnel
- Quality Manual
- Quality system procedures for clinical, support, administrative and patient related processes
- Work instructions
- Forms and formats
- Record maintenance
- Innovation, Continual Improvement and Customer Value Management
- Biomedical Waste Management including processes, resource requirements and maintenance
- Any other topic deemed necessary

It would be desirable to distribute reading material at the time of training.

13. Resource Mobilisation

Very often, it is believed that implementation of QMS is a capital intensive exercise, which entails incurring considerable expenditure, however, this is not so. It has been the experience of NHSRC that approximately 70 percent of the gaps can be closed locally by the facility In-charge without incurring much expenditure. For approximately 30 percent of the gaps, support of other departments at the district level may be required. Few gaps may entail mobilisation of human resources where appropriate action at the state's level may be warranted.

14. System of periodical review

The Health Facility would have a system of periodical review (preferably every fifteen days) for (a) review of progress vis-à-vis the activity chart, (b) removing bottlenecks, and (c) mid-term course correction.

15. Corrective and Preventive Action

Corrective Action: Corrective action implies actions taken to eliminate the cause of a detected non-conformity or other undesirable situation.So corrective action procedure must elucidate:

- Review of non- conformance and customer complaints
- Decide the cause of the problem (Root cause analysis)
- Decide an appropriate course of action to stop the problem from recurring
- Put the plan into action
- Verify that the action has solved the problem.
- Document such changes if necessary.

Preventive Action: Preventive action implies actions taken to eliminate the causes of a potential nonconformity in order to prevent occurrence. So preventive action procedure must explain:

- Review mechanism for potential problems
- Decide the potential cause of the problem
- Visualize an appropriate course of action to stop the problem from happening

- Put the plan into action
- Ensure that the preventive action has solved the potential problem
- Document such changes if necessary.

16. Management information system (MIS)

An organised approach to the study of the information needs of an organisation's management at every level in making operational and strategic decisions. Its objective is to design and implement procedures, processes, and routines that provide suitably detailed reports in an accurate, consistent, and timely manner. Effective and vibrant MIS ensures evidence based decision making.

MIS provides information needed to manage organisation effectively. MIS is able to capture, transmit, store, analyze, utilise & retrieve information as & when required for improving clinical outcome as well as ensures efficiency of hospital operations. Few regularly used MIS indicators in the public health facility could be ALOS, LSCS rate, Bed occupancy rate, bed turnover rate, post operative infection rate etc. Format for MIS of public hospital is given at Appendix …….. of these guideline.

Table 1: Example of a SMART objective

SMART Meaning	Examples
Specific – Objectives should specify what they want to achieve.	For example a soft drinks company may want to achieve three percent market share in 12 months.
Measurable – You should be able to measure whether you are meeting the objectives or not.	A three percent market share over 12 months means, that each month market share targets can be measured against a specific goal.
Achievable - Are the objectives you set, achievable and attainable?	Is the three percent objective for 12 months achievable? Does the company have the resources, manpower and finances to achieve it?
Realistic – Can you realistically achieve the objectives with the resources you have?	Is the three percent objective over a 12 month period realistic or does the company need a longer time? Does the company have the skills and resources to achieve this over the time period set?
Time – When do you want to achieve the set objectives?	In our example, the company has set themselves a period of 12 months to achieve the three percent market share target.

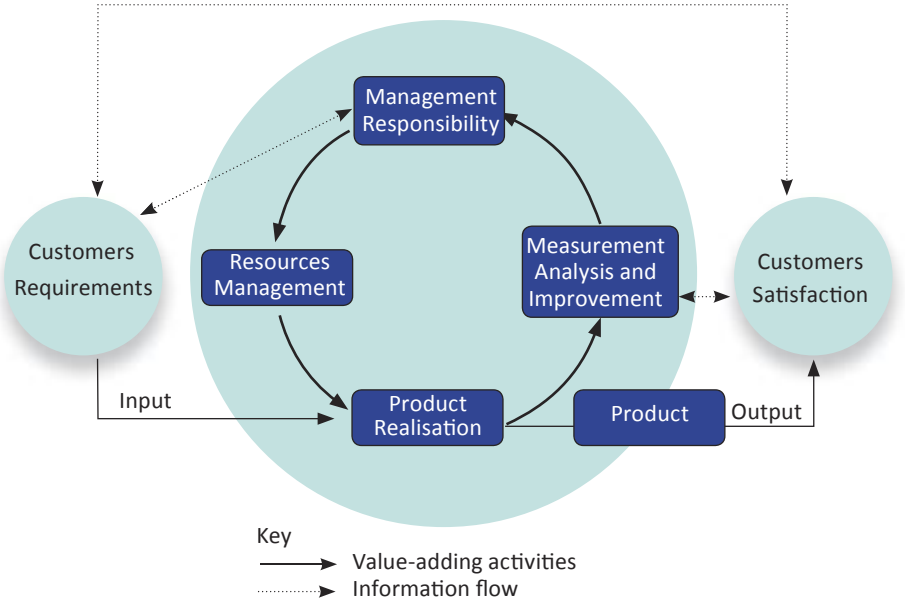
Example of Quality Objectives (Target)

Hospital
- Increasing OPD access by Below Poverty Line (BPL) population by 'x% 'in 'y' months
- Increasing overall patient satisfaction by 'p' points in 'q' months

Dept.
- Increasing Lower Segment Caesarian Section (LSCS) rate to 'g%' in 'h' months
- Increasing major surgery by 'm%' in 'n' months/one year

Dept.
- Increasing night time deliveries by 'd%' in 'C' months
- Reducing post-partum infection by 'k%' in 'l' months

Figure 1: Model of a Process based Quality Management System



Model questions and review of ISO 9001:2008

1. Suggest names and designation of hospital staff, who should be nominated to Quality Committee of your hospital.
2. Identify three gaps at your health facilities, which can be traversed by local action.
3. Prepare a list of rules/regulations, which are frequently referred by the staff of Accident & Emergency Department of the hospital. Does the hospital have copies of such rules & regulation?

CHAPTER 3

Introduction to Quality Management System

ISO 9001:2008 requirement

0.1 GENERAL

The adoption of a QMS should be a strategic decision of an organisation. The design and implementation of an organisation's QMS is influenced by:

- Its organisation's environment, changes in that environment, and the risks associated with that environment
- Its varying needs
- Its particular objectives
- The products it provides
- The processes it employs
- Its size and organisational structure

It is not the intent of this International Standard to imply uniformity in the structure of QMS or uniformity of documentation.

The QMS requirements specified in this International standard are complementary to requirements for products. Information marked "Note" is for guidance in understanding or clarifying the associated requirement.

This international standard can be used by internal and external parties, including certification bodies, to assess the organisation's ability to meet customer, statutory and regulatory requirements applicable to the product, and the organisation's own requirements.

The quality management principles stated in ISO: 9000 and ISO: 9004 have been taken into consideration, during the development of this international standard.

What it means in a hospital setting

Whenever a hospital decides to implement QMS, such a decision should be taken by the top management – Chief Medical Superintendent/Civil Surgeon/DDHS/CMO/State Mission Directors/ Secretary. The design and implementation of a hospital's QMS is influenced by:

- Hospital's environment (internal and external), changes in that environment, and the risk associated with the changed environment
- Services provided by the hospital
- Its vision[2]
- The healthcare service needs of the community
- The processes it adopts to render services
- The hospital's capacity to serve the community with available resources and leadership system

The intent of the implementation hand book is to bring about a kind of consistency and commitment towards providing safe, secure and optimum healthcare services and also to provide enabling environment to the patient.

The QMS requirements specified in this handbook are in accordance with the requirements of healthcare services provided by the hospital.

This implementation handbook is for the hospital to implement the QMS throughout the hospital and continually move towards excellence in providing healthcare service to patients and service seekers.

During the development of the implementation handbook ISO 9001:2008 and ISO 9000:2005 standards have been referred to.

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[2] Vision - Aspirational description of what an organisation would like to achieve or accomplish in the mid-term or long-term future. It is intended to serve as a clear guide for choosing current and future courses of action.

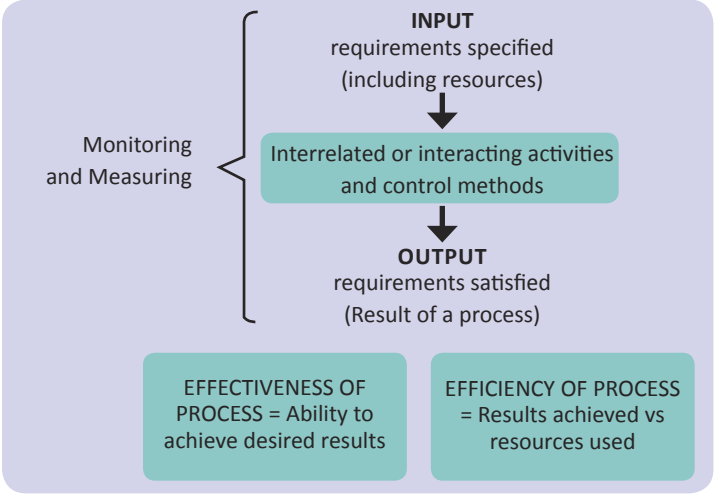
Chapter 3

(i) Introduction to Quality Management System

It is vital for a hospital to map all processes/activities that are required for the delivery of quality healthcare and enhancing user satisfaction in order to meet the expectations of patients and satisfy their healthcare needs..

A “Process” can be defined as a “set of interrelated activities, which transforms inputs into outputs”. These activities require allocation of resources such as man, material, machine and money. The Figure below shows a generic process.

Hospital Management should define the scope of the QMS for all processes. The scope of QMS is the area in which the hospital/healthcare facility acts or operates or has control and for which you want to establish QMS. For example, a Public Health Facility may outsource the terminal disposal of Biomedical Waste (BMW), if the BMW management is out-sourced. However, segregation, collection, on-site disinfection, mutilation of SHARPS, storage of waste would still be the responsibility and would be covered within the



ISO 9001:2008 requirement

0.2 PROCESS APPROACH

This international standard promotes the adoption of a process approach when developing, implementing and improving the effectiveness of a QMS to enhance customer satisfaction by meeting customer requirements.

For an organisation to function effectively, it has to determine and manage numerous linked activites. An activity or set of activities using resources, and managed in order to enable the transformation of inputs into outputs, which can be considered as a process. Often, the output from one process directly forms the input to the next.

The application of a system of processes within an organisation, together with the identification and interactions of these processes, and their management to produce the desired outcome, can be referred to as the "process approach".

An advantage of the process approach is the ongoing control that it provides over the linkage between the individual processes within the system of processes, as well as over their combination and interaction.

When used within a QMS, such an approach emphasises 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.

What it means in hospital setting

It should be the endeavour of public hospitals to improve patients' satisfaction. In order to achieve this goal, it is important to look at the processes being undertaken in the hospital. An effective QMS works best with the 'process approach'.

For a hospital to function effectively, it has to determine inputs, coordinate and manage interrelated and interacting processes to have the best output. In a hospital, inputs could be drugs, linen, laboratory consumables, electricity, human resources, etc., while outputs would be treatment of patients, counselling, preventive and promotive services.

For example:

A patient explained his complaints (Input to doctor)

↓

The doctor processes the information (input) and conducts clinical examination. Then he makes provisional diagnosis and advises investigation and/or treatment (either indoor or outdoor) (Process).

↓

The patient goes to the laboratory for a blood test (output from doctor becomes input for pathologist).

↓

The laboratory technician will conduct test (Process) using equipment and consumables (inputs) and the provide report (output).

To implement the planned processes we need to monitor and measure processes against targets/ deadlines for evaluating the effectiveness of the healthcare services being provided by the hospital to their seekers.

ambit of scope of services. The responsibility and supervision of outsourced agency shall still be with the outsourcing organisation.

PROCESS STEP

A **box** is used to indicate a single accomplishment (or step) in a process. 

- The **box is labelled**, using the past tense form of the verb to describe the accomplishment.
- Use of the **past tense** facilitates placement of a time line along the process, since you can measure time more accurately from accomplishment to accomplishment rather than from activity to activity.
- Each box is assigned a **reference number for easy identification** when discussing the process.

INPUT/OUTPUT

A **line**, with a directional arrow, is used to connect each box (or diamond) to the box that precedes it and the box that follows it, in the process.

- Indicates input/output that is moving to/from each box (or diamond); could be material or information.
- All lines are labelled with the appropriate input/output, except when it is very obvious.

DECISION

A **diamond** is used to indicate that a decision is made within the process. 

- Usually “yes/no” (binary) decisions.
- Divides the continuing process flow into two separate paths in response to the question inside the diamond.

HOW TO CREATE CROSS-FUNCTIONAL PROCESS MAPS

A linear process map overlaid on several horizontal bands which represents the functions involved in the process.

The model of a process-based QMS shown in Figure 1 (on page 18) illustrates the process linkages presented in clause 4 to 8. The illustration shows that the customer plays a significant role in defining requirements as inputs. Monitoring of customer satisfaction requires the evaluation of information relating to customer perception as to whether the organisation has met the customer requirements. The model shown in Figure 1 (on page 18) covers all the requirements of this International Standard, but does not show processes at a detailed level.

Note: In addition, the methodology known as Plan-Do-Check-Act (PDCA) can be briefly described as follows:

Plan: Establish the objectives and processes necessary to deliver results in accordance with customer requirements and the organisation's policies.

Do: Implement the processes.

Check: Monitor and measure processes and product against policies, objectives and requirements for the product and report the results.

Act: Take action to continually improve process performance.

The PDCA Cycle ISO 9001 promotes a Process Approach to quality management, and the PDCA cycle can be applied to all processes – making it perhaps the key principle behind the standard.

In a hospital, PDCA consists of the following principles:

1. End user Satisfaction: Satisfying patients' needs should be paramount for all workers in the hospital.

2. Management by Fact: Decision making is based on data collected from various departments of the hospital and analysed using statistical tools. Decision makers practice and encourage a scientific approach to problem solving.

3. Respect for People: A sustainable problem solving and continuous improvement approach works better where the employees are self-motivated and hence, capable of coming up with effective and creative ideas. This is more important for health facilities, where doctors, nurses, technicians and class IV staff play a critical role in the treatment of patients, coming to the hospital.

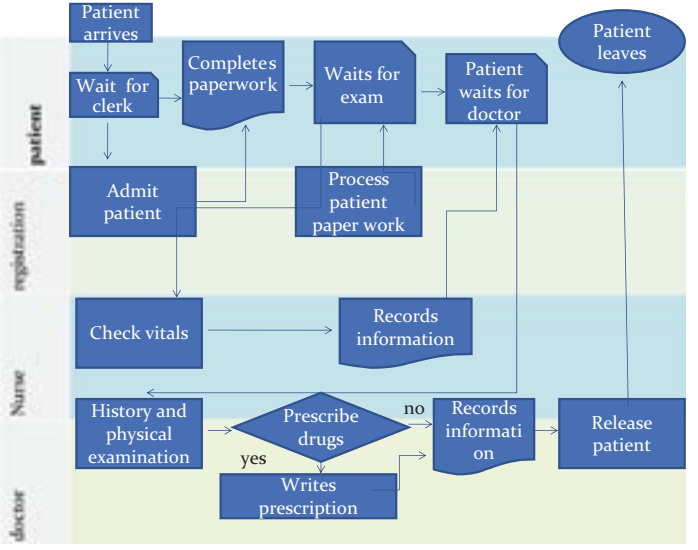
- PLAN – Develop plan to establish and improve service delivery process to enhance user satisfaction.
- DO - Implement the plan and measure its performance, implement the solution or process change.
    - Monitor results and collect data
- CHECK - Assess the measurements and report the results to decision makers. Review and evaluate the result of the change.
    - Measure progress against milestones.
    - Check for any unforeseen consequences.
- ACT- Decide on changes needed to improve the process. If successful:
    - Standardise process changes.
    - Communicate to all involved.
    - Provide training on new methods.

- The same conventions box, arrows, and diamonds are used to track accomplishments.
- Time flows across the map from left to right.

CROSS-FUNCTIONAL PROCESS MAPS ARE CONSTRUCTED AS FOLLOWS:

1. ***Process***: Identify the process to be mapped and define the start/end points of the process.
2. ***Functions***: Identify the functions that participate in the process, including the customer.
3. ***Functional bands***: Create a horizontal band for each function and place the name in the left margin of its respective band, starting with the customer at the top and proceeding down in order of each function's participation in the process.
4. ***Sub-processes***: Identify the large process phases or segments (sub-processes) and their output(s).
5. ***Process steps/Decisions:*** Identify the major accomplishments that lead to the output of each phase or segment. Write each accomplishment (step) of the process in a separate box. Include decision points.
6. ***Sequence***: Locate the steps of the process in their proper sequence, and within the proper function band.
7. ***Inputs/Outputs***: Represent the output of each box or diamond as an appropriately labelled arrow leading to the next step in the process.
8. ***Number:*** Number the boxes for reference.

Figure 2: Process map of patient flow in OPD



(ii) Scope, Normative References, Terms and Definitions

ISO 9001:2008 requirement

1 SCOPE

1.1 General

This International Standard specifies for a QMS where an organisation:

- Needs to demonstrate its ability to consistently provide product that meets customer and applicable statutory and regulatory requirements.
- Aims to enhance customer satisfaction through the effective application of the system, including processes for continual improvement of the system and the assurance of conformity to customer and applicable statutory and regulatory requirements.

Note 1: In this International Standard, the term "product" applies only to:

- Product intended for, or required by, a customer.
- Any intended output resulting from the product realisation processes.

Note 2: Statutory and regulatory requirements can be expressed as legal requirements.

What it means in a hospital setting

It specifies the requirements for a QMS where a hospital:

- Needs to demonstrate its ability to consistently provide healthcare service that meets its end users expectation and also complies with the statutory and regulatory requirements.
- Aims to enhance the level of patient care services and satisfy their beneficiaries (patient, government authorities, community etc.,) through the effective application of the QMS meeting objectives related to the processes in providing healthcare services and making efforts for continual improvement.

It also applies to:

- Service intended for end users.
- Any intended output (desirable department related output that is expected e.g. - The Radiology Department is expected to provide X ray reports of the patient) resulting from the service realisation processes related to the healthcare service to the patient.

The statutory and regulatory requirements related to the healthcare services provided by the hospital may be relevant to the existing law of the land or guidelines provided by regulators e.g., the Pre-Conception and Pre-Natal Diagnostic Techniques (PCPNDT) Act.

1.2 Application

All requirements of this International Standard are generic and are intended for organisations, regardless of the type, size and product provided.

Where any requirement(s) of this International Standard cannot be applied due to the nature of an organisation and its product, this can be considered for exclusion.

Where exclusions are made, claims of conformity to this International Standard are not acceptable unless these exclusions are limited to requirements within Clause 7, and such exclusions do not affect the organisation's ability or responsibility to provide products that meets customer and applicable statutory and regulatory requirements.

2 NORMATIVE REFERENCES

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies. ISO 9000:2005, Quality Management Systems-Fundamentals and Vocabulary.

3 TERMS AND DEFINITIONS

For the purpose of this document, the terms and definitions given in ISO: 9000 apply Throughout the text of this International Standard, wherever the term "Product" occurs, it can also mean "Service".

What it means in a hospital setting

The requirements are applicable to all healthcare services provider such as District Hospitals, Primary Health Centres (PHCs), Community Health Centres (CHCs) and sub-centres or any other public health centres regardless of the type and size.

Any service requirement stipulated in ISO 9001 standard which is not intended to be the part of the healthcare service provider (hospitals) due to the nature of the service provided by the facility. The same can be considered for exclusion which is specifically defined in the related document with a proper explanation.

At primary health centre, service design is not done; rather it pursues a designed set of services through special processes. Hence, the relevent clause, i.e. 7.3 is excluded.

Where exclusions are made with healthcare service provision of hospitals, claims of non-conformity will not be raised. Such exclusion is limited to the requirement within Clause 7 of the ISO 9001 standard, provided that such exclusion does not affect the ability of the facility to provide healthcare services to end users and does not result in non-compliance to the statutory and regulatory requirement.

This implementation hand book is prepared by taking references from the International Standard ISO 9001: 2008 requirements and ISO 9000: 2005 and other related documents.

Model questions and review of ISO 9001:2008

1. What are inputs and outputs in the dressing room of your hospital?
2. Please draw process-map of OPD consultation at your hospital.
3. Please elaborate meaning of P, D, C & A in PDCA cycle and give two examples from your health facility, where PDCA cycle could be used.

CHAPTER 4

Quality Management System Requirements

ISO 9001:2008 Requirements

4.1 General requirements

The organisation shall establish, document, implement and maintain a QMS and continually improve its effectiveness, in accordance with the requirements of this International Standard.

The organisation shall:

- determine the processes needed for the QMS and their application throughout the organisation;
- determine the sequence and interaction of these processes;
- determine the criteria and the methods needed to ensure that both the operation and control of these processes are effective;
- ensure the availability of resources and information necessary to support the operation and monitoring of these processes;
- monitor, measure where applicable, and analyse these processes; and
- implement actions necessary to achieve planned results and continual improvement of these processes.

These processes shall be managed by the organisation, in accordance with the requirements of this International Standard.

Where an organisation chooses to outsource any process that affects product conformity to requirements, the organisation shall ensure control over such processes. The type and extent of control to be applied to these

What it means in a hospital setting

The first task after the decision to put in place a QMS is taken to determine what would be required for the effective functioning of the healthcare facility. There are three sets of processes considered in this context in this guideline:

- Administrative Processes
- Clinical Processes
- Mandatory Processes for ISO 9001: 2008 Standard

It is for the hospital governance to choose which processes are to be brought under control. After establishing the system, efforts have to be made not only to sustain the effectiveness of the identified process of the hospital, but also to continually improve upon the indicators of effectiveness of services. While defining the processes, the following needs to be observed:

- All processes that are vital for healthcare should be included.
- All services to be provided by a hospital need not be included- unless it is judged that the particular service needed for achieving quality is in place. Thus, a hospital without an X-ray machine would not opt to get its radiological services under the QMS, till the time it is purchased. But the Labour room and Operation Theatre which are adequately resourced need not wait for the X-ray section to be brought under the QMS.

Quality Management System Requirements

The set of core processes as applicable to a hospital can be divided into three groups:

A. Clinical Procedures (General)

- Outdoor Patient (OPD) Management
- In-Patient (IPD) Management (General/Critical/Intensive Care)
- Hospital Emergency and Disaster Management
- Maternity and Child Health Management
- Operation Theatre and CSSD Management
- Hospital Diagnostic Management
- Blood Bank/Storage Management
- Hospital Infection Control Management
- Data and Information Management
- Hospital Referral Management
- Pharmacy Management
- Management of Death

B. Hospital Administration Procedures

- Patient Registration, Admission and Discharge Management
- Hospital Stores and Inventory Management
- Procurement and Outsourcing Management
- Hospital Transportation Management
- Hospital Security and Safety Management
- Hospital Finance and Accounting Management
- Hospital Infrastructure/Equipment Maintenance Management
- Hospital Housekeeping and General Upkeep Management
- Human Resource Development and Training Management
- Dietary Management
- Laundry Management
- Hospital Waste Management

outsourced processes shall be defined within the QMS.

Note 1: Processes needed for the QMS referred to above, include processes for management activities, provision of resources, product realisation, measurement, analysis and improvement.

Note 2: An "outsourced process" is a process that the organisation needs for QMS and which the organisation chooses to have performed by an external party.

Note 3: Ensuring control over outsourced processes does not absolve the organisation of the responsibility of conformity to all customer statutory and regulatory requirements. The type and extent of control to be applied to the outsourced process can be Influenced by factors such as:

- The potential impact of the outsourced process on the organisation's capability to provide a product that conforms to requirements.
- The degree to which the control for the process is shared.
- The capability of achieving the necessary control through the application of 7.4.

- All processes needed for statutory and legal requirements must be included e.g., radiological safety, PNDT Act, Biomedical Waste (BMW) (management & handling) rules, 1998, etc.
- All processes needed for compliance with a state's policy framework must be included. For e.g. if a state has declared that all its facilities would have safe delivery services, free services to BPL, food to escorts of labour cases if arrived in evening all these have to be included.
- Processes that are to be outsourced should be specified. Outsourced processes must also be documented and controlled.
- The flow chart of the services rendered by the hospital needs to be drawn for clear understanding of the processes and its sequence by the stakeholders.

Key to establishing a QMS is:

- Document the needed processes.
- Monitor and measure these processes. subsequently to ensure that they are taking place as intended. This could be self-assessments too.
- Where it is not taking place, initiate corrective action, and where it is taking place, plan for continual improvement, analysis of the potential problems and preventive action.

C. Mandatory Quality Management Processes

- Control of Documents
- Control of Records
- Internal Audits
- Control of non-conforming Products
- Corrective Action
- Preventive Action

Whilst documenting the process, the following points must be addressed:

- Identify the process owner.
- Identify inputs and expected outputs/results.
- Define the characteristics of inputs and outputs.
- Define the boundaries of the process.
- Determine the activities and the sequence.
- Identify resources and responsibilities.
- Determine the criteria and methods to ensure the operation and control are effective for Standard Operating Procedures (SOPs).
- Generate records where necessary.
- Determine process performance measures.
- Review process for process performance.

General documentation requirements

The extent and nature of process documentation and records should be appropriate to that healthcare facility. Documentation and records may be in any form or in any media suitable to the needs of the healthcare facility. Requirements for documentation and records arise from:

- Need for ensuring consistent healthcare delivery as per standards.
- Statutory and regulatory requirements
- In compliance to decisions by the healthcare facility and/or its governance system, e.g. RKS, state directorate etc.
- To create evidence, especially in medico-legal situations.
- To improve the process.

The documents required at the facility level would be of four types:

- Quality System manual which consists of indicative details of its overall functioning.

ISO 9001:2008 Requirement

4.2 Documentation requirements

4.2.1 General

The QMS documentation shall include:

- Documented statements of a quality policy and quality objectives.
- A quality manual.
- Documented procedures and records required by this International Standard.
- Documents, including records, determined by the organisation to be necessary, to ensure the effective planning, operation and control of its processes.

Note 1: Where the term "documented procedure" appears within this International Standard, this means that the procedure is established, documented, implemented and maintained. A single document may address the requirements for one or more procedures. A requirement for a documented procedure may be covered by more than one document.

What it means in a hospital setting

The hospital must establish and have the following documents to demonstrate its commitment and evidence of service provision for patients and other interested parties:

a. **Quality Policy:** A brief document demonstrating commitment to patient satisfaction and continual improvement of hospital processes, based on vision of the healthcare facility. The vision and mission statements express the purpose of existence of that healthcare facility.

As per standards, the definition of Quality Objectives is: “Something sought, or aimed for, related to quality”.

b. **Quality Manual:** Refer clause 4.2.2. on Page 36

Definitions

1. Document: It provides guidance and/or direction for performing work and making decisions, or rendering judgments. A document may be written or electronic, e.g., instructions, orders, circulars, notices, agenda paper for RKS meetings, SOPs and Standard Treatment Protocols for core healthcare processes to exercise effective controls and management of that process/activity. These SOPs/STPs are generally developed on the 5W-1H approach. This approach means considering **What, Why, When, Who, Where and How** criteria while developing such documents.

To manage documents, effectively, they should be controlled, maintained and protected.

- Procedures, Protocols (STP) related to clinical, administrative and mandatory procedures for QMS.
- Work instructions/Guidelines/Handbook to define tasks for personnel performing work or operation.
- Standard formats for collection and reporting of data and information.

The purpose of documentation in QMS is to bring about consistency in performance. Reviews and analysis of records provides inputs for corrective and preventive action and thence, process improvements.

Quality Policy

An organisation's quality policy defines the top management's (top management in a Public Health System is equivalent to the Governing Board, RKS or District Health Society) commitment to quality. A quality policy statement should describe an organisation's general quality orientation and clarify its basic intentions.

Quality Objectives

A quality objective is a quality oriented goal. A quality objective is something you aim for or try to achieve. Quality objectives should meet a minimum of five requirements:

- They should be user focused.
- They should be measurable.
- They should be appropriate for the organisation's/hospital's vision.
- The objectives should be maintained on a controlled document that is printed and posted around the facility.
- The objectives should be reviewed at management review meetings.

Quality Manual

A document containing the quality policy, quality objectives, organisation structure chart, and description of the quality system of an organisation is a quality manual. A quality manual often explains how the requirements of a quality standard are to be met and identifies the person responsible for quality management functions.

Note 2: The extent of the QMS documentation can differ from one organisation to another due to:

- the size of the organisation and the type of activities;
- the complexity of processes and their interactions; and
- the competence of the personnel.

Note 3: The documentation can be in any form or type of medium.

2. Record: It is a document which proves that some type of required action has taken place, e.g., the OPD register, Labour Room register, The Stock Register the patient's Medical Records, books of accounts or minutes of meetings. A reporting form or a blank register page is a document but once it is filled in, it becomes a record.

The healthcare facility requires sufficient records to demonstrate conformance to all process requirements.

ISO 9001: 2008 Requirement

4.2.2 Quality manual

The organisation shall establish and maintain a quality manual that includes:

- the scope of the QMS, including details of and justification for any exclusions (see 1.2);
- the documented procedures established for the QMS, or reference to them; and
- a description of the interaction between the processes of the QMS.

What it means in a hospital setting

Quality manual is an adequacy manual which describes the hospital structure, its scope, policies and objectives. This manual depicts the overall management structure of a healthcare facility.

The quality manual describes:

- Core services of that healthcare facility
- All processes which are being brought under control and
- Their inter-relationships with defined process objectives/expectations.

This quality manual is necessarily to be approved by hospital leadership.

A quality manual includes the following:

- Overall hospital management system
- Management commitment and responsibilities
- Resource provision in terms of people available and other resources like fixed assets
- Healthcare services and their objectives
- Measurement and monitoring system of hospital performance.

The quality manual is located at the top of the documentation pyramid because it establishes the quality policies to which the lower level procedures must be aligned and integrated. It is also the representative document fulfilling the requirements of the ISO 9001 standards.

In the quality manual, the responsibilities and authorities of key personnel is detailed for clarity and uniform understanding.

Control of Documents: *Keeping the QMS Current*

A cornerstone of QMS is the control of documents. Document control is an essential preventive measure ensuring that only approved, current documentation is used throughout the organisation. Inadvertent use of out-of-date documents can have significant negative consequences on quality, costs and service users satisfaction.

The term “documents” include all policies, procedures, protocols, work instructions, forms, registers, specifications, and other documents affecting the QMS.

All documents used in hospitals must follow a standard pattern Header and Footer with the following details: Name of Hospital (preferably with a logo if one exists), Title of the Document (Subject), Issue Date, Revision Status, Issuing Authority, Approving Authority etc.

- A copy of each document must be maintained with the process owner. The Document Control In-charge maintains a list of persons to whom the documents are

ISO 9001: 2008 Requirement

4.2.3 Control of documents

Documents required by the QMS shall be controlled. Records are a 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 to:

- to approve documents for adequacy prior to issue;
- to review and update as necessary and re-approve documents;
- to ensure that changes and the current revision status of documents are identified;
- to ensure that relevant versions of applicable documents are available at points of use;
- to ensure that documents remain legible and readily identifiable;
- to ensure that documents of external origin determined by the organisation to be necessary for the planning and operation of the QMS are identified and their distribution controlled; and
- to prevent the unintended use of obsolete documents and to apply suitable identification to them if they are retained for any purpose.

What it means in a hospital setting

It is as important to prepare a document, as it is to have a control mechanism to control that document.

A document control procedure is one of six mandated procedures in the ISO: 9001 standard and it must address the following:

- Designate the approving authority for processes and take signatures prior to the release of the document. The date of all approvals must precede the document's release date.
- When a document is updated, a record must be kept of the change (state the reasons for and nature of the change).
- There has to be a centralised storage place in the hospital for the master and obsolete documents. Note that older versions of a document need to be retained.
- The documents must be clearly identified through a title, document number and other suitable identification.
- Documents that do not originate within the organisation/hospital, but are necessary for ensuring quality and meeting patient requirements, must also be available. However, the extent of control is limited to clear identification and controlled distribution since these cannot be reviewed internally. A log or other record would suffice to track the latest version of the external documents.
- Out-of-date documents or older versions of revised documents must be protected from unintentional use. This usually is required.

issued. The documents should be issued to all incharges of the functions and also those who are expected to use the documents.

- Hospital leadership must review the documents and records periodically and discuss them during the Management Review Meetings.
- When any revision of a document is made, the master list should have a record of this change, giving the date when it was revised.
- Take care to ensure that the place of storage of documents and records is damp proof, damage proof and free from access of rodents. For electronic records, back-ups are required. Some documents like an order received or fax may fade and hence do take a good quality Xerox which will not fade and keep a record of the same.
- Any obsolete documents that are kept for reference or other purposes must be clearly identified and kept in separate storage areas, or other means in accordance with the procedure for control of documents.

For the first time in the hospital, MR assigns the responsibility of creating a document to the designated person who, after preparing the same, sends it to MR for review and approval. MR sends an approved document to DCI and unapproved document to the person who has prepared it with his/her comments.

DCI photocopies the approved document and stamps it with “controlled copy” and “uncontrolled copy” as the case may be and distributes as per procedure.

Control of Records: *Maintaining objective evidence of compliance*

WHY KEEP RECORDS?

Records must be identified, filed, protected and controlled throughout their lifecycle. The discipline of maintaining records ensures that you will have an objective means of evaluating and improving QMS effectiveness. With this historical evidence one can:

- Understand how well your hospital is performing.
- Trace back to the source of problems.
- Demonstrate compliance to requirements.
- Evaluate trends in hospital performance.
- Elucidate performance gaps and transverse them.
- Monitor improvements.

HOW TO KEEP THE PROCESS SIMPLE

- Fix responsibility for filing, maintaining and disposing of each record pertaining process to a “Process Owner”.

ISO 9001:2008 Requirements

4.2.4 Control of records

Records established to provide evidence of conformity to requirements and of the effective operation of QMS shall be controlled.

The organisation shall establish a documented procedure to define the controls needed for the identification, storage, protection, retrieval, retention and disposition of records.

Records shall remain legible, readily identifiable and retrievable.

What it means in a hospital setting

The hospital must have a documented procedure for the ways by which to control records for their identification, storage, protection, retrieval, retention and disposal.

The hospital must ensure such records remain legible (fax paper which may be required to be photocopied immediately to protect the ink from vanishing from thermal paper), readily identifiable (indexing) and immediate by retrievable (accessibility).

The mandated ISO: 9001 records for healthcare set up could be related to:

- Document Control
- Management Review
- Education, Training, Skills and Experience
- Service Realisation
- Customer Requirements Review
- Supplier Evaluations
- Service Delivery Processes
- Identification and Traceability
- Damaged/Lost Customer Property Calibration
- Internal Audit
- Service Conformity
- Non-conforming Product/Services
- Corrective Action
- Preventive Action.

The above list is indicative and not exclusive.

- Provide adequate storage capacity so that filing can be maintained.
- Keep records only as long as necessary, then dispose them off through the proper procedure.
- Develop a records retention matrix that shows who is responsible, storage locations, protections, security, retention requirements and disposal methods.
- Move as many records as possible to a searchable, electronic format to keep storage costs down and make them easy to retrieve when needed.

Various departments in the hospital maintain records. Let us consider a few of them:

- Out-patient Management: OPD register
- In-patient Management: IPD register, case records, discharge summaries, PTR Chart.
- Hospital Waste Management: Records all categories of waste, register for recording weight of the bags before sent out of the hospital, number of bags collected.
- Internal Quality Audits: Records of reports of all internal audits held in hospital
- Training Records: Needs Assessment, Plan, Report and Feedback, Evaluation
- Records related to procurement and inventory management
- Records related to diet supplied daily and so on…….

Model questions and review of ISO 9001:2008

1. Prepare a list of ten important processes in your hospital and also mention names of process owners.
2. Name the six mandatory procedures, prescribed by ISO 9001:2008 Standard.
3. Please prepare a list of records, which are generated in any one ward of your hospital.
4. Please define quality objectives of operation theatre of your hospital. (Ensure that the quality objectives meet SMART criteria).
5. True/False
   i. Quality manual is a Record. (True/False)
   ii. Printed copy of Biomedical Waste. (management & handling) rules 1998 is a document of external origin. (True/False)
   iii. Records are only taken in printed formats. (True/False)
   iv. Bed Head Ticket (Case sheet of admitted patients) is a document. (True/False)
   v. Obsolete documents are stamped as 'Controlled'. (True/False)

CHAPTER 5

Management Responsibility

ISO 9001: 2008 Requirements

5 MANAGEMENT RESPONSIBILITY

5.1 Management commitment

Top management shall provide evidence of its commitment to the development and implementation of QMS and continually improve its effectiveness by:

- Communicating to the organisation the importance of meeting customer as well as statutory and regulatory requirements.
- Establishing the quality policy.
- Ensuring that quality objectives are established.
- Conducting management reviews.
- Ensuring the availability of resources.

What it means in a hospital setting

Top management in a hospital is its RKS or equivalent and/or the State Health Department. The hospital in-charge who is designated as Management Representative (MR) is a representative of the top management

It is the responsibility of top management to communicate its commitment to provide effective and good quality care to people. It can do this by clearly stating and displaying the Quality Policy and the objectives it sets out for the hospital management to achieve.

It has also to review to see whether it is achieving those objectives.

It is most important to ensure that the resources needed to achieve the objectives are organised and provided.

ISO 9001:2008 Requirement

5.2 Customer focus

Top management shall ensure that customer requirements are determined and are met with the aim of enhancing customer satisfaction (see 7.2.1. and 8.2.1.).

What it means in a hospital setting

For a healthcare facility, the customer is the user/patient who visits the healthcare facility for treatment, health promotion and disease prevention and including those seeking emergency services.

Customer Focus means that the healthcare facility must establish all clinical and non-clinical services to meet user requirements and thus, enhance their satisfaction.

Chapter 5

Management Responsibility

Introduction

Public health facilities have two levels of management. One level is that of the top management and is also referred to as Governance. This refers to the structure by which the public exercises its control over the government run health facilities. Ministry of Health, Directorate of Health Services, the District Health Society and the Governing Board of the RKS may be considered synonymous with Top management. The hospital Superintendent as head of the hospital, is appointed by these structures and is therefore their (management) representative. He/She may therefore, considered "Top Management" representative.

The Hospital Superintendent, Resident Medical Officer, Hospital Administrator, Senior Matron and other senior posts with administrative function taken together, would be the management team at hospital level.

Management responsibilities include:

- Setting policies and objectives and leading the healthcare facility.
- Communicating its policies, objectives, its commitment to providing quality care and performance expectations to the entire work force and to the public it serves. This communication may be made to the public by putting up Quality Policy, and the Citizen's Charter displaying the status and services guarantee at appropriate places.
- Ensuring compliance to Statutory and Regulatory requirements. (Table 2 on page 47) This should not only be done but be seen to have been done (visible and transparent) and form a part of the communications mentioned above.
- The Management Review Committee meetings that conduct regular reviews of the management of the hospital, reviews the progress and sets action plan for achieving the policies and objectives that had been set out to achieve.
- Ensuring that the resources needed for the hospital to run, especially in form of financial resources, sanctions for hiring staff or technical assistance are made available to the organisation.

All hospital functions (clinical/non-clinical) should be oriented towards patient/user satisfaction. All individual service providers must be trained and made aware of the importance of patients, keeping focus on their satisfaction by providing services required by them in time and with a smile.

The user of a hospital facility belongs to two categories. Some are persons with diseases who need treatment. We refer to them as patients. Others are normal people seeking counselling and preventive care, e.g., children for getting immunisation, pregnant women seeking assistance at delivery or ante-natal care, health check-ups for aged people, an adolescent seeking counselling or health education. However, since the majority are patients who are clearly differentiated from others, it may also be used in the context.

Needs and expectations of a patient

A patient visiting a healthcare facility counts on the service provider for good quality care. The needs and expectations of a patient may be as follows:

- Appropriate and correct medical care.
- Waiting Time Efficiency especially in OPD for registration, Consultation rooms for clinical attention and consultation and diagnostic labs for investigations.
- Courtesy extended by staff.
- Discharge efficiency.
- Availability of medicines at the dispensary.
- Hygienic conditions at the hospital.
- Availability of clean linen.
- Availability of requisite diet.
- Availability of running water, water cooler and clean toilets etc.
- Safety, security, power supply etc.

Patient or user's focus prompts the provider towards:

- Capturing and understanding patient needs and expectations.
- Ensuring that the objectives of the organisation/hospital are linked to patient needs and expectations.
- Communicating patient needs and expectations throughout the organisation/ hospital, so that every service provider is aware of it
- Measuring patient satisfaction and acting on the results to enhance it.
- Systematically managing patient relationships.
- A balanced approach towards the needs of patients and other interested parties (such as stake holders, local communities and society as a whole).

Table 2: Statutory and Regulatory Requirements

S.No.	Act/Requirements
1	Building Permit
2	Bio-medical Management and Handling Rules, 1998
3	Radiation Protection Certificate with respect to all X-ray and CT Scanners from BARC. Atomic Energy Regulatory Body approvals
4	Excise permit to store spirit/alcohol
5	Narcotics and Psychotropic Substances Licence and Act
6	Vehicle Registration Certificates
7	Air (Prevention and Control of Pollution) Act, 1981
8	Consumer Protection Act, 1986
9	Dentist Regulations, 1976
10	Drugs and Cosmetics Act, 1940
11	Fatal Accidents Act, 1955
12	Indian Lunacy Act, 1912
13	Indian Medical Council Act and Code of Medical Ethics, 1956
14	Indian Nursing Council Act, 1947
15	Maternity Benefit Act, 1961
16	MTP Act, 1971
17	Persons with Disability Act, 1995
18	Pharmacy Act, 1948
19	PCPNDT Act, 1996
20	Protection of Human Rights Act, 1993
21	Registration of Births and Deaths Act, 1969
22	Licence for Blood Bank
23	Licence for Lift and Escalators

This list is not comprehensive

ISO 9001:2008 Requirements

5.3 Quality policy

Top management shall ensure that the quality policy:

- Is appropriate to the purpose of the organisation.
- Includes a commitment to comply with requirements and continually improve the effectiveness of the QMS.
- Provides a framework for establishing and reviewing quality objectives.
- Is communicated and understood within the organisation.
- Is reviewed for continuing suitability.

What it means in a hospital setting

Quality Policy is an intent "Statement" of a healthcare facility which is generally co-created by members of that facility and approved by the top management.

The **Quality Policy** should be in accordance with the purpose and mission of the organisation it is written for. It should be easy to understand by all members of the organisation.

The quality policy of a hospital is generally based on the capacity and strategic direction of the facility and is sensitive to the needs of the users.

ISO 9001:2008 Requirements

5.4 Planning

5.4.1 Quality objectives

Top management shall ensure that quality objectives, including those needed to meet requirements for products (see 7.1 a), are established at relevant functions and levels within the organisation. The quality objectives shall be measurable and consistent with the quality policy.

What it means in a hospital setting

Establishing quality objectives in a hospital ensures that all healthcare services provided by the hospital to the user and all other services to support the delivery of healthcare services meet the standards that are set. These standards should be measurable and consistent with the quality policy. It is also a tool to overcome the challenges the organisation faces and it helps to develop such measures which lead to improvement in the performance of the organisation.

Quality Policy is short, succinct and most importantly, documented. It should be appropriate to the purpose of the hospital. It provides a framework for establishing the hospital's objectives and review mechanism of these objectives. Quality policy is co-created for the involvement and better understanding among hospital staff, is communicated to all and understood by all in the hospital and is reviewed for continuing suitability. It should be signed by the MR with the date and displayed at important locations in the hospital.

For example:-

"We shall strive to provide preventive, promotive and secondary level of curative healthcare services to the people in the hospital with sustained efforts to ensure that it is equitable, affordable, accountable and responsive to the people's needs, within the limit of its resources.

RKS/Management Committee of the hospital shall mobilise resources and ensure its efficient utilisation to improve the functioning of the Hospital.

We are committed to satisfy the end users by efficient delivery of our services.

We shall build and upgrade competencies of our people involved in service delivery to keep abreast of changing professional requirements and to overcome emerging challenges. Continuous improvement shall be the guiding principle in all our endeavours."

The quality policy should be periodically reviewed to ensure that it is current with the changing environment.

Planning

Quality Objectives

Quality Objectives are the practical outline of the Quality Policy. **Quality Objectives** are something you aim for or try to achieve. They are an expression of aim to achieve in time bound manner certain performance level like a response time below a specified limit for a certain service e.g., the cycle time for OPD Patient Registration at 5 minutes. It is important that **Quality Objective** are measurable. **Quality Objectives** can apply to all specific functions of a healthcare facility and these are derived from the quality policy. They must be consistent with it. They are usually formulated at all relevant functions.

“SMART”

S	**=**	**Specific**
M	=	Measurable
A	=	Attainable
R	=	Relevant
T	=	Time Based

Specific describes the details of what is to be accomplished in a clear and simple way. The goal must be easy to understand and well defined in order to make achieving it possible. Unclear goals are easily misunderstood and therefore typically do not accomplish the desired results. Being specific answers the question of what has to be done, so that appropriate actions can be taken.

Measurable uses quantifiable terms in order to compare where the goal is in reaching the desired target. Establishing performance criteria for measuring the goal will allow for changes during the goal period in order to manage the process and stay on track to meeting the target. Utilising a definite tracking method shows how much will be gained by accomplishing the goal while it encourages continued improvement.

Attainable means the goal is within the ability and capability of those involved while stretching their collective talents to reach the most desirable target. It means that the defined goal is both possible and realistic while still being challenging for the organisation and its people. Having a goal that stretches people and allows for growth opportunity often leads to very worthwhile business results.

Relevant indicates that the goal is not only within reach of skill levels but also has meaning and relates directly to the purpose or vision of those who are responsible for meeting the goal. Relevancy means everyone involved can understand how they influence the goal and how it affects them. When a goal is relevant to those involved, it increases commitment and makes meeting the goal a highly motivational tool.

Time-based defines the period for meeting the measurements in the goal or the deadline date for accomplishing the overall target of the goal. Having a time frame established allows a frequency for monitoring progress, staying on track, making adjustments to meet the overall goal, and gaining momentum with each accomplishment, along the goal path. Without a time-based element to the goal, it will be impossible to make a targeted plan.

For example, a few basic hospital wide objectives could be in terms of annual target for the year:

- Out-Patient care:
  - Waiting time for registration/examination/at pharmacy should be reduced from the present 60 minutes to 15 minutes within next one year.
  - Outpatient Satisfaction Score should be increased by 10 percent to 60 percent
- In-Patient care:
  - Bed Occupancy Rate should be increased 45 percent to 80 percent
  - Average length of stay should be reduce from 6 days to 4 days
  - Inpatient Satisfaction Score would be increased from 60 percent to 70 percent
- Diagnostics: (results should be available within 12 hours to present 24 hours.
  - Cycle time of reports and diagnostics
  - Reliability: x numbers of lab tests be validated every month with external labs.

Similarly, in each function, some parameters can be elucidated which is critical to the success of the facility and improvement targets can be set for the year as quality objectives.

ISO 9001:2008 Requirements

5.4.2 Quality Management System Planning

Top management shall ensure that:

- the planning of the quality management system is carried out in order to meet the requirements given in 4.1, as well as the quality objectives; and
- the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.

What it means in a hospital setting

The planning of the management system means that the healthcare facility should plan its services in a manner so as to meet patient requirements and instill a sense of satisfaction amongst service users.

Whenever inputs of process elements are changed, it has to be ensured that the process output continues to focus on the end user of the health services and expressed intents do not get altered.

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 organisation.

What it means in a hospital setting

Responsibility and authority go hand in hand for any organisation and this is true for a hospital too. A written job description/ authority should be available for each process owner/service provider in the hospital to guide his or her work profile. It does not require to be comprehensive but it should be indicative of the main areas of work. It is important for the personnel to understand and know the job profile and performance expectations.

Management may also identify Key Result Areas (KRA) of functionaries for making them accountable for the work assigned which works as a tool for evaluating performance. It also works as a tool to identify the capacity building needs of employees.

Administration

For every process, there should be a clearly defined "process owner" who is responsible and accountable for that process. It is important to clearly define and communicate responsibility and authority of each process owner (position specific) in order to effectively and efficiently implement and maintain the functioning of the hospital in line with the stated policy.

Management Representative

A Management Representative is a person appointed by the top management to oversee the performance of the hospital management system. He is generally a senior person in the hierarchy of the hospital and is able to attend to requirements in terms of gathering performance data, analyse this data and put it to use for continual improvement with a consultative approach. The MR is appointed and given authority by the top management to manage, monitor, evaluate and coordinate QMS processes. MR works to enhance effective and efficient operation of the QMS.

The MR should report to the top management which in case of a district hospital is chairman of the RKS. MR is required to communicate the vision, mission, values, performance expectations, review findings, issues of various non-compliances and best practices with all interested parties. He/She should encourage innovation and present himself/herself as a role model within the healthcare facility.

In addition to his normal duties, MR's responsibilities include the following:

- Ensuring that processes needed for QMS are established, implemented and maintained.
- Reporting to top management on the performance of the QMS and any need for improvement.
- Ensuring the promotion of awareness of customer/patient requirements throughout the healthcare facility.
- Coordinating with external auditors appointed by the top management of the healthcare facility.
- Planning internal quality audits and ensuring audits are conducted across functions as per the plan.
- Convening management reviews to review hospital performance.

ISO 9001:2008 Requirement

5.5.2 Management representative

Top management shall appoint a member of the organisation's management who, irrespective of other responsibilities, shall have responsibility and authority that includes:

- ensuring that processes needed for the QMS are established, implemented and maintained;
- reporting to top management on the performance of the QMS and any need for improvement; and
- ensuring the promotion of awareness of customer requirements throughout the organisation.

Note 1: The responsibility of a management representative can include liaison with external parties on matters relating to the QMS.

What it means in a hospital setting

The hospital Superintendent or civil surgeon is the MR, where the top management is taken as similar to governance. However, in many of our public hospitals, the top position is given too many transfers, and is under a lot of pressure and influences. Thus, it makes sense to build institutional memory and leadership skills at a more constant second level, i.e., a second person who is dedicated to administrative functions and is also charged with supervising and leading the QMS.

This MR or alternate Management Representative must be a senior person in the management team. He/She ensures that hospital management practices are implemented and everyone in the hospital is made aware of the requirement of systems and patient expectations.

He/She assists the Medical Superintendent (or equivalent) in implementing strategic plans towards hospital improvement.

5.5.3 Internal communication

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

What it means in a hospital setting

It is important that the information regarding the available services, patient requirements and resource needs are communicated across the departments. Hospital management must institute communication systems between service providers and also between service seekers and providers.

5.5.4 Internal communication

Communication plays a vital role in managing work effectively in hospitals. It is important to define and implement processes for the communication of objectives, infrastructure and achievements especially pertaining to patient information and healthcare service deliverables.

Some tools for communication include:

- Meetings at different levels,
- Notice-boards, in-house journals/magazines/office orders,
- Open door policy,
- Letters, emails, LAN, intranet, website
- Phone/Mobile calls
- Informal communication
- Newspapers/Media

For example, in case of a decision for change in the duty of doctors or nursing staff is taken by management within the framework of applicable rules, the same must be communicated in writing with the issue date to all departments for ensuring 100 percent compliance. If outpatient timings are changed, it must be conveyed in appropriately.

ISO 9001:2008 Requirement

5.6 Management review

5.6.1 General

Top management shall review the organisation's QMS, at planned intervals, to ensure its continuing suitability, adequacy and effectiveness. This review shall include assessing opportunities for improvement and the need for changes to the QMS, including the quality policy and quality objectives.

Records from management reviews shall be maintained (see 4.2.4).

What it means in a hospital setting

This review can take place in many forms, based on the need and urgency of the review. Ideally management review in a hospital environment should take place frequently (may be monthly/bi-monthly/quarterly) by the management team, to review the overall hospital performance.

Hospital performance review in presence of the Management team in public hospitals is an ideal example. It is important to conduct such meetings with planned arrangements, agenda notes circulated at least one week before and minutes that are recorded, approved and circulated to all present and all concerned.

Review of Hospital Performance

Management reviews are required to be conducted periodically to review the overall performance of a healthcare facility by senior members of the hospital. It is important to form a three to seven member team of management review committee with provision to invite non-members where required.

In this meeting, the functioning of processes critical to the success of the organisation are reviewed for its performance in terms of targets and objectives. In addition, the hospital management should analyse current activities that may require change and consider opportunities for improvement of hospital functions.

Review Input

The review input in the hospital simply means the inputs from various process owners on their performance in a structured manner.

- Audit Results: Results of compliance verification against commitments like set policies and objectives after the external or internal audit for the facility has been done. The discussion includes details of plans and efforts to close all the non-conformities (NC) in the existing system.
- Customer Feedback: Measurements of the satisfaction index of interested parties like patients, other users and employees are reviewed along with the related action plans.
- Process Performance: Performance of operational processes as seen in the relevant documents, in process results and process output measures. The performance of the processes is analysed on the basis of the performance indicators for this specific function.
- Preventive and Corrective Actions taken: Analysis of healthcare service non-conformance through reviews, inspection and audits.
- Measures should be adopted to prevent the occurrence of similar NCs in future. There is non-compliance in the collection and segregation of Biomedical Waste in the hospital due to shortage of different coloured collection bags as per the BMW guidelines. The non-conformity can be corrected by addressing the shortage of bags.

ISO 9001: 2008 Requirements

5.6.2 Review input

The input to management review shall include information on:

- results of audits;
- customer feedback;
- process performance and product conformity;
- status of preventive and corrective actions;
- follow-up actions from previous management reviews;
- changes that could affect the QMS; and
- recommendations for improvement.

What it means in a hospital setting

Inputs for the management review should include:

- Customer feedback: Measurement for satisfaction index of OPD and IPD
- Analysis of the processes performance on the basis of indicators
- The hospital authorities should take appropriate corrective measures to close the NCs or gaps identified in the hospital.
- Follow-Up action: Status of corrective and preventive actions discussed during previous meetings are reviewed for adequacy of effort.
- Improvement: The status of action items from previous reviews.

ISO 9001:2008 Requirement

5.6.3 Review output

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

- improvement of the effectiveness of the QMS and its processes;
- improvement of product related to customer requirements; and
- resource needs.

What it means in a hospital setting

Review Output means the decisions taken, based on such review meetings. It is important to have an action plan to close the loop on decisions or initiatives proposed during the meeting.

The action plan must mention what action is planned to be taken, how it would be taken, who is responsible for implementing the action plan and what the timelines are. It is also important to record the frequency of the review of the planned action and the names of those who would review.

However there is need to look into the root cause of such shortage which could range from non-raising of indent for procurement to failure of the supplier. Once the root cause is identified various options to address the root cause are weighed and the best option is accepted for implementation, by instituting a system of making bags available without fail so that the same non-conformity does not occur again.

- During the RKS meeting or the management review meeting, improvement points may be suggested within the existing system or by adopting something new for the enhancement of service delivery.
- Changes in original assumptions (e.g., those arising from new technologies, treatment procedures and protocols, quality plans, contracted service provider's terms and conditions, social, environmental conditions and Statutory and Regulatory changes).

Additional inputs to consider for review include:

- Status and results of healthcare and support service activities.
- Results of self-assessment of the healthcare facility.
- Results against available benchmarks.
- Performance of contractor/sub-contractors,
- Status of partnership initiatives with various agencies and NGOs.
- Financial implications of change management
- Evolution of new technology.

Review Output

Results of the review should, for example, focus on further improvements in every area.

Observations, recommendations, conclusions and proposed actions planned should be recorded to facilitate monitoring of progress, and it should be used as an input to subsequent reviews.

The output may include issues concerned with:

- Improvement of the effectiveness of the laid down healthcare management practices. This could be reflected by improvement in process parameters.
- Improvement in healthcare delivery system including technology for better patient care which is in line with the patient's need.
- All resource requirement for functioning, and overall hospital improvement.

Model questions and review of ISO 9001:2008

1. What are expectations of patients, who visit your hospital for treatment?
2. Please draw organogram of your hospital. Who should be performing the role of Management Representative (MR) and why? Also in the Organogram, identify training in-charge, document control in-charge and quality assurance in-charge.
3. Enumerate three main responsibilities of the MR.
4. How does top management of your hospital communicate with the hospital staff?
5. For implementation of Quality Management System at your hospital, quality policy is required to be developed. Please make draft quality policy, which is relevant for your hospital.
6. What are the inputs or issues, which should be discussed by the hospital management committee during management review meeting?
7. True/False
   - For implementation of Quality Management System, leading to certification against ISO 9001:2008 standards, the hospital should have a Management representative. (True/False).
   - The Hospital and its departments should have quality objectives, which are SMART. (True/False)
   - Record of review meetings may not be maintained. (True/False)
   - Review meeting should also discuss action planning. (True/False)

CHAPTER 6

Resource Management

ISO 9001:2008 Requirements

6 RESOURCE MANAGEMENT

6.1 Provision of resources

The organisation shall determine and provide the resources needed:

- to implement and maintain the QMS and continually improve its effectiveness; and
- to enhance customer satisfaction by meeting customer requirements.

What it means in a hospital setting

Explanation of Clause

Any hospital on health management should plan and determine the provision of resources, viz:

- Human Resource - Men
- Infrastructure - Material
- Financial Resource - Money
- Skill sets - Method

In addition we could use technology - the knowledge and skills of systems for delivering patient care and skill development.

ISO 9001:2008 Requirements

6.2 Human resources

6.2.1 General

Personnel performing work affecting conformity to product requirements shall be competent on the basis of appropriate education, training, skills and experience.

NOTE: Conformity to product requirements can be affected directly or indirectly by personnel performing any task within the QMS.

What it means in a hospital setting

Explanation

It is important to ensure that the people working in the hospital and especially those providing patient care are competent. It requires them to have appropriate education, training, skills and experience. This involves two aspects:

- Recruitment and posting process which ensures that people with appropriate education, skills and experience are brought in.

Assessment of the work performance and skills of each employee and developing an in-service training module to ensure that they have the needed skills.

General guidance

Introduction

In a public healthcare facility, the government is responsible for fulfilling the resource needs of hospitals in terms of infrastructure, manpower, finance and other resources required for patient care.

This requirement is tied to management review in section 5, which specifically states that the review must lead to actions relating to resource needs.

The term resource includes financial resources, human resources, infrastructure, equipment, technology, drugs and supplies etc.

Determining resource requirements

Once a hospital has decided which processes it shall bring under its QMS, it should define with some clarity what resources it needs for the same.

These shall be decided with reference to each service delivered, and also with reference to overall institutional goals.

What is required to be done for this are available in both the IPHS and in specific operational guidelines, like the operational guidelines for maternal newborn health, for immunisation, for malaria control etc. The hospital management must try to reach these standards.

However, the IPHS is for an entire range of services that the facility may provide. In event of budget constraints, the organisation would have balance the needs and ascertain as to how it would maximise utilisation. It could also plan for raising more resources at the local level - through donations, use of other government schemes etc within the framework of government guidelines.

Check with the IPHS for a facility of your size, and see what the current gap between their standards and your situation is. Based on this, the management will be able to decide how much of the gap could and should be closed in a time frame. Revisit this plan annually. The following is the format to be used for this:

S. No.	Designation/ positions	Sanctioned position	IPHS requirement	Current availability	Vacancy as per sanctioned position	Vacancy as per IPHS \ requirement

Human Resources Management

- It is important to define the human resources needed for the hospital. This includes both clinical service provision and support services like security, sanitation, diet, laundry etc. Start with the IPHS, estimate the gaps and what adaptations pre required to meet the local context and what is possible in the year.
- Establish individual and team objectives. This should include methods of measuring performance and evaluating results, facilitating involvement of staff in this objective setting and decision making.
- Define competencies needed and organise mapping competencies of the human resources at the healthcare facility. This would help to identify the competence needed for each position that affects its performance. The identification should be based on an analysis of present and expected needs of the healthcare facility, compared with the existing competence of its people.
- Make a recruitment plan. Most importantly for every post there should be a job description specifying deliverables and there should be a list of the professional qualifications and experience required.
- Make a training plan after assessing the training needs of each individual against his/her job requirements, and in view of the existing capacity of the individual. This analysis should result in development of training plans to provide people with knowledge, which together with skills and experience, leads to required competence in them.

Training plans should include:

- What is intended to be achieved through the training?

- When will the training be conducted (timeframe)
- Training Schedule details should have Logistics. (date, time, venue, LCD, white board, markers, language aids, water, lunch, power backup, speakers etc.)
- Training Record – When the training is actually conducted, a training record is generated which consists of the details of the participants, the curriculum adopted, name of the trainer, topic of the training and the signature.
- Trainers/Faculty
- Training Feedback - Evaluation of training through participants' feedback.
- Training Effectiveness Evaluation - Measurement of the effectiveness of training and the impact on the healthcare facility. This is done by taking the feedback as well as keeping an eye on the performance related to the training of the trained person, on his job performance.

Training material for skills related to service provision can be found in operational guidelines of respective health programmes or may be prepared in consultation with the faculty of medical colleges. Training for the management of the hospital's non-clinical patient care services and QMS would be needed in all hospitals taken up under this programme.

An indicative list of training topics that could be considered for training in district hospitals is given below. However, this is not exhaustive and more topics depending on local needs must be incorporated into this.

- Quality Management Systems
- Document Control Management
- Internal Quality Audits
- Corrective and Preventive Action Management
- Patient Satisfaction Measurements and Action on Gaps

- BMW Management
- Operation Theatre Management
- Disaster Management
- Clinical Emergency Preparedness and Management
- Infection Control Methods and Procedures
- Hospital Legal and other Statutory Requirements
- OPD Management
- IPD and Ward Management
- Housekeeping and Sanitation Management
- Hospital Inventory Management
- Outsourcing Management
- Management of Death

Since all this is quite a lot of training, it would make sense to package the training into two or three groups with clear responsibilities for those delivering the training and those who are responsible for it.

Table 3: Group of trainings in a public hospital

S. No.	Activity	Responsibility	Detail of Trainees
1	Induction & orientation: All new recruits; i.e., all those transferred in if their service record shows no training in required areas and testing shows training needs.	Hospital management/all department heads	New Recruits and staff transferred from other centre.
2	Clinical skill training: all clinical service providers training institutions identified and approved by the state.	Departmental heads	Clinicians/Nursing staff to be trained
3	Department Quality Objectives Training	Department heads-overall training coordinator	HODs & Admin Personnel.
4	Hospital Quality Objectives Training	MR/Training Coordinator	HODs & Head of the Organisation

6	BMW Management	Any Specialist/ Matron/Hospital Manager	All staff present in the Hospital except Admin person
7	Disaster Management	RMO	All staff
8	Infection Control	Any specialist/ICN	All clinicians/ Paramedical and upto some extent Class IV(OT,BB,Lab)
9	Housekeeping	Sanitory Inspector	All housekeeping staff
10	Medical Audit	1 person designated for this work.	All clinicians/ nursing staff and data operators.
11	Inventory Management	Chief Pharmacist	All pharmacists/ Nursing Incharge/ matron/steward
12	OPD Management	RMO	All MOs/Nursing Incharge of OPD/SI
13	IPD Management	Matron/Hospital Manager	All staff
14	OT Management	Surgeon	All Specialist/ nursing staff of OT
15	HMIS	IT personnel	People related with HMIS
16	Patient & Employee satisfaction Survey	Hospital Manager	Admin personnel
17	Behaviour of staff towards patients	Hospital Manager	All staff.

Infrastructure

Infrastructure means much more than just the buildings. Hospital infrastructure provides the foundation for healthcare operations. Depending on the extent of healthcare services, the infrastructure may include workspace, hardware, software, tools and equipment, support services, communication, transport and facilities. *Such infrastructure may include but is not limited to:*

ISO 9001:2008 Requirements

6.2.2 Competence, training and awareness

The organisation shall:

- Determine the necessary competence for personnel performing work affecting conformity to product requirements.
- Where applicable, provide training or take other actions to achieve the necessary competence.
- Evaluate the effectiveness of the actions taken.
- Ensure that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives.
- Maintain appropriate records of education, training, skills and experience (see 4.2.4).

What it means in a hospital setting

Explanation

- For every process identified for inclusion in the QMS, the hospital management should identify the human resources it needs to execute it and provide a clear job description as well as a listing of competencies, knowledge and skills required to execute this job.
- It shall determine whether the existing personnel doing that job have the required skills or not. If they do not have the skills, provide or arrange for training them. Adequate training depends upon securing reliable data as a basis for answering the following questions:
  - Who is to be trained?
  - On what do they need to be trained?
  - By whom are they to be trained?
  - How are they to be trained?
  - How is the effectiveness of the training to be evaluated?

- For this, Training Needs Assessment is done by four techniques:
  - Employees Needs Assessment
  - What the supervisor/immediate superior feels about the employee?
  - What is organisational need?
- On keeping abreast with the emerging environment.
  - It would see whether training outcomes have led to the person acquiring the skills and more importantly is the service or process being delivered and is it in conformity with the quality standards set for it.
  - Ensure that every employee knows the job description, and the quality objectives for the process in their respective area of work. For each employee, maintain records of the education, experience, skills and training received.

- OPD Registration Counter
- Help Desk Counter
- OPD Consultation Rooms
- IPD Wards
- Nursing Stations
- Pre Operative Room
- Operation Theatre
- Labour Room
- Sterilisation Rooms/Theatre Sterile Supply Unit (TSSU)
- Post Operative Room
- Medicine Store
- General Store
- Emergency Block
- Toilets
- Restrooms
- Sewage and waste water drainage
- Gardensenvironment
- Kitchen for patient/attendants
- Transport services
- HMIS
- Natural resource management system, e.g., air, light, water, (green hospital)
- Administrative office
- Work environment
- Security management system

Regarding the building, the hospital should:

- Define and provide adequate infrastructure for patient needs and healthcare service delivery processes. The infrastructure should meet objectives of patient care as well as functional objectives. The IPHS specifies the minimum infrastructure needed for important health services in the public sector.
- Develop and implement preventive maintenance approach to ensure that the available infrastructure continues to meet requirements. This approach should consider the type and frequency of maintenance and verification of operation of each infrastructure element, based on its criticality and usage,
- Consider environmental issues associated with infrastructure such as conservation, pollution, and waste management etc.

ISO 9001:2008 Requirements

6.3 Infrastructure

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

- Buildings, workspace and associated utilities
- Process equipment (both hardware and software)
- Supporting services (such as transport, communication or information systems).

What it means in a hospital setting

Hospitals should have infrastructure required to provide the planned services. The term infrastructure in this context would mean:

- Buildings room space with adequate maintenance and safety features-ventilation etc.
- Equipment - like DG Set for power backup and service delivery equipment such as X-ray machine, BP Apparatus, Suction Machine, Defibrillator, operational equipment etc.
- Hardware and software for data compilation, patient investigation report generation.

Support services EPBAX system, telephone exchange, ambulance and other vehicles for delivery of patient care, transport of goods, information services, security services and dietary services.

ISO 9001:2008 Requirements

6.4 Work environment

The organisation shall determine and manage the work environment needed to achieve conformity to product requirements.

What it means in a hospital setting

Explanation

Work environment in a healthcare facility is a combination of human and physical factors.

The physical factors impacting work environment are:

- Cleanliness and hygiene in all areas across the hospital and its surroundings
- Good level of illumination within the hospital premises. The illumination in the wards, corridors and other various parts of the hospital should be as per the BIS standard for Lighting, IS 10905.

- Natural phenomena that cannot be controlled may impact the infrastructure. The plan for infrastructure should consider the associated risks and include strategies to maintain the quality of healthcare services during disasters, e.g., earthquake, flood etc.

Regarding equipment, the hospital should

- Identify what equipment is needed for each service to be delivered as well as the approximate life of each equipment. Categorise into minor equipment and major equipment - based on financial norms, timelines and degree of replacement required.
- For all major equipment define technical specifications required and ensure that the procurement of machines complies with this. Procurement may be done by due process.
- For all minor equipment, it is advisable to define technical specifications and make sure there is a surplus stock in the warehouse from which if the equipment is damaged, another replacement can be easily got, even as repairs are carried out.
- Processes for condemning and disposing off equipment and furniture which is not in use and not needed is usually very well defined in states/UTs but its implementation is sluggish due probably to the complexity of the process.
- For all major equipment there should be a maintenance contract. For each equipment, it is important to maintain a log of the date of purchase of the equipment, its last calibration date, preventive maintenance schedule, recommended lifetime of the equipment. AMCs are best operated at the state level.

Note 1: The term "work environment" relates to those conditions under which work is performed, including physical environmental and other factors (such as noise, temperature, humidity, lighting or weather).

- Controlled temperature, ventilation, humidity and airflow in specific critical areas like drug storage or operation theatres, blood banks etc.
- Stray animal, rodent free and pest free wards, storage areas and resting areas in the hospital.
- Ambient noise levels.

Human factors impacting work environment:

- Creative work methodologies and opportunities for greater involvement to realise the potential of all people e.g. ergonomics.
- Safety rules and guidance, including use of protective equipment especially in radioactive prone areas like the X-ray room,
- Special facilities for employees like rest room, canteen etc.

These factors influence motivation, satisfaction, and performance of people, especially those delivering patient care (doctors, nursing staff and general duty attendants, sanitation and security staff), thereby enhancing the performance of that healthcare facility.

Support services

- Support services can be in house or outsourced. For the in-house support services, there should be work instructions circulated to all those who are responsible for carrying out specific jobs. In case some training is required, the same should be arranged.
- For the outsourced services, the Terms of Reference (ToR) for the particular job should cover the scope of services fully. Activities which constitute default should be clearly mentioned in the ToR. The termination clauses in case of default should also be made clear to the outsourced agency.
- The Hospital Manager or a person designated by the hospital authorities should be responsible for the supervision of outsourced activities/services.

Work environment

Physical environment

- Cleanliness and hygiene in all areas across the hospital and its surroundings
- Good level of illumination within the hospital premises. The illumination in the wards, corridors and other various parts of the hospital should be as per the BIS standard for lighting.
- Controlled temperature, ventilation, humidity and airflow in specific critical areas like drug storage or operation theatres, blood banks etc.
- Stray animal, rodent free and pest free premises including storage areas and resting areas in the hospital.
- Ambient noise levels: The hospital must take extra effort to ensure that there is total silence around the hospital, preventing disturbance to service providers as well as patients. Improve temperature by installing air conditioning, air cooling or heating whichever is applicable according to that place's seasonal conditions, ensure there is acceptable humidity by installing dehumidifiers especially in the critical care areas. Ensure adequate lighting arrangements are established for adequate luminosity in wards other care areas and OT and also ensure work areas are protected from bad weather conditions.

Service providers must also ensure that the hospital is hygienically clean and sanitised and BMW is managed and disposed properly.

Human Environment

Protection against radioactive exposure in radio-diagnostic areas for preventing occupational hazards and infection control is vital for ensuring prevention against cross contamination while providing patient care. Towards ensuring a safe and sound work environment, the hospital management must take steps to protect people working in the healthcare facility against such occurrences.

Model questions and review of ISO 9001:2008

1. Categorise resources needed for running of the hospital where you work. Prepare a list of Human Resources available in your hospital. Compare this list with State Government HR norms for your hospital and also with IPHS norms.
2. Based on the list prepared for HR resources in your hospital, critically examine requirement of the Human resources for each department of the hospital. Your recommendation for the HR should focus on functional aspect of service delivery, like its commitment of services mentioned in the citizen's charter, minimum HR requirement for attaining the quality objectives, assurance of service guarantee (as applicable to the facility), etc.
3. Enumerate infrastructure requirement, which are critical for attaining Quality Management System in your Hospital. Please find out water and electricity requirement of your hospital vis-à-vis availability. If there are short falls in the electricity availability, please prepare an action plan to mitigate the shortage.
4. Please develop a competency matrix of nurses, working in the labour room of your hospital.
5. Enumerate support services of your hospital. Whether these services are being delivered 'in-house' or the services have been 'outsourced'. What are the criteria for monitoring the House-keeping services?
6. True/False
   - Training feedback on conclusion of training session does not help in improving the training quality. (True/False)
   - The services, that have been outsourced do not fall within the purview of ISO 9001:2008 standards. (True/False)
   - Distance between centres of two beds in General Ward of a Public Hospital should be at least 2.25 metres. (True/False)
   - Minimum Illumination level in General Ward of a Public Hospital should be 100 lux. (True/False)

CHAPTER 7

Service Realisation

ISO 9001:2008 Requirements

7 PRODUCT REALISATION

7.1 Planning of product realisation

The organisation shall plan and develop the processes needed for product realisation. Planning of product realisation shall be consistent with the requirements of the other processes of the QMS. (see 4.1)

In planning product realisation, the organisation shall determine the following as appropriate:

- Quality objectives and requirements for the product.
- The need to establish processes and documents, and to provide resources specific to the product.
- Required verification, validation, monitoring, measurement, inspection and test activities specific to the product and the criteria for product acceptance.
- Records needed to provide evidence that the realisation processes and resulting product meet requirements (see 4.2.4).

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

Note 1: A document specifying the processes of the QMS (including the product realisation processes) and the resources to be applied to a specific product, project or contract can be referred to as a quality plan.

Note 2: The organisation may also apply the requirements given in 7.3 to the development of product realisation processes.

What it means in a hospital setting

A hospital must determine, define and plan the delivery of healthcare services that it commits to provide to patients who visit the hospital.

Objective targets should be developed for each such service which the hospital offers, and/or for each department of the hospital. It essentially entails that departments set their targets which would be achieved in a given time-frame.

It should develop a process flow chart of the sequence of events to deliver that service (or achieving the targets which the department has set for itself).

The hospital provides health services as per Standard Treatment Guidelines (STG) & protocols – asking for investigations which are required to arrive at a diagnosis, writing generic prescriptions as per STG, conducting medical audit, prescription audit, validation of test results, calibration of instruments, etc.

The hospital maintains records of the above activities.

Chapter 7 Service Realisation

Service realisation in a health facility refers to all the processes/activities, which are undertaken by the health facility to deliver the intended service(s) for which the health facility exists. For instance, service realisation for a First Referral Unit (FRU) would be providing comprehensive obstetric and neonatal care, which is in addition to all other functions of a designated FRU, as mentioned in Level III facilities of 'Operational Guidelines on Maternal & Newborn Health'. For achieving this kind of functionality, it would be essential that all stakeholders function in a cohesive and complementary manner, thereby supporting each other's efforts.

The hospital shall identify and plan the processes that are required for the intended service delivery.

Hospital processes can broadly be categorised into three groups:

- Those processes which have a direct bearing on patient care, i.e., the OPD, Accident and Emergency Department, Diagnostic Services, IPD management, Operation Theatre etc.
- Processes required for supporting aforementioned clinical processes - also includes those administrative processes, which indirectly support patients' diagnosis and treatment. A few of such examples would be purchasing, inventory, ambulance services, diet, laundry, etc.
- Processes related to introduction of QMS and its sustenance – patients' feedback from OPD and wards, complaint redressal, employees feedback, internal audit, management review meetings etc.

ISO 9001:2008 Requirements

7.2 Customer-related processes

7.2.1 Determination of requirements related to the product

The organisation shall determine:

- Requirements specified by the customer, including requirements for delivery and post-delivery activities.
- Requirements not stated by the customer but necessary for specified or intended use, where known.
- Statutory and regulatory requirements applicable to the product.
- Any additional requirements considered necessary by the organisation.

Note: Post-delivery activities include, e.g., actions under warranty provisions, contractual obligations such as maintenance services, and supplementary services such as recycling or final disposal.

What it means in a hospital setting

Patients and the community who are dependent upon the hospital for their health needs and are seeking healthcare services at the hospital.

The requirement of the patient is cure, relief or at least amelioration or palliation. It also includes prevention of disease and promotion of good health.

- In healthcare, due to information asymmetry, it is often difficult for a user to know whether the care is of good quality or not, especially in situations where cure is not possible. However, in most of the situations, the requirement is specific that a patient visits the hospital to get relief from his symptoms
- The patient may not state or may be aware of each and every need. For example, in the case of institutional delivery, care of the newborn is implied.
- The hospital should also ensure that all Statutory and Regulatory requirements applicable to healthcare services are established and complied with. For example, termination of pregnancy in compliance with the MTP Act, storage and transfusion of blood as per the

For each service, the hospital must:

- Define the quality objectives, which the hospital and its departments intend achieving during a pre-defined period. We have already discussed the quality objectives.
- The hospitals/departments should document current processes, which are undertaken in the hospital.

Please answer the following questions –

- Are exiting processes adequate in number, cutting across all key functions?
- Are they supporting objectives of the health facility and/or its departments?
- Are the processes efficient OR are they creating 'bottle-necks'?
- Are the processes synergistic with processes of other departments?

- After creating and documenting the processes which are considered essential and required for achieving hospital services; review the process and amend/ modify them, when needed. Subsequently all members should be trained on the procedures. The department of the hospital or the concerned section of the hospital should work, according to the changed procedures.
- Establish a mechanism of verification during the implementation. For instance, there is a practice in hospitals that, during labour pains, pregnant women report at the Accident and Emergency Department of the hospital. After a review, it is found that there is a time gap between reporting at the A&E Department and shifting the women to the labour room. It is decided that all such women would be taken straight to the labour room of the hospital. Simultaneously, the admission process would be undertaken centrally. In this case, labour room procedures, admission SOP and work instructions for the ambulance driver would require to be changed and all concerned are to be made aware of the changes.
- Maintain records of the service delivery and the processes followed, so that there is evidence that they meets the standards set by the Health Facility/Department.

There may be a need to review them periodically and assess their suitability.

- Developing an action-plan for the implementation of:
  (a) Resources, (b) Knowledge and Skill, and (c) Timeframe.
- This may entail TRAINING/RE-TRAINING.

Drugs & Cosmetics Act, compliance to the PNDT Act, operation of imaging services with AERB clearance.

- Other than rendering treatment, hospitals are expected to meet the other requirements – immunisation of newborn baby Oral Polio Vaccine and Bacillus Calmette Guerin (OPV & BCG), counselling and advice on contraceptives during the postpartum phase.

ISO 9001:2008 Requirements

7.2.2 Review of requirements related to the product

The organisation shall review the requirements related to the product. This review shall be conducted prior to the organisation's 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:

- product requirements are defined;
- contractor order requirements differing from those previously expressed are resolved; and

What it means in a hospital setting

Once the services to be delivered are understood, it is important to review the quality requirements of intended care to the patient before making any commitment to them or their attendants.

The patient needs are evaluated against the available resources and the internal capabilities are assessed before committing to deliver that service. For example, a district hospital may not be equipped to treat a patient of Acute Coronary Insufficiency, but is responsible for rendering first aid treatment before transferring the patient to a cardiac centre.

EXAMPLE

- The hospital should develop a plan for the Emergency Department in terms of quality objectives. Having approved emergency protocols, availability of infrastructure, investigation facilities and personnel who have the knowledge and skill to treat and manage patients in the Emergency Department. At the same time, there should be a system to record evidence of all important activities while providing emergency care, which may also include undertaking procedures required as per the existing law, e.g., medico-legal examination. These records are evidence of compliance with standards.
- The hospital should develop a plan to make maternal and newborn healthcare services and child-care services achieve quality objectives, as set forth in the department's Family Friendly Hospital (FFH) initiatives. This would include having approved clinical protocols for management of normal pregnancy, protocol for referral, protocol for management of normal labour and care of newborns, with as little out of pocket expenditure as can be provided.

Translating the above-mentioned requirement into practice

- A hospital must define the services it will offer (written document, in a public domain). In a district hospital, it could be secondary level care in those specialities which are available in the hospital and are supported by appropriate diagnostic and treatment facilities.
- Objective targets should be developed for almost each such service which the hospital offers, and/or for each department of the hospital. It essentially entails that departments set their targets which would be achieved in a given timeframe.
- It should develop a process flow chart of the sequence of events to deliver that service (or achieving the targets which the department has set for itself).
- The hospital provides health services as per Standard Treatment Guidelines (STG) & protocols – asking for investigations which are required to arrive at a diagnosis, writing generic prescriptions, as per STG, conducting medical audit, prescription audit, validation of test results, calibration of instruments. etc.
- The hospital maintains records of the above activities.

- the organisation has the ability to meet the defined requirements.

Records of the results of the review and actions arising from the review shall be maintained (see 4.2.4).

Where the customer provides no documented statement of requirement, the customer requirements shall be confirmed by the organisation before acceptance.

Where product requirements are changed, the organisation shall ensure that relevant documents are amended and that relevant personnel are made aware of the changed requirements.

Note 1: In some situations, such as internet sales, a formal review is impractical for each order. Instead, the review can cover relevant product information such as catalogues or advertising material.

The Citizen's charter displays such services which are available in the hospital. This may need to be updated on a regular basis. For example, if a hospital adds Intensive Care Unit (ICU) facilities, it should to be added to the display board at the reception.

Secondly, under the QMS, the hospitals should review their SOPs at pre-defined intervals to include new modalities of treatment or new administrative activity, so that obsolescence could be avoided. We need to remember that QMS is a dynamic system.

Planning for quality of patient related processes:

- Identify the list of the services to be delivered.
- Define scope of SOPs to be used.
- List the quality parameters of each.
- Define who is responsible for the quality of each.
- Define the resource requirements of each.
- List the records and registers which are to be maintained for verification.

We explain this below with two examples: one institutional delivery, i.e., basic emergency obstetric and newborn care level, and another is an emergency or casualty department.

ISO 9001:2008 Requirements

7.2.3 Customer communication

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

- product information;
- enquiries, contracts or order handling, including amendments; and
- customer feedback, including customer complaints.

What it means in a hospital setting

The hospital must establish effective ways to:

- Communicate to the patient services being delivered, the costs of care, the standards of care being assured, the rights of patients and those responsible for different functions.
- Respond to requests for information, except those which are of a confidential and private nature, guide users to access different services with greater concern for those with low literacy levels or who come from marginalised sections, convey changes regarding the assured services.
- Have an effective mechanism to accept complaints and suggestions and a grievance redressal mechanism to respond to them. It would also include Patient Satisfaction Surveys (PSS) (from OPD and indoor patients) to provide feedbacks.
- Patient's charter should be displayed at prominent locations within hospital premises, so as to make patients aware of services offered at the health facility along with the rate list.

	Institutional delivery	Casualty department
List of services	• Normal delivery • Assisted delivery • Delivery of complicated deliveries • Caesarean section facility • Blood transfusion facility	Life and limb saving treatment
Quality parameter for the service	• Mortality and morbidity rates • Patient satisfaction scores • Infection rates in mother/newborn • Institutional delivery rate • Night delivery rate • Caesarean section rate • No. of units blood transfused in a month • Incidence of postpartum infection • Neonatal sepsis - no. of admissions • Umbilical sepsis • Incidence of retained placenta • Incidence of Primary Postpartum Haemorrhage (PPH)	• Receipt of call and dispatch of ambulance • Number of patients, attending the casualty department on holidays and non-working hours • Utilisation of ambulance for conveying patients vs ambulance usage for other purpose • Time between origin of calls and patient attended by doctor and/or patient.
Who is responsible?	• Head of the Department of Obstetrics and Gynaecology (OBG) • Duty Gynaecologist • Blood Bank Officer • Paediatrician • Anaesthetist • Doctor trained in EmOC • Nurse in Maternity Ward • Nurse in Labour Room • Medical Officer In-charge Ward • Staff trained in Small Business Administration (SBA)	• Telephone Operator • Receptionist • Casualty Medical Officer • Casualty Nurse • OT Technician

ISO 9001:2008 Requirements

7.3 Design and Development

7.3.1 Design and development planning

The organisation shall plan and control the design and development of product. During the design and development planning, the organisation 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.

The organisation shall manage the interfaces between different groups involved in design and development to ensure effective communication and clear assignment of responsibility. Planning output shall be updated, as appropriate, as the design and development progresses.

NOTE Design and development review, verification and validation have distinct purposes. They can be conducted and recorded separately or in any combination, as suitable for the product and the organisation.

What it means in a hospital setting

Hospital should plan and control design and development of main processes of healthcare services, such as Treatment, Drug Distribution, Dressings, Laboratory Investigations, Operation, Post-op. care, etc. In event of hospital contemplating to induct a new service or process following considerations are essential to be kept in mind:

a) design and development of new service or process includes following steps:
    - Conceptualise the design
    - Access the resource requirement
    - Serialize the interrelations of each step
    - Control of in process measures
b) Whatever processes are developed in hospital, which could be treatment protocol, Standard treatment guidelines, SOPs for various departments need to reviewed by hospital functionaries and verified. Sources of such verification would be standard medical text books, journals, publications of WHO, UNICEF, NACO and Government Guidelines. Few activities may need validation like sterilisation procedure, laboratory report, disinfection in OT & labour room.
c) Any change in the above mentioned processes needs to be authorised by designated person, before it gets implemented.

Top management such as Civil Surgeon/DMS should identify personnel, who be nodal person for such activities. They would be communicting with hospital functionaries and various other stakeholders.

Design and development

General Guidance

It is essential for healthcare facilities to design and develop its processes that are required for the delivery of quality healthcare and enhancing patient satisfaction.

Top management should ensure that processes not only support their main function but also take in to consideration the factors that contribute to meet service and process performance expected by patient and community.

e.g. If a patient is going for diagnosis before treatment, organisation should take into account the safety of patient and employee from radiations through use of personnel protective equipments like lead apron, TLD badges or appropriate thickness of walls, proper signage etc. outside the x ray room and responsibility of provider is that all such provisions be suitably organized.

Design Process

Health service design process should be documented in form of Standard operating procedures (SOP)/standards treatment protocol (STP)/work instruction. SOP/STP are written instructions to achieve uniformity of the performance of a specific function and which also meets compliance standards. These compliances requirement/standards are set by regulatory bodies, clinical protocols, standard treatment guidelines, and intellectual inputs from clinicians, guidelines from Indian Public Health Standards (IPHS). SOP/STP should describe how expected health service outcomes are identified. Need assessment for the service delivery are used to design medical care and its evolution e.g. In case of needle stick injury to any of employee in healthcare facility, the action taken by emergency medical officer would be:

7.3.2 Design and development inputs

Inputs relating to product requirements 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.

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

Design & development inputs related to the healthcare service requirements are received in the form of available clinical protocols, standard treatment guidelines, intellectual inputs from clinicians, guidelines from Indian Public Health Standards (IPHS), etc. Hospital customers (patients) may provide their inputs through customer perception surveys, which could trigger the change process in the hospital. For any such changes, appropriate records for reasons would be maintained e. g. CPS data, Standards Treatment Guidelines, Government Directives/circulars, etc.

7.3.3 Design and development outputs

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

Design and development outputs shall:

a) meet the input requirements 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.

NOTE Information for production and service provision can include details for the preservation of product.

Design and development outputs should be made available in the form of Standard Operating Procedures, Standard Treatment Protocols, Work Instructions, General Guidelines and Quality Assurance Plans that enables verification against the input and should be approved by Civil Surgeon/Head of Departments/Facility Incharge as applicable prior to release. For example, if a new drug has been introduced in the pharmacy, prior to its introduction in routine prescription, detail information on its indication, contraindication, side effects, etc should be intimated to all personnel, concerned directly with that drug.

Design and development input

Healthcare facility should identify inputs which directly affect the design and development of processes required for healthcare delivery. Major inputs in healthcare facilities are human resource, Infrastructure, financial resources and skill requirement. All these inputs require planning which should address patient's privacy, safety and effectiveness and efficiency of process performance in order to meet patient's expectations. For e.g. during equipment planning the healthcare facility should take following inputs in to consideration:

• Identify need of equipment/ instruments that are required to delivery each service.	• Statutory or regulatory requirements to operation and installation of equipment
• Categorise into essential and desirable equipment - based on financial norms.	• Training required for operating the equipment
• Infrastructural needs for installation of equipment	• Projected work load/utilisation for each equipment
	• Maintaince plan requirement and agency to minimise down time.

Design and development output

The output should include information that facilitates reviews of inputs. Therefore, design and development of outputs should be reviewed against inputs to provide objective evidence that outputs have effectively and efficiently met the requirements for the processes. For e.g. during equipment planning outputs taken in to considerations:

• Purchase of equipment based on technical specification ensures that procurement of equipment is as per the specifications	• Maintenance contract (AMC/CMC) of equipment and such contract should specify process, timelines, penalty for non compliance etc.
• Training of employees to utilise of equipment	• Processes for condemning equipment and its final disposal as and when needed.

7.3.4 Design and development review

At suitable stages, systematic reviews of design and development shall be performed in accordance with planned arrangements (see 7.3.1)

a) to evaluate the ability of the results of design and development to meet requirements, and
b) to identify any problems and propose necessary actions.

Participants in such reviews shall include representatives of functions concerned with the design and development stage(s) being reviewed. Records of the results of the reviews and any necessary actions shall be maintained.

The healthcare service processes should be evaluated at pre-defined interval. It could either be done internally by the hospital or by external organisation. The hospital would maintain records of such reviews.

7.3.5 Design and development verification

Verification shall be performed in accordance with planned arrangements (see 7.3.1) to ensure that the design and development outputs have met the design and development input requirements. Records of the results of the verification and any necessary actions shall be maintained.

Responsible person should verify developed processes of clinical and administrative services to ensure that the outputs satisfy the requirements of hospital. Records of verification and necessary actions thereupon should be maintained post review and verification by top management (Civil Surgeon) assisted by responsible person may be Dy. Medical Superintendant or Resident Medical Officer.

Design and development review

Hospital authorities should ensure that appropriate people are assigned to manage and conduct systematic review to determine that design and development objectives are achieved.

E.g.: The main objective of hand hygiene policy is to minimize the risk of disease transmission to patients via the hands of staff. It can be assured by hospital infection control exercise through:

• Completion of mandatory training on hand hygiene to all healthcare workers.	• Monitoring the volume of alcohol-based hand rub used per 1,000 patient days.
• Statistical status in hospital acquired infection rates.	• Providing feedback to healthcare workers about hand washing habits.

Design and development verification

Verification should be used to monitor ongoing trend in relation to set criteria and standards to reach maximum healthcare perfection. Records of verification result shall be maintained and necessary action shall be taken for same, e.g. maternal mortality rate should not be more than 1% or nurse patient ratio in ICU is 1:1 during day time.

7.3.6 Design and development validation

Design and development validation shall be performed in accordance with planned arrangements (see 7.3.1) 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 prior to the delivery or implementation of the product. Records of the results of validation and any necessary actions shall be maintained

Validation of design and development in healthcare facility means validating actual services with respect to designed ones. Such validation can be done only by competent personnel handling processes by evaluation of suitability throughout established healthcare practices. Medical audits could be one the important sources of validation in the hospital.

Validation of designed and developed healthcare services is carried out by validating inputs with respect to outputs through following performance indicators both prior to delivery of healthcare services and during healthcare service delivery as applicable:

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 on constituent parts and product already delivered. Records of the results of the review of changes and any necessary actions shall be maintained

Design and development changes in healthcare services should be identified and a documented procedure called Document Modification Note (DMN) should be implemented for change control of revised design of that service (s). All changes should be reviewed, verified and validated, as appropriate, and approved by Civil Surgeon/ Facility Incharge before implementation.

Design and development validation

Healthcare processes can be evaluated for clinical and administrative services to ensure that the outputs satisfy the requirements of hospital, patient, and community. e.g. Validation of hospitals laboratory services by external laboratory. In this system laboratory of the hospital have arrangement with some or other good reference laboratory where samples are sent periodically for cross checking and confirming the proficiency and quality of own tests result.

Control of design and development changes

Periodic review or validation of processes lead to change in design and development of healthcare services which should be identified from time to time and captured in documented procedure All changes should be reviewed, verified and validated and approved by Civil Surgeon/Facility In charge before implementation.

ISO 9001:2008 Requirements

7.4 Purchasing

7.4.1 Purchasing process

The organisation shall ensure that the purchased product conforms to the specified purchase requirements. The type and extent of control applied to the supplier and the purchased product shall be dependent upon the effect of the purchased product on subsequent product realisations or the final product.

The organisation shall evaluate and select suppliers based on their ability to supply the products in accordance with the organisation's requirements. Criteria for selection, evaluation and re-evaluation shall be established. Records of the results of evaluations and any necessary actions arising from the evaluation shall be maintained. (see 4.2.4)

What it means in a hospital setting

Purchasing of material in government hospitals is a systematic process based on laid down procurement procedures of the concerned government department and/or District Health Society (RKS).

The hospital should ensure that the purchased product conforms to the specified purchase requirements based on indent specifications/work order specifications

Selection of suppliers is governed by the departmental rules. However, in most of the states, there is a rate contract which gets finalised at the beginning of the financial year. For small quantities, a reasonable decision can be made locally. That it is reasonable is decided by getting three to five quotes from the market from independent suppliers, as per laid down procedures of respective state governments/UTs.

Depending upon the guideline for purchases above a certain level, a tendering process is mandatory. Where the product can come in many different qualities and performance range with very different prices, the technical competence of the supplier is evaluated through specifications enclosed with the tender document. There are processes specified for identifying suppliers, for requesting proposals from them, for evaluating them and even for black listing them, in case of non-performance. Depending on the nature of supplies or equipment being purchased, the specific processes would get modified – within the rules.

The performance of each supplier is evaluated. If there have been instances of suppliers not meeting the requirements of the hospital or supplying sub-standard drugs, the contract of such suppliers is

	Institutional delivery	Casualty department
Resource requirements	• Number of Staff to provide 24X7 service • Staff's knowledge and skill development • Labour room • OT equipment • Blood storage facility	• Number of staff • Training of staff • Drivers • Ambulance • Emergency OT • Emergency ward
SOPs to be used	• Admissions • Ward management • Labour room management • OT & CSSD management • Neonatal Intensive Care Unit (NICU) management • Discharge management • Training	• Ambulance/Transportation SOP • Casualty department SOP • OT & CSSD
Infrastructure	• OT • Labour room • 100% power back up • 24X7 water supply • NICU • Ambulance services	• Emergency department space • Lighting • Power backup • Running Water
Equipment	• Boyle's apparatus • Equipment for NICU • Scale of equipment as recommended under NRHM • Baby warmers • Consumables	• Trolley/Chair car • Oxygen cylinder • Life saving drugs/equipment • Emergency OT equipment • Power back up • Ambulance • Crash cart • Emergency equipment on board of ambulance
Records to be maintained.	• Antenatal Care (ANC) card • Admission Register • Labour room/birth register • Case sheet • Medical record • Birth certificate • Records for Janani Suraksha Yojana (JSY) benefits	• Telephone log book • Ambulance log book • Emergency register • Admission register • OT Record/Emergency record register • Medico-legal record

terminated as per rules and they are not permitted to participate in the tendering process the following year. The entire process of procurement of drugs, supplies or equipment should be well documented through records and this should be available for review and should get evaluated annually.

It becomes imperative that while defining the terms of reference, material/service requirements and specifications are defined clearly to ensure right material/service is procured.

ISO 9001:2008 Requirements

7.4.2 Purchasing information

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

- Requirements for approval of product, procedures, processes and equipment.
- Requirements for qualification of personnel.
- QMS requirements.

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

What it means in a hospital setting

The hospital will decide on the quantity of drugs to be purchased, the rate at which it will be supplied and the delivery schedule. For equipment, the hospital will provide technical specifications including the duration and type of 'after sale service' and the Annual Maintenance Contract (AMC). The purchase order for the equipment may also include training on the new machine which the hospital staff would be required to undergo.

This may require concurrence of the people who are prospective users amongst the hospital staff e.g., the medicines would be prescribed by doctors and the Blood Pressure (BP) apparatus would be used by doctors. This would mean establishing a committee or making a person responsible for making the essential drugs and supplies list, another for equipment purchase, and another for procurement of services. Product specification of drugs, equipment or services to be procured should be finalised through this mechanism and documented.

Every service has its quality requirements. These include those related to the user, whose main concern is whether it is effective and if it is delivered with minimum discomfort and maximal safety and dignity.

It also relates to meeting statutory requirements. Management also has its quality objectives as part of larger social objectives and as part of efficiency of service.

Reflection on a few such services and their quality requirements is tabulated below:

	User defined	Statutory and legal compliance defined	Administration defined
Labour Room Services	Safe delivery and healthy baby	Placenta and other waste are disposed off as per BMW (management & handling) rules 1998	Deliveries are conducted by the professional staff, who are SBA trained and such staff are available on 24X7 basis. Labour room protocols are followed.
Emergency services	Patients coming to Emergency Department expect to be relieved on symptoms by professional care.	Medico legal record made for inflicted wounds, or road accidents, or attempted suicides and police duly informed.	Attended to within 5 minutes and definitive treatment started by doctors within 20 minutes. No patient stays more than 24 hours on an emergency bed.

7.4.3 Verification of purchased product (service provided)

The organisation shall establish and implement the inspection or other activities necessary for ensuring that the purchased product meets the specified purchase requirements. (client needs)

Where the organisation or its customer intends to perform verification at the supplier's premises, the organisation shall state the intended verification arrangements and method of product release in the purchasing information. (service delivery)

The hospital must establish quality plans for verification of the purchased material against the specifications laid down in the Purchase Order/Rate Contract to approve supplies. The Control Plan generally contains the following criteria:

a. Inspection Criteria
b. Method of Inspection
c. Sample Size
d. Reaction Plan (what to do in case non-conforming material has been received).
It is before the supplier bills are approved, inspection of purchased products is carried out for qualification of products. In case of services, midterm review and validation of services is carried out, to evaluate the performance through a checklist methodology.

ISO 9001:2008 Requirements

7.5 Production and Service Provision

7.5.1 Control of production and service provision

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

- The availability of information that describes the characteristics of the product.
- The availability of work instructions, as necessary.
- The use of suitable equipment.
- The availability and use of monitoring and measuring equipment.
- The implementation of monitoring and measurement.
- The implementation of product release, delivery and post-delivery activities.

What it means in a hospital setting

Delivery of health services should be controlled, i.e., it should be as per pre-defined specifications:

- Specifications defining quality of service should be available.
- STPs for that treatment or SOPs for support services.
- Suitable medical and non-medical equipment as needed, to ensure quality of the service and equipment is maintained to level of optimal functionality.
- Where needed, there should be equipment or methods that can measure the service delivered and opine on whether or not it met quality specifications. This is achieved by undertaking audits – Medical Audit, Prescription Audit, Death Audit.
- These methods should be used to monitor compliance to quality standards.

Follow up of patients should also be built in to see that long term benefits are there.

	User defined	Statutory and legal compliance defined	Administration defined
X-ray services	Done on same day as is ordered. Good quality of image with reporting by a qualified radiologist	AERB regulations complied with	BPL patients are exempted from paying for it. No stock-out of films. Wastage of films is avoided.
Laundry services	• Clean sheet and hospital dress available for each patient • Blood and body fluid stains removed completely	The Water (Prevention & Control of Pollution) Act 1974	Policy on demand and stocking of laundry Laundry SOP
Sanitation services	Surroundings clean - no insects or rodents Toilets clean and usable No stinking smells	• Municipal Waste Act • BMW Management & Handling Rules 1998	Efficient use of financial resources

While understanding patient requirements, the hospital must also factor in:

- Post treatment requirements of patients like the preventive measures the patient has to take after he or she is discharged, and suggest time for the next visit.
- Requirements not stated by patients but necessary for the hospital to communicate, like telling the patient about side effects of medicines prescribed or the diet that he/she should preferably take.
- Understanding the Statutory and Regulatory requirements like ensuring an FIR in the police station, in case of an accidents or getting the consent form filled in before surgery etc.

7.5.2 Validation of processes for production and service provision

The organisation shall validate any processes for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement and, as a consequence, 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 organisation shall establish arrangements for these processes including, as applicable:

- Defined criteria for review and approval of the processes.
- Approval of equipment and qualification of personnel.
- Use of specific methods and procedures.
- Requirements for records. (see 4.2.4)
- Revalidation

What it means in a hospital setting

Validation of lab reports should be undertaken periodically by sending samples to a reputed facility outside the hospital. However, the outcome of healthcare delivery may not be immediately apparent. For example, if patient is given treatment of OPD and she does not come back, it may be because she got cured, or because she was not satisfied and went to another service provider or it may be because she died. This is also true of in-patients at discharge.

Outcomes, therefore, need to be measured, both at the point of exit from the hospital and also on a longer term. This is essential to validate or verify the service delivery characteristics.

The hospital must establish arrangements for defining how it would measure its outcomes, Medical audits are an important tool for measuring outcomes. Indicators like “cure rate” and “case detection rates”, specific to each health condition, are also valuable tools.

Citizen's Charter

- Services being provided by the hospital
- Charges being levied by the hospital
- Information on available key personnel
- Information on methodology of availing services by Below Poverty Line (BPL) population
- Emergency contact numbers
- Good signage plan
- ***Develop SOPs for as many processes as deemed necessary.***
- Record of compliance on SOPs helps in efforts to improve the process.

Review of service requirements

- The hospital will review its capabilities in terms of availability of people, their clinical competence, medical treatment technology and other resource requirement to meet patient requirements.
- Before taking in any patient for treatment, the hospital should assess the requirements of the patient as against its capabilities, in order to deliver patient care.
- Healthcare services are defined for a particular hospital in its Citizen's Charter. Requirements, e.g., clinical protocols for treatment are established.
- Outsourced activities of the hospital should be appropriately expressed to the patient e.g., if the diagnostic services are outsourced, the patient should be informed about its formalities like rates of different tests.

ISO 9001:2008 Requirements

7.5.3 Identification and traceability (service delivery)

Where appropriate, the organisation shall identify the product by suitable means throughout product realisation.

The organisation shall identify the product status with respect to monitoring and measurement requirements throughout product realisation.

Where traceability is a requirement, the organisation shall control the unique identification of the product and maintain records. (see 4.2.4)

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

What it means in a hospital setting

This means that the healthcare service like out-patient care or in patient care or surgery must have identified service delivery characteristics in terms of process flow and STPs.

While delivering such services, its characteristics must be monitored and measured. This can be done by ensuring case records are maintained. Medical Case record is a strong example of identification and traceability for a patient, which can be referred to on the next visit and for other purposes. BHT is monitored for in-patient flow throughout the service delivery process.

For a support service like diet, appropriate records would show how many persons required it, how many were served and whether SOPs for this were followed.

For support clinical service like diagnostics also, the same principle applies.

7.5.4 Customer property

The organisation shall exercise care with customer property while it is under the organisation's control or being used by the organisation. The organisation 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, the organisation shall report this to the customer and maintain records. (see 4.2.4)

Note: Customer property can include intellectual property and personal data.

What it means in a hospital setting

Customer property in a healthcare facility means Patient Property, which should, after identification and verification, be protected as per legal requirements. e.g., Patient Records are also a property and should be protected and safeguarded against all odds. Samples collected for histopathology is patients property. Safeguarding the belongings of a patient being taken for procedures is the responsibility of the healthcare facility.

- The healthcare facility should except in emergency situation take consent from the patient or its attendants before admitting him/her or before any major treatment is to be administered.
- All patient related records should be maintained like Bed Head Ticket (BHT), consent forms etc.

Communication

It means communication between staff and patient as well as inter departmental communication.

The healthcare facility should ensure that there is a help desk and an enquiry counter near the reception for supplying information to the service seekers/users.

The concerned personnel of the hospital should be aware of the outsourced contracts, their terms and conditions pertaining to their respective work areas, e.g. where the laundry management is outsourced, the doctors, matron, nurses/sisters, ward-boys should be aware of the laundry contract so that they can keep a check on the outsourced person and the activities of the outsourced organisation.

Help Desk may be installed at the reception counter for the patient's convenience.

The list of doctors and specialities in the hospital should be displayed at the reception in English/Hindi and local/regional language.

ISO 9001:2008 Requirements

7.5.5 Preservation of product

The organisation shall preserve the product during internal processing and delivery to the intended destination, in order to maintain conformity to requirements. As applicable, preservation shall include identification, handling, packaging, storage and protection. Preservation shall also apply to the constituent parts of a product.

What it means in a hospital setting

Preservation of products in a hospital means preservation of those items which have a shelf life - such as, drugs, chemicals and blood and urine samples etc.

The healthcare facility must exercise sufficient controls to ensure these items are preserved – including handling, packaging, storage and protection against the environment.

ISO 9001:2008 Requirements

7.6 Control of measuring and monitoring equipment

The organisation shall determine the monitoring and measurement to be undertaken and the monitoring and measuring equipment needed to provide evidence of conformity of product to determined requirements.

The organisation shall establish processes to ensure that monitoring and measurement can be carried out and are carried out in a manner that is consistent with the monitoring and measurement requirements.

Where it is necessary to ensure valid results, the measuring equipment shall:

- Be calibrated or verified, or both, 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 (see 4.2.4)

What it means in a hospital setting

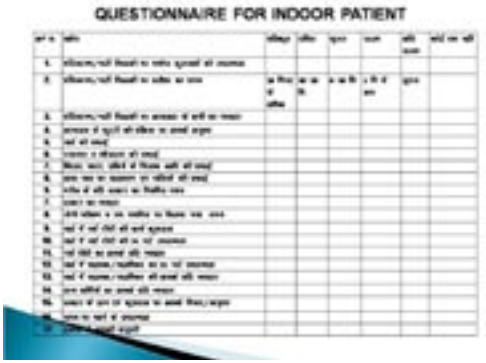
Hospital equipment used for healthcare delivery including devices for measurement and monitoring such as Weighing Scales, Temperature Controllers, Pressure Gauges (autoclaves), Thermometers, BP Apparatus etc., must be calibrated for their accuracy.

Calibration of such equipment must be carried out by a competent calibration agency only.

The hospital must plan the calibration and ensure calibration records are available in the hospital.

Patient feedback is critical to the success of the service delivery at the hospital. It should be done every three months on a random sample basis. Analysis of patient feedback should be done simultaneously.

Complaint boxes should be placed at various places in the hospital for the patients. Complaint resolution time and mechanism should be defined by the top management of the hospital.


QUESTIONNAIRE FOR INDOOR PATIENT

Interdepartment Communication

Protocol for interdepartmental communication should be established. It could be in the form of circular, referral on BHT, register etc.


Patient Satisfection Survey Analysis

Purchasing Process

The healthcare facility should have a purchasing process for selection, evaluation, and control of purchased products and services to ensure that they satisfy its needs and requirements, as well as, those of interested parties.

Purchasing processes address:

- Identification of needs
- Method for Inquiries, quotations and tenders
- Selection of contractor/sub-contractors including unique processes/suppliers/partners as per requirement
- Purchase and tender documentation
- Placing orders
- Verification of purchased product and services
- Contract administration
- Method to deal with non-conforming purchased product and services.


QUESTIONNAIRE FOR OUTDOOR PATIENT

- Be adjusted or re-adjusted as necessary
- Have identification in order to determine its calibration status.
- Be safeguarded from adjustments that would invalidate the measurement result.
- Be protected from damage and deterioration during handling, maintenance and storage.

In addition, the organisation shall assess and record the validity of the previous measuring results when the equipment is found not to conform to requirements. The organisation 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).

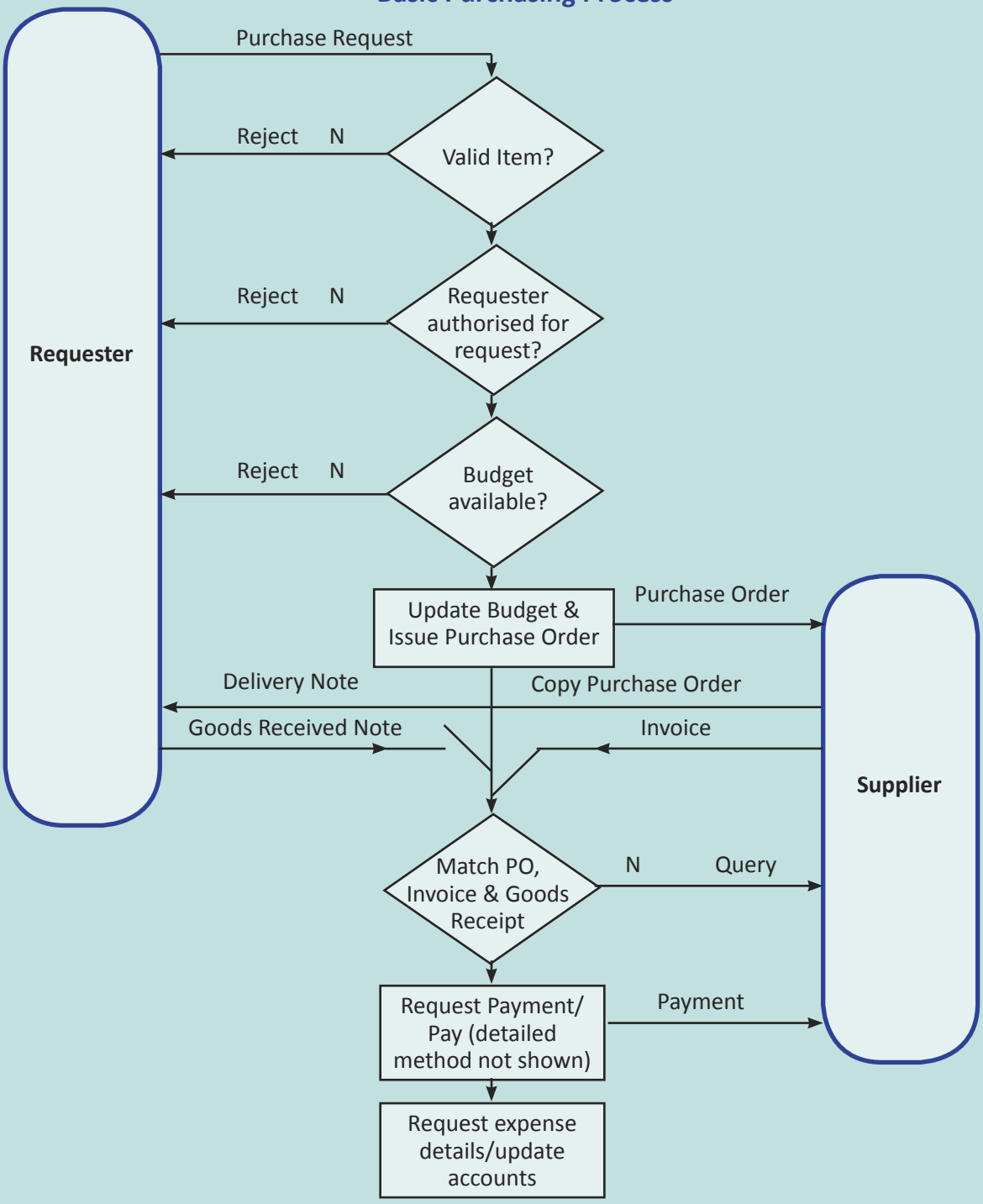
When used in the monitoring and measurement of specified requirements, the ability of computer software to satisfy the intended application shall be confirmed. This shall be undertaken prior to initial use and reconfirmed as necessary.

Note: Confirmation of the ability of the computer software to satisfy the intended application would typically include its verification and configuration management to maintain its suitability for use.


JAGANATHS SLIP GAUGES & COMPANY

CALIBRATION CERTIFICATE

Basic Purchasing Process



Primary objective of purchase process

To arrange to deliver on time-high quality drugs, medicines, surgical and suture items to the government medical institutions

Key objectives of purchase management (specific to drug procurement)

- Improving management of drug procurement and supply, with special emphasis on logistics.
- Ensuring quality in drug supply.
- Ensuring continuous availability of drugs to all health facilities.
- Centralised procurement of all drugs on essential drugs list of the state.
- Efficient distribution through decentralisation at district drug warehouses.
- Simplified indenting to facilitate the order process for facilities at all levels.
- Computerised information system to allow continuous monitoring of warehouse inventories.
- Training and sensitisation of all stakeholders towards acceptance and usage of the improved drug management system.

To achieve these objectives:

- It adopts a rational drug management system, abiding by the applicable laws of the land and other regulatory requirements pertaining to drugs and medicines.
- Established a continually improving QMS with involvement and empowerment of personnel.

Purchasing information

The hospital shall define the purchase requirements specific to the usage in the hospital either in the tender document or as a separate annexure procurement instrument.

The requirements should be taken from the users of the product/service before processing or placing an order, e.g., procurement of an X-ray machine should be in consultation with the Radiologist/Radiology Department and specifications should be taken from them for purchase.

Design and/or development

Design and/or development is generally used for developing a specific service process and in case of healthcare service domain, it falls under the general schedule of service and design.

Verification of purchased product/service provided

The healthcare facility should establish a process of verification of the purchased product both before and after the purchase of the product. In case the services are procured, then there should be a monitoring checklist to verify the services on a quarterly basis.

Example of the purchase of a new item

The Radiology Department of a hospital projects a requirement of another Ultrasound Machine, as the images from the old machine are found to be hazy. The Radiologist of the Hospital develops Technical Specifications, in consultation with others concerned. Its purchase approval from RKS fund is accorded by the Executive Committee (RKS). Draft technical specifications are approved by the committee where among others, there is an external Biomedical Engineer as an expert. The committee includes that the vendor would also be responsible for providing an 'all inclusive' comprehensive warranty for three years. The Purchase Committee invites quotations from suppliers, along with technical specifications of their Ultra Sonography (USG) machine. Subsequently, a purchase order is issued to the lowest bidder.

On arrival of the machine, the purchase committee verifies the technical specifications of the supplied machine with technical specifications mentioned in the Purchase Order. After installation, the machine is taken 'on-charge' and an entry is made in the stock-book and a log-book before the new machine is opened. The radiologist and the obstetrician of the hospital are imparted two days training by the company. The performance of the vendor (supplier) is analysed and recorded.

Identification and traceability

The healthcare facility should establish a process of documentation for each service delivery for identification and traceability for control of service to satisfy patient. The need for identification and traceability can include:

- Status of healthcare service being provided
- Contract requirement
- Statutory and regulatory requirement
- Intended benefits of healthcare services (diagnostics/therapeutic)
- Hazardous material
- Risk mitigation
- Signages

Where appropriate, identify service by suitable means throughout the service realisation. Processes such as Admission, Diagnostic Lab should be identified for the purpose. Identify status with respect to measurement and monitoring requirements and where traceability is required, control and record unique identification of service.

Protecting patient property

Patient property should be safeguarded properly till such time that it is within the premises of the healthcare facility. Patients may be provided with bedside lockers with lock and key to store their valuables. An appropriate number of security guards should be positioned in the hospital to safeguard against thefts or other menace. In case any patient's property is lost, damaged or found unsuitable, it must be recorded and reported to the patients/service seeker.

Examples of patient property:

- Patient data given by the patient
- Diagnosis done outside and such reports carried by the patient
- Blood products like platelets, plasma, whole blood, autologous donations
- Personal valuables
- Hearing aids
- Dentures
- Mobility aids like walkers, splints, chairs and crutches

Preservation of product/service

Preserve conformity of products (drugs, chemicals etc.) as well as healthcare services (clinical) during internal processing and final service delivery to intended destination/end customer/patient. This may include:

- Identification, handling, packaging, storage and protection of drugs and consumables
- Maintenance of sterilisation of appropriate facilities and equipment
- Proper handling of materials and purchased product
- Restraint and seclusion, or isolation of patient/client as appropriate - to prevent harm, infection, contamination or communicable disease
- Control of medical tools
- Control of medical devices
- Control of medicines (including drugs and poisons)

Control of measuring and monitoring devices

The healthcare facility should ensure that where measuring and monitoring devices are used for verification, they are calibrated and maintained to accepted standards, giving confidence to verification results.

Calibrate or verify Measuring and Monitoring Devices (MMD) at specified intervals or prior to use against international or national standards. In case of absence of such standards and calibration facilities, the healthcare facility must perform the following steps to ensure correct use of such MMD.

Steps to ensure control of MMD

- Adjust or re-adjust as necessary.
- Identify to enable the determination of calibration status.
- Safeguard MMD from adjustments invalidating calibration.
- Protect MMD from damage or deterioration during handling, maintenance and storage.
- Record results of calibration.
- Assess and record validity of previous results when the device is found to be out of calibration.

Calibrated BP Instrument

Model questions and review of ISO 9001:2008

1. Enumerate services, which are offered at the hospital where you work.
2. Are work instructions displayed in labour room, laboratory, Operation Theatre?
3. Develop work instructions for new born corner in the labour room of your hospital.
4. How is 'FIFO' (first-in – first out) being ensured at the hospital's medical store/ dispensary?
5. On what criteria would you evaluate your drug supplier, from whom the hospital makes purchases to meet emergency requirement and/or short fall in the stock?
6. Prepare a checklist for inspection of consignment of the drugs, which have been received in the hospital.
7. Prepare list of equipment at your hospital, which are required to be calibrated.
8. How do you ensure that sterilisation of OT linen/dressing material has been adequate?
9. True/False –
    - Hospital records of patients are their property. (True/False)
    - Investigation reports from the hospital laboratory should be validated by an external laboratory at pre-defined interval. (True/False)
    - Culture surveillance of the Operation theatre needs to be done periodically. (True/False)

CHAPTER 8

Measurement, Analysis and Improvement

ISO 9001:2008 Requirements

8 MEASUREMENT, ANALYSIS AND IMPROVEMENT

8.1 General

The organisation shall plan and implement the monitoring, measurement, analysis and improvement processes needed to:

- to demonstrate conformity to product requirements;
- to ensure conformity of the QMS; and
- to continually improve the effectiveness of the QMS.

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

What it means in a hospital setting

You must plan and implement processes that measure, analyse and improve the health of your QMS. (please refer page 31 for 24 mandatory processes 12 clinical processes and 12 administrative processes) The focus of these processes must be on service and process conformity and improving QMS effectiveness. Develop performance indicators for each of our QMS processes and activities. Start with objectives that focus on meeting customer requirements and then slowly develop meaningful objectives for key processes and risk-prone processes, as initial targets are achieved.

Planning of measurement and data analyses processes must consider the methods and resources (time, manpower, computer, software, statistical tool, etc.,) needed to collect, organise and analyse service and QMS performance data. Measurement involves process parameters against acceptance criteria at predefined intervals and sampling sizes, using predefined measurement devices.

Monitoring usually involves conducting ongoing periodic checks to determine whether service characteristics or process parameters are within acceptable limits. The frequency of monitoring may vary on the risk and reliability of the product and processes.

Improvement processes adequate to close the gaps must also be put in place and the hospital must measure to determine whether these improvements were adequate.

Thus measurement serves three objectives:

- Shows that service delivery is as per clinical/ professional and administrative standards and it meets the patient's expectations.
- That the QMS standard in place is being complied with.
- That there is a continuous effort to improve the QMS.

Chapter 8 Measurement, Analysis and Improvement

Introduction

"Measurement is the first step that leads to control and eventually to improvement. If you can't measure something, you can't understand it. If you can't understand it, you can't control it. If you can't control it, you can't improve it."

- H. James Harrington

"What gets measured gets done, what gets measured and fed back gets done well, what gets rewarded gets repeated."

- John E. Jones

"You get what you measure. Measure the wrong thing and you get the wrong behaviors."

- John H. Lingle

"When you can measure what you are speaking about and express it in numbers, you know something about it."

- Kelvin

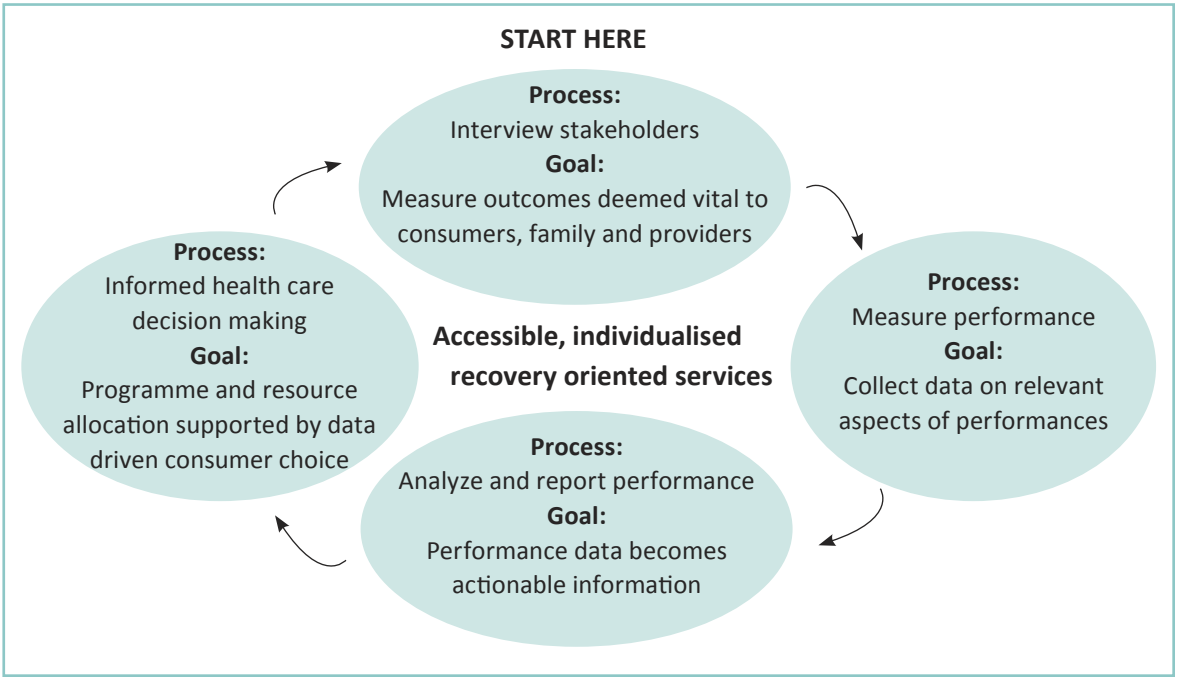
These are often-quoted statements that demonstrate why measurement is important. Yet it is surprising that hospitals find the area of measurement so difficult to manage. In the cycle of never-ending improvement, performance measurement plays an important role in:

- Identifying and tracking progress against hospital goals
- Identifying opportunities for improvement
- Comparing performance against both internal and external standards

Reviewing the performance of a hospital is also an important step when formulating the direction of the strategic activities. It is important to know where the strengths and weaknesses of the hospital lie, and as part of the PDCA cycle, measurement plays a key role in quality and productivity improvement activities. The main reasons it is needed are to:

- Ensure customer requirements ***have*** been met
- Be able to set sensible ***objectives*** and comply with them
- Provide ***standards*** for establishing comparisons

- Provide ***visibility*** and a "scoreboard" for people to ***monitor*** their own performance level
- Highlight ***quality problems*** and determine areas for ***priority attention***
- Provide ***feedback*** for driving the improvement effort



The heart of a QMS is in building systems where you can measure every process and then analyse to identify how that process is performing in respect to the standards or the objectives, and use this information to identify causes and plan for improvements.

It is not enough to have a general perception about whether the service delivery is good or bad and whether patients are more satisfied now, than before. We must be able to capture this information in terms of numbers as well as measurements. Every healthcare facility should provide for the measurement and evaluation of services delivered, the integrity of the processes and patient satisfaction at appropriate intervals.

Measurement of processes includes recording, collecting, analysing, summarising and the communication of relevant data needed to monitor and improve the healthcare facility performance.

The results of measurement at a given point of time can show a level of achievement but consideration should also be given to change in the measurement over a period of time in terms of trends and variation. The causes of trends and variation should be identified in order to ensure they are understood. Statistical techniques selected for use should be suitable for the application.

This information should then be used for initiating both corrective action and preventive action.

This section describes the standards for measurement and for corrective and preventive action.

The top management must play an active role in section 8, which requires making decisions about key measures and analysing the results of information from sources such as audits, customer feedback and analysis of other information relating to products, trends and suppliers.

There are four key steps in a performance measurement framework - the strategic objectives of the Hospital are converted into desired standards of performance, metrics are developed to compare the desired performance with the actual achieved standards, gaps are identified, and improvement actions initiated. These steps are continuously implemented and reviewed:

Measurement, Analysis and Improvement of Hospital Performance

Measurement, analysis and improvement are inter-linked terms. Measuring process and output parameters and then analysing these, leads the facility to take measures for improvement in areas where the processes or output are weak.

To the extent possible, the process of measurement and analysis should not be a separate additional burden of work to hard pressed service providers and administrative staff. On the other hand, it should help them improve the effectiveness and efficiency of the services they provide.

The main tools of measurement are thus the records that capture each activity. Each of these records are analysed in one of the two ways. The first is where the information from the recording register (also called primary register) is converted into reporting formats. This is best done electronically- as part of a computerised HMIS. If every primary register is computerised, that would make for a comprehensive and sophisticated hospital information system.
But if that is not feasible, each process owner could provide a report at defined interval in a standardised format and this could be fed into a computer and analysed. With such information, one could show how each process is performing and what are the trends and the variations from month to month or between different providers.

In addition to data that is available through HMIS, one also gets important information from periodic reviews of key records. One should specify the frequency with which such records would be reviewed.

Examples of a few processes and how these could be measured are given in next two pages.

These measurement tools employed by the healthcare facility should be reviewed periodically and data should be verified for accuracy and completeness on a continual basis. If each process owners' data is available as information, self-assessment on a periodic basis of each process and of the healthcare facility as a whole can be done and it becomes possible to define improvement opportunities.

Measurement and analysis also help in benchmarking - both internal and external. In internal benchmarking, performance of two departments (high performing and low performing) can be measured and compared. The processes employed by the high performing department can be emulated by the low performing departments. Similarly the performance of the hospital can be benchmarked with the "best in the class" hospital having comparable level of inputs.

For example, for laundry services one could identify a hospital that is the quality benchmark for a certain level of budget expenditure and other hospitals try to achieve the same measurable level of quality with a similar budget. Benchmarking provides substantial motivation for improvement.

Not all processes can be captured from the records. Some, like patient satisfaction levels, need specific surveys.

Table 4: Process measurement

Process name	Records that would be generated	Concerned HMIS data
In Patient Care		
• Labour room/normal delivery management	• Patient case record and discharge summary • Labour room register • Partographs	• Maternal mortality • LSCS: normal delivery ratio • Postpartum complications rate • Percentage of mothers leaving hospital in less than 48 hours
• Management of complications of normal delivery.	• Patient case records including BHTs and discharge summary • Minor OT register	Percentage of each complication and its outcome
• OT Management	• OT register • Surgery notes • Patient case record	• Surgical Site Infection (SSI) rate • OT utilisation rate • Death in OT rate • Re-exploration rate
• Newborn care	• Labour room register • Infant's resuscitation record and discharge summary	• Neonatal mortality rate and stillbirths • Percentage of newborn requiring NICU care • Percentage of newborn breastfed within 1st hour • Percentage of babies weighed in labour room • Percentage of infants developing complications, e.g., umbilical stump infection
• Sick newborn care	• NICU register • Newborn resuscitation record, treatment record and discharge summary • Referral register	• Percentage of newborns shifted to higher centres. • Survival rate of newborns with Low Birth Weight (LBW) and IUGR • Percentage of LBW
• Sick childcare	• Child case record and discharge summary	• Average length of stay of children • Percentage of children developing hospital acquired infections • Percentage of children died within 2 hours of admission • Percentage of children died within 48 hours of admission • Percentage of admitted children died • Percentage of children requiring referral to higher centres

• Family planning	• MTP register • Intra Uterine Contraceptive Device (IUCD) register • Tubectomy, vasectomy and No Scalpel Vasectomy (NSV) register • Labour room register • Stock register	• No. of MTPs conducted • No. of IUD insertions done • No. of NSV, tubectomy and vasectomy conducted • No. of condoms distributed • Preferred method of family planning • Percentage increase or decrease in family planning procedures
• OPD management	• OPD register • Patient satisfaction survey file • Doctors' attendance register • Complaints and suggestions box	• Average OPD attendance • Average waiting time for consultation • Average waiting time for registration • Department wise distribution of patients • Patient satisfaction index • No. of days when doctors were not available • Total no. of complaints received
Supportive Care		
• Diet	• Diet requisition slip/register • Diet distribution records from kitchen • Nurse records in each ward	• Percentage of in-patients who got all dietary entitlement • Percentage of special diets served • Cost to quality of supply analysis
• Laundry	• Housekeeping records of linen in stock issued/washed • Hospital inspection reports	• Percentage of sheets used for in-patients • Inspection reports which found dirty or stained sheets in use – or non issue of sheets • No. of new linen purchased • No. of old linen condemned
• Security	• Attendance register of security guards • Complaints book • Hospital inspection report	• Percentage of days without adequate no. of guards • No. of security related complaints including theft, assault and affray and missing patient
• Stores and inventory	• Store Stock register • Store Receipt register • Store Issue register • Purchase Order file • Temperature record of refrigerator • Goods received note file	• Money spent on local purchase • Percentage of medicines expired • Percentage of medicines or equipment lost by pilferage, spillage or breakage • No. of incidences of stock – out of essential drugs
• Hospital transport	• Vehicle log book • Fuel book • Maintenance book • Drivers' attendance register	• No. of vehicles available on road • Average consumption of fuel • Average mileage of each vehicle • Down time of each vehicle • Utilisation of each vehicle • Incidences of non-availability of ambulance or driver

Measurement and monitoring of patient satisfaction

Why measure patient satisfaction?

- It provides an objective parameter of community's perception of hospital services to assess the adequacy of services
- Helps in action planning for continual improvement process
- An input for Management Review Meeting (MRM) under the QMS.

Sources of Information:

The sources of information on patient/service seeker's satisfaction (positive as well as negative) include:

- **Patient/Service seeker's complaints.** Every healthcare facility shall have a **complaint/suggestion box** at the OPD/IPD. It shall be opened on a regular basis. Each complaint and suggestion shall be analysed for the root cause, followed by corrective and preventive action. Complainants shall be provided with the feedback on the explanations and action taken.
- **Communicating directly with patients/service seekers** during hospital inspection. This is much more time consuming, but it is an excellent way of getting to know the needs of patients. The method itself can contribute to raising customer satisfaction.
- **Patient Satisfaction Surveys (PSSs)** and self filled questionnaires with collection and analysis of data. This is a relatively cost effective way of measuring customer satisfaction. But the down-side is that the response may be low.
- **Focus Group Discussions (FGDs)** with users.
- **Reports from consumer organisations/civil society organisations/various media.** This information gives a good overview, but it is not always available and seldom gives information about the individual customer.

How to carry out Patient Satisfaction Surveys:

This should be undertaken from both out-patients and In-patients in the form of exit interviews to receive their feedback on the effectiveness of the patient care delivery process and analysed on a regular basis along with the complaints received, to take appropriate measures for quality improvement.

- Take a sample (at least 30 OPD and 30 IPD patients). The larger the sample size, the lesser is the bias.

ISO 9001:2008 Requirements

8 Measurement, Analysis and Improvement

8.2 Monitoring and Measurement

8.2.1 Customer satisfaction

As one of the measurements of the performance of the QMS, the organisation shall monitor information relating to customer perception as to whether the organisation has met customer requirements. The methods for obtaining and using this information shall be determined.

NOTE Monitoring customer perception can include obtaining inputs from sources such as customer satisfaction surveys, customer data on delivered product quality, user opinion surveys, lost business analysis, compliments, warranty claims and dealer reports.

What it means in a hospital setting

Probably one of the most crucial categories of information is the satisfaction of customers. Since patients determine the future of the hospitals. It needs to be determined how satisfied they are. In order to do this, hospitals need to know which issues are important for their customers and then define how they will measure whether the patients are satisfied with these issues.

Patients are primarily the end users of your service, but this also includes organisations to whom some of the services have been outsourced (housekeeping, laundry, security, kitchen), dealers and suppliers who provide drugs and equipment. You need to consider feedback from all these customers to determine whether or not you have met their specified and perceived requirements.

Patients' requirements may relate to effectiveness/ competence of clinical care, timeliness of care, correct diagnosis and speedy treatment No harmful effects or new disease, minimal waiting time, courtesy extended by the service providers, personalised service, quality of support services (cleanliness of wards and toilets, clean linen, promptness of payment of JSY, quality of diet, availability of drugs etc.,), and cost of services. You must have controls to identify and meet these requirements

You are expected to have a process that defines your customer satisfaction indicators, frequency and method of data collection, summarisation, review and evaluation of data, actions to improve, timeline, responsibility and follow-up.

You must monitor trends in customer satisfaction indicators and use these as a baseline for continual improvement. You should consider both external as well as internal customer satisfaction. Your employees are your internal customers.

- The sample shall be representative of the population including women and BPL population (all wards and OPDs). It comprises patients and visitors of all ages, gender, casts, and socio-economic status from all departments.
- Explain the questionnaire in the language, which is spoken and understood by the patient.
- Be as objective as possible.
- The questionnaire must be developed carefully to capture patient satisfaction with each dimension of patient care.
- Survey for In-patients shall be carried out at the time of discharge, when all the formalities are over.
- It should be done every quarter on random sample basis regularly within 5-6 continuious working days for OPD and analysis should be done within 3-4 working days. Based on the analysis of the available data, action plan should be developed by leadership team of the hospital and implemented and reviewed on regular basis.

The template for OPD and IPD PSS: The Healthcare facilities are encouraged to develop their own satisfaction survey forms. While designing, type and size of the hospital, socio-economic status of the patients and visitors, disease burden, education status of the patients and visitors and other important factors contributing to the patients' satisfaction shall be considered.

Sample templates for taking feedback from patients (OPD and IPD) are given in following pages.

In-patient Feedback

Dear friend, it will help us in our endeavour to improve the quality of service, if you share your opinion on the service attributes of this hospital, enumerated in the table below.

Please (√) tick the appropriate box and drop the questionnaire in the Suggestion Box

S.No.	Attributes	Poor (1)	Fair (2)	Good (3)	Very Good (4)	Excellent (5)	No comments
1.	Availability of sufficient information at Registration/Admission counter						
2.	Waiting time at the Registration/ Admission counter	>30 mins	10-30 mins	5-10 mins	Within 5 mins	Immediate	
3.	Behaviour and attitude of staff at the registration/admission counter						
4.	Your feedback on the discharge process						
5.	Cleanliness of the ward						
6.	Cleanliness of bathrooms & toilets						
7.	Cleanliness of bed sheets/pillow covers etc						
8.	Cleanliness of surroundings and campus drains						
9.	Regularity of doctor's attention						
10.	Attitude and communication of doctors						
11.	Time spent for examination of patient and counselling						
12.	Promptness in response by nurses in the ward						
13.	Round the clock availability of nurses in the ward hospital						
14.	Attitude and communication of nurses						
15.	Availability, attitude and promptness of ward boys/girls						
16.	All prescribed drugs were made available from hospital supply						
17.	Your perception of doctor's knowledge						
18.	Diagnostic services were provided within the hospital						
19.	Timeliness of supply of diet						
20.	Your overall satisfaction during the treatment as In-patient						

Your valuable suggestions (if any) .....

Out-patient Feedback

Dear patient, you have spent your valuable time in the hospital in connection with your/ relative's/friend's treatment. You are requested to share your opinion about the service attributes of this hospital which will be used for improving the services

Please (√) tick the appropriate box and drop the questionnaire in the Suggestion Box

S. No.	Attributes	Poor (1)	Fair (2)	Good (3)	Very Good (4)	Excellent (5)	No comments
1.	Availability of sufficient information in hospital						
2.	Waiting time at the registration counter	>30 mins	10-30 mins	5-10 mins	Within 5 mins	Immediate	
3.	Behaviour and attitude of hospital staff						
4.	Cleanliness of the OPD, bathrooms and toilets						
5.	Attitude and communication of Doctors						
6.	Time spent for examination and counseling						
7.	Availability of Lab and Radiology tests.						
8.	Promptness at medicine distribution counter						
9.	Availability of drugs at the hospital dispensary						
10.	Your overall satisfaction during the visit to the hospital						

Your valuable suggestions (if any) .....

Community Satisfaction Surveys: Issues of Social Exclusion: One of the objectives of a public hospital is to provide social protection for the cost of healthcare even to the poorest. But National Sample Survey Organisation (NSSO) estimates that there are some 20 percent who are too poor to come even to a public hospital. This may be because they are unable to pay user fees or informal charges and unable to show a BPL card to get exemption from user fees. It may also be because of rude behaviour and rarely, the active denial of care. It could also be because affirmative action is needed to help them access care-this is especially true in the case of special marginalised categories like homeless, street children etc. A few well planned FGDs and community surveys could bring this out. Exit surveys of referred patients, at the facility from which they are referred, could also bring out what in QMS terms is "lost business."- poor patients who should have gone to the district hospital for referral care, but who chose to go elsewhere or not go to any facility at all.

ISO 9001:2008 Requirements

8.2.2 Internal audit

The organisation shall conduct internal audits at planned intervals to determine whether the QMS:

- conforms to the planned arrangements (see 7.1), to the requirements of this International Standard and to the QMS requirements established by the organisation, and
- 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. The selection of auditors and conduct of audits shall ensure objectivity and impartiality of the audit process. Auditors shall not audit their own work.

A documented procedure shall be established to define the responsibilities and requirements for planning and conducting audits, establishing records and reporting results.

Records of the audits and their results shall be maintained (see 4.2.4).

The management responsible for the area being audited shall ensure that any necessary corrections and corrective actions are taken without undue delay to eliminate detected Non-conformities (NC) and their causes.

Follow-up activities shall include the verification of the actions taken and the reporting of verification results (see 8.5.2).

What it means in a hospital setting

Internal audit allows a hospital to determine the strengths and weaknesses of the quality system in place. Internal audit is the second important tool used to gauge the health of your QMS. How effective is it in meeting ISO 9001, your own QMS and statutory and regulatory requirements.

- You must have a **documented procedure** for your internal audit process
- The **scope** of your internal audit programme must cover the:
  - Audit of service realisation processes (all clinical, administrative and mandatory processes described in section 3)
  - To determine conformity of both service and service realisation processes to customer and applicable regulatory requirements.
  - Audit of the QMS - to determine conformity to the ISO 9001 standards and hospital requirements.
  - The time frame during which the audits specified above will be conducted.
- Consider adjusting the **audit frequency** when:
  - You experience internal or external non-conformities.
  - Get customer complaints.
  - Have significant or frequent changes of processes.
- Your **internal audit programme** should consider the following:
  - Input from the audited area and related areas
  - Key customer oriented processes
  - Opportunities for continual improvement
  - Feedback from customers.

- **Audit criteria** refers to the specific QMS policies, objectives, ISO requirements, documentation; **customer and regulatory requirements, etc., that the audit is referenced to or conducted against.**

Internal audit

Audit Philosophy:

"In God we trust, in all others bring Data."

- Deming

Internal audits are not for POLICING but meant for POLISHING.

Internal audits are fact finding exercises and not fault finding missions.

The ideal frequency of internal quality audit is quarterly and during a specific quarter, selected sample processes should be covered and audited by trained and certified internal quality auditors. The qualification criteria for internal quality auditors are a minimum two-day workshop on Internal Quality Auditing Practice by a competent agency.

Many districts have quality assurance committees in place. These committees use check lists to identify gaps. By placing the active members of the quality assurance committee through this two day workshop, using their check lists and the internal audit protocol, we gear them up to be able to do their job more effectively and at the same time move towards a QMS of international standards. The difference between just "monitoring with check lists" and the internal audit of a QMS is that, whereas the former has a focus on physical gaps, the latter has a focus on systems gaps. For example, a monitoring committee reports dirty toilets or lack of clean sheets – whereas, an internal audit report should, in addition, point the finger at lack of sweeping schedules, or supervisory record maintenance or stock management of linen, contract management for laundry services etc.

Documented procedures of a hospital QMS must define:

- The internal audit plan and schedule for the year
- List of internal auditors
- Responsibility and requirements for planning and conducting audits
- Audit Matrix Sheet
- Reporting results and maintaining records.

The hospital top management must ensure that an internal auditor must not audit his/her own work. The management also ensures corrective actions without undue delay and follows up in order to verify actions taken.

In addition if a hospital is interested in a particular accreditation programme like ISO or National Accreditation Board for Hospitals and Healthcare (NABH), the hospital management should identify some key members for a five-day Lead Assessor Course by a competent agency. This qualification would help the hospital perform effective audits by these qualified auditors.

Guidelines for organising an audit

- **Audit methods** refer to the specific techniques that auditors use to gather objective audit evidence that can be evaluated to determine conformity to audit criteria. Examples of audit methods include - interview of personnel, observation of activities, review of documents and records, etc.
- You must define the minimum **qualification requirements** for internal auditors. These requirements include knowledge of - QMS processes and their interaction, customer requirements, applicable regulatory requirements, the ISO 9001standard, the audit process and audit techniques.
- You must have **appropriate resources** for your annual audit programme. These would include - sufficient trained auditors, sufficient time to perform audits, availability of department or process personnel to be audited, time and tools to prepare audit records and reports, etc.
- **Auditor independence** - Auditors can audit their own department provided their objectivity and impartiality is not compromised, but they cannot audit their own work. You must ensure auditor independence when assigning personnel to specific audits.
- **Audit results** must be summarised and reported for management review (see clause 5.6.2). The MR must analyse the results of each audit as well as the annual audit programme to determine the strengths and weaknesses in QMS processes, interactions, functions, products, etc., to identify and prioritise opportunities for improvement.
- **Audit records** include - annual audit schedule, audit plan - (criteria, scope, frequency, methods, auditor selection and assignment, etc.), auditor competence and training, audit checklists and forms, audit notes and other evidence gathered, audit findings, NC reports, audit reports, corrective actions and follow-up of internal audit non-conformities, analysis of audit program performance indicators and trends, and identified improvement opportunities.
- You must have performance **objectives** (indicators) to measure the effectiveness of your internal audit process and monitor trends in these indicators, to continually

improve your audit programme. Performance indicators may include reducing the number of - late or delayed audits, incomplete audits, incomplete audit records and late reports, auditor errors, auditee complaints, and use of untrained auditors, etc.

Healthcare institutions are unique in many ways. In the first case these are the only places where we come across wide skill differential among the people working there. On the one hand we see highly skilled physicians and paramedics, while on the other hand, a very large number of people who are easily replaceable. The second dimension is added because of their criticality and their ability to make an impact on the well being of the community is undisputable. The third dimension is the communities' dependence on healthcare facilities. Hence, apart from the audits mentioned above, all healthcare facilities must carry out the following periodic audits:

- Death Audits
- Medical Audits
- Prescription Audits
- Inventory Audits

NOTE: THESE SAMPLES ARE TO BE USED ONLY AS TEMPLATE BY HEALTHCARE FACILITIES TO DEVELOP THEIR OWN FORMATS AND PROCEDURES.

I -Sample format for annual internal audit plan

FOR THE YEAR .....

DEPARTMENT	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar
01.....												
02.....												

Note: Refer to detailed audit schedule for other details.

II-Sample format for internal audit schedule

Areas of Audit	Date	Time		Scope of Audit	Responsibility	
		From	To		Auditee	Auditors
01……						
02…….						

III-Sample format for audit report

Scope of audit : ISO9001/ISO14001/OHSAS18001 Auditee Department/Area: Auditee Responsible: Date(s) of Audit:				Auditor(s): Audit Report No:	
S.NO.	CHAPTER/ PROCEDURE NO.	PARA NO.	DETAILS OF NON NCs	CATEGORY OF FINDING #	REFERENCE ISO 9001/14001/OHSAS 18001 CLAUSE

Note: Use additional sheets if required

AUDITEE'S SIGNATURE DATE: AUDITOR'S SIGNATURE

CORRECTIVE ACTION PLAN (GIVE TARGET DATE FOR EACH NC) AUDITEE'S SIGNATURE
CORRECTIVE ACTION TAKEN, PREVENTIVE ACTION TO BE TAKEN/PERSON RESPONSIBLE DATE: AUDITEE'S SIGNATURE
Follow up Report: Satisfactory/Unsatisfactory Closure of NC YES/NO Date: MR/Dy. MR's Signature

Category: MA-Major NC, MI- Minor NC, OBS-Observation, COM-Complying NC - Non-conformity

SUMMARY OF FINDINGS

AUDIT NO……. FOR THE PERIOD……

Audit areas	Findings			Status		
	MA	MI	OBS	Description of NCs	Closed/Open	Remarks
01……						
02……						

_____ Signature Deputy/MR & Date

TO: MR

IV-Sample format for medical record audit

Select 10 active patient charts with at least 3-5 prior visits, the most recent visit should have taken place within the past 6-12 months. If the information should be present and is not, place 0 in the box for that chart. If the information is present, rate the quality of the information with 3 = Superior, 2 = Satisfactory, and 1 = Unacceptable. Use "NA" to score items that do not apply to a given chart (e.g., patient has no allergies).

Chart number	1	2	3	4	5	6	7	8	9	10
Pages have patient ID										
Contains biographical and/or personal data										
Person providing care identified on each chart entry										
Entries are dated, timed & signed										
Entries are legible										
Problem list is complete										
Allergies and adverse drug reactions are prominent										
Absence of allergies and reactions prominent										
Appropriate past medical history										
Smoking, alcohol, or substance abuse history documented										
Pertinent history and physical examination										
Lab and other tests ordered as appropriate										
Working diagnoses are consistent with findings										
Plans of action/treatment are consistent with diagnosis(es)										
Problems from previous visits addressed										
Evidence of appropriate use of consultants										
Evidence of continuity and coordination of care between primary and specialty physicians										
Consultant summaries, lab, and imaging study results reflect primary care physician review										
Completed immunisation record										
Prescriptions and refills noted										
Med sheet used and appropriately located										
Chronology maintained										
Informed consent noted for all procedures and appropriate prescriptions										

Patients are adequately informed (i.e., there is documentation of patient education, follow-up instructions)										
Missed/Cancelled appointments										
Follow-up on missed/cancelled appointments										
Telephone calls regarding patient care noted										
Charts are organised in a consistent manner internally										
Transcription, if used, is accurate and physician review is noted										
There is a consistent, organised format for notes (i.e., is SOP or similar format used?)										
Chart contents are securely fastened to the jacket										
No inappropriate information is in the chart (e.g., subjective or personal remarks about patient, family or other caregivers)										
No inappropriate alterations or omissions (e.g., erasures, missing pages)										

V-Sample death audit format

Name of Hospital – District Hospital ----------

1.	Date of Audit	Day			Month			Year			
2.	Name of Patient					Age		……years ……. months			
						Sex		Male		Female	
3.	Occupation										
4.	Date of admission to hospital					Time of admission		-------- (AM/PM/midnight/ noon)			
5.	Nature of admission	Routine/Emergency				Remarks (if any)					
6.	Provisional diagnosis at the time of admission										
7.	Presenting symptom(s) at the time of admission										
8.	Significant past illness/existing medical condition(s)/if already on any medications										
9.	General condition at the time of arrival in hospital	Grave/Very Poor/Poor/Normal				Please elaborate					

10. Information of immediate treatment	Treatment started immediately/Treatment started after examination by specialist (mention in terms of Physician/Surgeon/Obstetrician & Gynaecologist etc.)/ Treatment started after diagnosis/Treatment not started			
11. Investigations asked by the admitting MO/ Specialist	List of investigations from hospital laboratory	Time and date of requisition of investigations	Time and date - the reports are entered in patient file/BHT	
	a. b. c. d.	a. b. c. d.	a. b. c. d.	
	List of investigations from outside laboratory	Time and date of requisition of investigations	Time & date of availability of results	
	a. b. c. d.	a. b. c. d.	a. b. c. d.	
12. Referral to another doctor/specialist	Date and time of referral note		Date and time of opinion	Any change in treatment after the opinion
13. Communication to NOK/family members about seriousness of the sickness			Time and date	-------- (AM/PM/Midnight/ Noon), dd/mm/yyyy
14. Date of Death			Time of Death	-------- (AM/PM/Midnight/ Noon)
15. Clinical notes at the time of death (appropriateness)				
16. Any advice rendered to NOK of patient on referral to another facility				
17. Total duration of stay in the Hospital	Days ---------- Hours ----------			
18. Opinion on management of the patient in the Hospital				

a.	Was the first line medical treatment rendered, timely?			
b.	Were investigations appropriate?			
c.	Were investigations asked in time?			
d.	Timely availability of reports			
e.	Time taken in arriving at final diagnosis			
f.	Timely institution of specific treatment			
g.	Opinion on appropriateness of treatment			
h.	Hospital's overall response during the terminal event			
i.	Any other action/ suggestion that could have influenced the course of the event			
19.	Please record learning			
20.	Name and designation of members of the Audit Committee	Signature	Date	Remarks
a.				
b.				
c.				

NOK: Next of Kin

VI-A Sample Internal Audit Procedure for reference

1. PURPOSE

To verify compliance and conformance to the planned arrangements

To identify areas for corrective and preventive action, both in the system and in its implementation

To achieve the desired objectives and continual improvement.

2. SCOPE

The scope of this procedure includes all activities related to auditing of the QMS.

3. RESPONSIBILITY

MR

4. PROCEDURE

4.1 Internal Audit shall be conducted at least once in six months. The frequency of audit may be changed in the Management Review Meeting (MRM) based on the following:

- Customer/Stakeholder complaints, if any
- Contractual requirements as applicable
- Significant changes in Management, organisation, policy, product and technology etc.
- Changes, such as legal requirements, affecting the QMS
- Results of previous audits (internal and external)

4.2 The MR prepares an annual internal audit plan in format based on the above. The plan is updated as necessary. The MR also prepares the detailed audit schedule for each audit cycle. These are circulated to all concerned, well in advance.

4.3 Only competent auditors shall carry out the internal audit. The head of the HRD shall maintain the auditor's records. The list of competent auditors is also maintained by the MR. The auditor shall not audit his own area.

4.4 The auditors, if required, may prepare audit checklists for collection of objective evidence through interviews, examination of documents and observation of activities. The information gathered is cross checked from other sources for the allotted areas covering all aspects of ISO 9001.

4.5 The auditors shall generally carry out the audit as per schedule, on the agreed date and time. The date and time may be slightly changed due to non availability of the auditee.

4.6 The auditors also verify the pending actions/results of actions taken of previous audits if any.

4.7 The audit notes are taken in the audit observation sheet. During the audit, the auditors give special emphasis on repetitive non-adherence to procedures.

4.8 The auditors prepare the audit report along with NCs and observations in the format. The corrective action plan for each non compliance is recorded on the audit report by the auditee.

4.9 The audit report is submitted to the MR with a copy to the auditee after completion of the audit by the auditor.

4.10 The MR verifies the implementation of corrective actions by way of one or more of the following methods,

- Follow-up audit
- Submission of corrective action reports by the auditee along with the evidence
- Verification of related evidence.

4.11 based on the audit results, the MR shall prepare a summary report in the format on the corrective actions proposed and their status. The summary report is presented in the MRM for discussion to review suitability, adequacy and effectiveness of the QMS.

4.12 Auditors should adhere to applicable personal safety requirements while auditing.

ISO 9001:2008 Requirements

8.2.3 Monitoring and measurement of processes

The organisation shall apply suitable methods for monitoring and where applicable, measurement of the QMS processes. These methods shall demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, correction and corrective action shall be taken, as appropriate.

NOTE: When determining suitable methods, it is advisable that the organisation considers the type and extent of monitoring or measurement appropriate to each of its processes in relation to their impact on the conformity to product requirements, and on the effectiveness of the QMS.

What it means in a hospital setting

For every process that has been brought under the QMS, one needs to define an objective method of measurement of the same.

For every output/outcome that the hospital has set itself – and this largely pertains to service delivery - the QMS would specify the indicator by which it would be measured and the methods and tools of measurement.

The healthcare facility should establish and specify the measurement requirements including the acceptance criteria for its services. The measurement of service should be planned and performed to verify conformance to specified requirements.

The methods of measuring processes would include:

- Analysis of records
- Periodic Inspections by
  - Statutory or regulatory authorities
  - Department supervisory officers
  - In-hospital role allocation of inspection function

Of these, the most important and frequent is the in-hospital inspection, which could be as frequent as the daily rounds of the Department Head or Chief Matron and the weekly rounds of the medical superintendent.

The exact content of the inspection visit would vary with the process being observed.

Key explanation points and what is required to be done at hospital to comply with the clause:

The third source of information is related to measurement of processes (activities). Healthcare facilities need to determine how they are going to measure whether the activities are being adequately carried out or not. The healthcare facility must establish methods and indicators to monitor and measure QMS processes to demonstrate process capability and to achieve planned results and identify opportunities to improve the process.

It is important to measure and monitor the processes of service delivery and to compare the outputs with the targets and benchmarks. If the planned results, in terms of patient outcomes (case fatality rate, cure rates, hospital infection rates), patient satisfaction and access to services are not achieved, then one should look at the process and review its indicators to understand the root cause and take corrective and preventive action where needed.

This in turn implies, that the appropriate process indicator be chosen, which is sensitive to any deviation in the process which affects the final results/outputs.

What is required to be measured in a process?

- What is most critical in order to satisfy customer needs?
- Where do we have problems today?
- Where can problems arise tomorrow?

What can be measured in an activity?

- **Timeliness:** For example, OPD consultation takes 45 minutes from registration to dispensing of medicine. How often is this being performed in 46 minutes or more?
- **Efficiency:** How many surgeries are being performed by a certain number of surgeons and anaesthetists? What is the reaction time taken to respond to patient/visitor's complaint?
- **Cost reduction:** Money spent for local purchase because of frequent stock-outs.

For example, to monitor and measure the processes of the blood bank, the following indicators could be used:

- Percentage of transfusion reactions.
- Percentage of wastage of blood including blood units found unfit for use.
- Turnaround time for issue of blood.

Indicator 1 Percentage of transfusion reaction not only reflects the patient's safety but also indicates the efficacy of processes of storage, blood grouping and cross matching. All these factors contribute in planned results (patient satisfaction, positive clinical outcome and patient safety).

Similarly, **Indicator** 2 indicates the optimal utilisation of blood bank services and **Indicator** 3 reflects effectiveness and efficiency of blood bank services.

Blood bank services could be monitored and measured by capturing and analysing data pertaining to these indicators. Whenever there is an increase in transfusion reactions, wastage of blood units or turnaround time of issue of blood, the root cause analysis should be done followed by corrective and preventive actions needed.

For a hospital, the product is healthcare services delivered and their effectiveness. A patient seeks to get cured of his illness and if that is not possible, to prevent it's worsening and if even that is not possible, to ameliorate the suffering. There are other users like pregnant women seeking care, children requiring immunisation, adolescents and newlyweds requiring counselling, or old people who are not sick – but are also users requiring check-ups. The product for them is the prevention or early detection of illness and promotion of health.

A hospital must monitor these outcomes - i.e., it must have figures that indicate how well it is doing on these criteria, in terms of clinical outcomes and in terms of patient treatment satisfaction.

For example, an injection room inspection visit may look at the injection room record maintenance, the use of sterile precautions and the BMW system. The Chief Matron may be in charge of this and the nursing assistant with her on her rounds may make a tick in an appropriate document and then file this record.

Similarly, an OPD inspection visit by the RMO may look at the orderly streaming of patients and the time taken to see the doctor, the functioning of amenities for patients who are waiting and the cleanliness of the toilets.

The Medical Superintendent on a weekly round of a ward may look at the cleanliness of sheets and toilets, talk to the patients about their diet and whether they have any

grievances and look at the discharge summaries to see whether they are complete and the nature of outcomes, as well as, the BHT and case records, to see whether they are being maintained.

The important step forward that a QMS insists on is a record of these inspections and a record of the analysis of records to ensure that quality management processes are functional.

ISO 9001:2008 Requirements

8 Measurement, Analysis and Improvement

8.2.4 Monitoring and measurement of product/service

The organisation shall monitor and measure the characteristics of the product to verify that product requirements have been met. This shall be carried out at appropriate stages of the product realisation process, in accordance with the planned arrangements (see 7.1). Evidence of conformity with the acceptance criteria shall be maintained.

Records shall indicate the person(s) authorising the release of products for delivery to the customer (see 4.2.4).

The release of products and delivery of service to the customer shall not proceed until the planned arrangements (see 7.1) have been satisfactorily completed, unless otherwise approved by a relevant authority and, where applicable, by the customer.

What it means in a hospital setting

Hospital shall monitor and measure healthcare services provided by them to verify conformity to requirements. The process of healthcare delivery shall be monitored and measured at every stage so that there is no medication error, harmful effects, adverse reaction, hospital acquired infection, or any other unwanted/ unintended effects.

Healthcare facilities shall develop means for measuring and monitoring of each and every stage of the surgical process.

Key Explanation Points and what is required to be done at Hospital to compile to the clause:

Hospitals shall monitor and measure healthcare services provided by them to verify conformity to requirements. The process of healthcare delivery shall be monitored and measured at every stage so that there is no medication error, harmful effects, adverse reaction, the hospital acquired infection, or any other unwanted effects not intended. For example, surgical process can be monitored and measured by:

- Correct identification of the patient
- Correct identification of the surgical site
- Correct pre-operative medication and procedure
- Correct anaesthesia
- Correct surgical procedure as per standard guidelines
- Correct post-operative care.

Similarly, in wards, monitoring can be done for:

- UTI
- RTI
- Surgical site infection
- Intra vascular device infection
- Hand washing
- Nursing assessment is completed within thirty minutes
- Incidence of haematoma at puncture site
- Percentage Incidence of adverse drug reactions
- Percentage of medication chart with illegible writing
- Percentage of transfusion reactions
- Percentage of wastage of blood and blood products
- Percentage of blood components usage
- Turnaround time for issue of blood and blood products
- Percentage of medication errors
- Incidence of fall from bed
- Incidence of bed sores developing
- Number of security related incidents i.e., theft or breach of security
- Incidence of needle stick injury

ISO 9001:2008 Requirements

8 Measurement, Analysis and Improvement

8.3 Control of Non-conforming Products

The organisation shall ensure that the product/service which does not conform to product requirements is identified and controlled, to prevent its unintended use or delivery. A documented procedure shall be established to define the controls and related responsibilities and authorities for dealing with nonconforming product.
Where applicable, the organisation shall deal with non-conforming product by one or more of the following ways:

- By taking action to eliminate the detected NC
- By authorising its use, release or acceptance under concession by a relevant authority and where applicable, by the customer
- By taking action to preclude its original intended use or application
- By taking action appropriate to the effects, or potential effects, of the NC when the non-conforming product is detected after delivery or use has started.

When the non-conforming product is corrected, it shall be subject to re-verification to demonstrate conformity to the requirements.

Records of the nature of NCs and any subsequent actions taken, including concessions obtained, shall be maintained (see 4.2.4).

What it means in a hospital setting

Non-conforming service is defined as service that does not conform to customer requirements, applicable regulatory requirements or our own hospital requirements. Non-conformities may relate to suppliers and outsourced work. In hospitals, non-conforming service includes:

- Medical errors (medication errors, wrong site surgery, wrong surgery)
- Hospital acquired infections (UTI, RTI, ventilator associated pneumonia, etc.)
- Adverse drug reactions
- Anaesthesia related deaths
- Fall from bed
- Bed sores
- Security related incidences-theft or breach of security
- Needle stick injuries
- Accidental removal of tubes and catheters
- Haematoma at puncture site
- Blood transfusion reactions
- Infant abduction

The hospital shall have a documented **procedure** for non-conforming services and it must include controls and responsibilities to identify, contain, keep records of the nature and other details of the non-conformity notify appropriate personnel and customer, where appropriate, evaluate what action needs to be taken, carry out timely inspections, establish performance indicators to measure the effectiveness of the control of non-conformance process, etc.

Measurement of autoclaving can be done by monitoring:

- Temperature
- Pressure
- Time
- Colour change of strip
- Wet test
- Spore test.

Measurement of pharmacy can be done by monitoring:

- Percentage of drugs procured by local purchase
- Percentage of stock-outs including emergency drugs
- Percentage of consumables rejected before preparation of good receipt note
- Incidence of variation from the procurement process

8.3 Control of Non-conforming Product/Service

All non-conforming healthcare services like medical errors occurring in the hospital whilst healthcare services are being delivered should be controlled by establishing protocols to first prevent and then control such errors. Evidence based medicine and standard clinical guidelines are adopted to guide patient care.

There may be other service delivery gaps which must be captured throughout the hospital and actions must be taken in a planned manner.

The healthcare facility should make a Non-Conformity Report after the audit and enlist steps to eliminate them.

If non-conformities arise in the hospital's system process like in any administrative process e.g., laundry management:

- The machine used by the vendor is tearing the linen and no action has been taken, then it is a NC and in this case, that machine should either be repaired or replaced.
- Laundry management should be reviewed by the hospital's designated in-charge for any non-compliances.
- Records of the repair or replacement of the machine and the proceedings to close the NC should be maintained.

Source of information for detecting non-conformities:

- Patient/Stakeholder/Employees views
- Non-conformity reports
- Internal audit reports
- Output from management review
- Output from data analysis
- Output from satisfaction measurement
- Relevant QMS records of healthcare facility
- Process measurement
- Result of self-assessment
- Complaints received from patients, visitors, staff and vendors.

Control of non-conformity

In addition to inspections and analysis of records all people within the healthcare facility should have the authority to report non-conformities at any stage of a process. This is particularly true for those people engaged in monitoring of process activities and process output verification. There should be clarity about where it is to be reported and how and who is empowered to act on this. Methodologies may also be considered for recording information on those non-conformities such that it happens and is corrected in the normal course of work. Records of such corrections also provide valuable information for process improvement.

The parameters on which quality is judged would vary with the processes being assessed, as would be the ways of identifying non-conformity.

For example, the quality parameters of laboratories would include:

Efficiency parameters

- Accuracy of diagnostic reports
- Timely delivery of diagnostic reports to attending doctor

Effectiveness parameters

- Effectiveness of diagnostic availability and reporting on holidays and evening hours
- Dispatch and presentation of reports and waiting time of patients to get the report

Cost parameters

- Wastage of reagents
- Repetition of tests and unnecessary use of diagnostics
- Equipment utilisation and down time.

The hospital should adopt regular quality control measures, to ensure proper functioning of the laboratory. In addition the quality control measures for a laboratory would have two types of verifications.

Internal quality control - The accuracy of reports is tested by retesting the same sample within the hospital.

External quality control - The sample is sent to reputed reference laboratories (CMC Vellore, Apollo Chennai, PGI Chandigarh) for verification of accuracy of the reports.

ISO 9001:2008 Requirements

8 Measurement, Analysis and Improvement

8.4 Analysis of Data

The organisation shall determine, collect and analyse appropriate data to demonstrate the suitability and effectiveness of the QMS and to evaluate where continual improvement of effectiveness of QMS 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:

- Customer satisfaction (see 8.2.1)
- Conformity to product requirements (see 8.2.4)
- Characteristics and trends of processes and products, including opportunities for preventive action (see 8.2.3 and 8.2.4)
- Suppliers (see 7.4)

What it means in a hospital setting

The sources of information given in clause 8.3 can provide hospitals valuable data, but this data is valuable only if it is analysed. The hospital must determine, collect and analyse appropriate data of hospital operations to evaluate performance. Operational indicators of the hospital must be identified with respect to patient requirements and internal improvement needs.

In Hospital management, we are required to take decisions at every step. QMS advocates knowledge based or fact based decision making rather than taking decisions based on intuitions or gut feeling. Intuitions and gut feelings are highly subjective and may differ from person to person. Decision-making based on them is prone to blunders. On the contrary, knowledge and fact based decisions are objective, easy to comprehend, and scientific. When requirements are placed to higher authorities (Health secretary, MD NRHM etc.,) supported with facts and figures, they are more likely to be accepted.

How do we get knowledge for decision making:

- Data → Information → Facts → Knowledge (for decision making)

For knowledge or fact based decision making we must have:

- **Data:** unprocessed facts and figures; e.g., total no. of OPDs, no. of IPDs, total surgeries performed, total no. of admissions, no. of laboratory tests done, etc.,
- **Data leads to information:** data that has been deliberately selected, processed, and organised to be useful. (e.g. Bed occupancy rate is only 35%)
- **Information leads to the facts:** a piece of information presented as the truth,
- **Facts lead to knowledge:** what we know.

It is amazing how public hospitals have wonderful system collecting data of various registers, forms and other records including online HMIS but it does a poor job in sorting, summarising and presenting this data for decision-making. Hospital must sort and summarise the data, collect, do trend analysis to determine longer-term progress, and identify opportunities for further improvement or prioritise correction action for negative trends.

List of the performance indicators for analysis and continual improvement may include:

- Bed occupancy rate
- Average length of stay
- Bed turnover rate
- Death rate
- LAMA rate
- OT utilisation rate
- Equipment down time
- Nurse patient ratio
- Surgical site infection rate

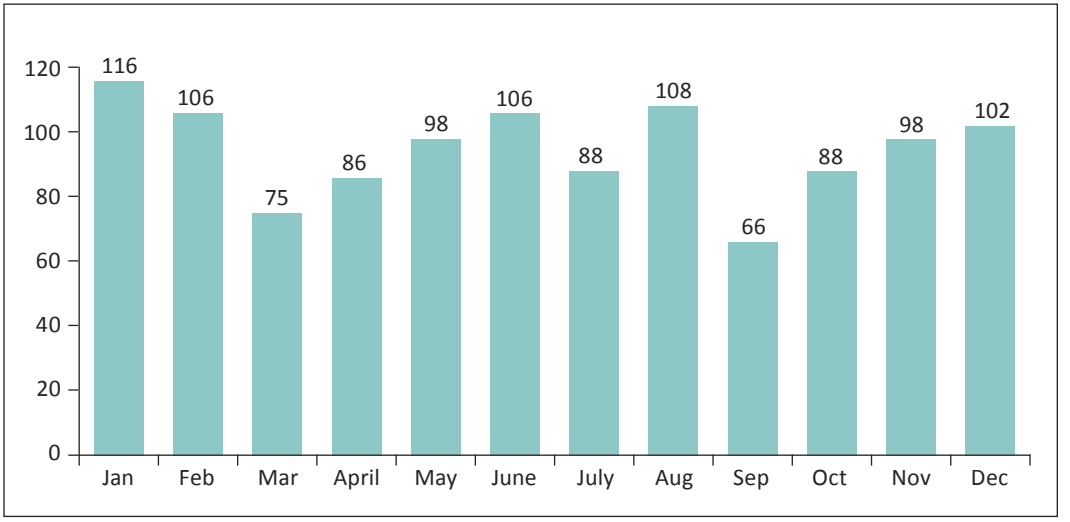
- OPD patient satisfaction index
- IPD patient satisfaction index
- Employee satisfaction index
- Percentage of stock outs including emergency drugs
- Blood transfusion reaction rate
- LSCS to Normal delivery ratio
- Maternal mortality rate
- Neonatal mortality rate
- Postpartum complication rate
- Power back up adequacy index
- Number of security related incidences including theft, assault, and affray and missing patient
- Percentage of BPL patients
- Average waiting time in OPD
- IV Fluids related infection rate
- Anaesthesia related mortality rate
- Nurse to Bed Ratio
- Percentage of rescheduling of surgeries
- No. of blood units procured through voluntary blood donation camps
- No. of cases of bites of rabies carrier animals
- On road status of ambulances
- Percentage of mothers leaving hospital in less than 24 hours of delivery
- Percentage of mothers getting JSY benefits within 72 hours
- Percentage of staff adherence to safety precautions and practices
- Cycle time for Lab reporting
- Biological indicator failure rate
- Staff absenteeism
- No of RKS meetings held
- Percentage of RKS funds utilised

These performance indicators help in evaluating and monitoring the effectiveness and efficiency of operations of a hospital.

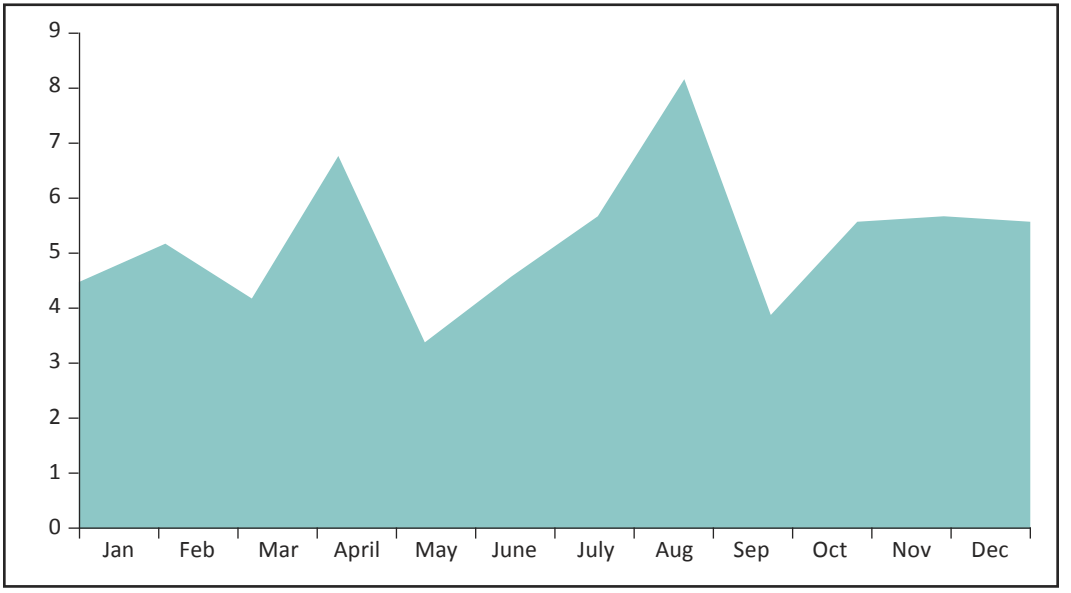
Data presentation and analysis techniques:

For the ease of understanding, the annual data could be graphically presented by means of:

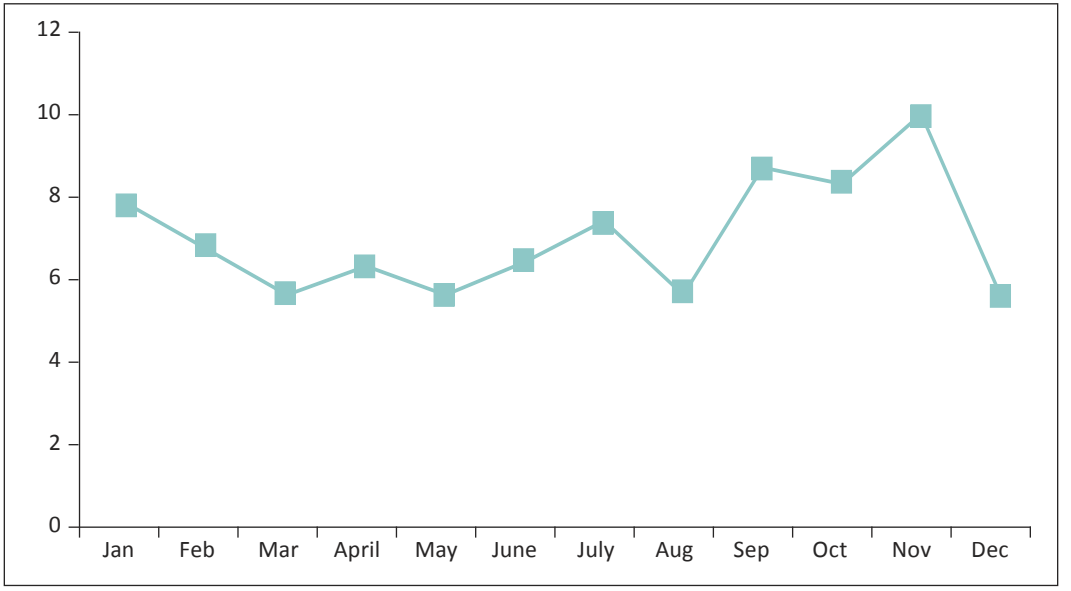
1. Bar Graph: (BOR)



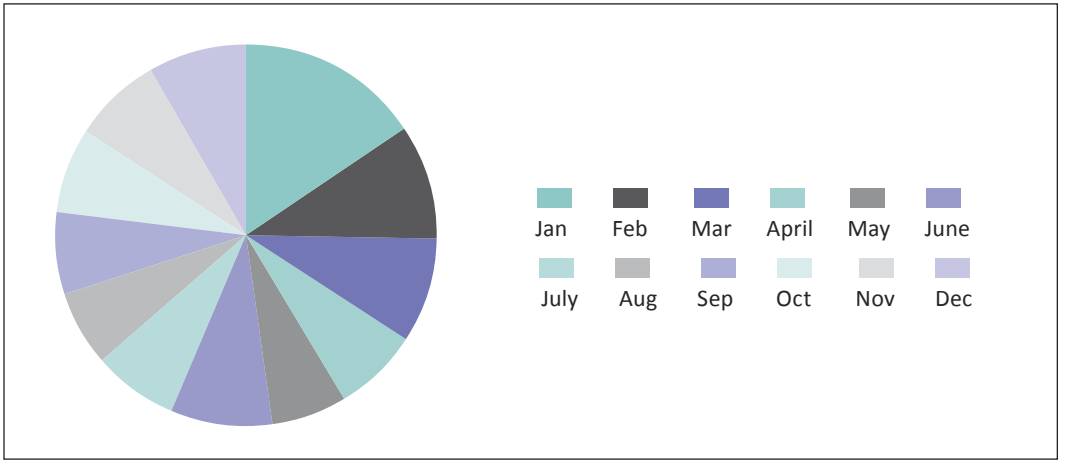
2. Area Graph (ALOS)



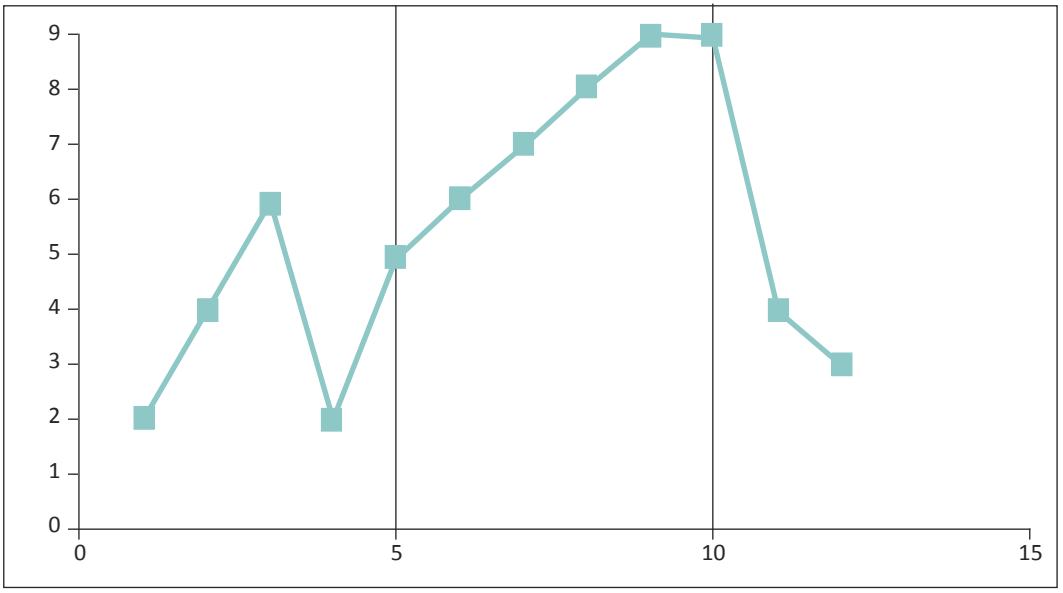
3. Line Graph (BTR)



4. Pie chart (LAMA Rate)



5. Scatter Diagram (LSCS rate)



How to perform Data Analysis

Let us assume the following is the data collected from Admission and Discharge Register of a 100-bedded District Hospital over the month of October.

Date	Mid night patient head count	No. of dis-charges	Admiss-ions	LAMA	Normal deliveries	LSCS s	Deaths	Abscon-ding
10/1/2010	110	12	22	9	22	2	2	0
10/2/2010	120	15	5	2	25	3	3	0
10/3/2010	110	20	50	12	28	1	0	0
10/4/2010	140	29	1	0	26	0	0	2
10/5/2010	112	12	34	11	20	2	0	0
10/6/2010	134	14	3	4	18	4	1	0
10/7/2010	123	17	15	3	23	6	1	1
10/8/2010	121	11	8	4	15	2	1	0
10/9/2010	118	9	7	2	18	4	0	0
10/10/2010	116	25	3	1	28	1	0	0
10/11/2010	94	24	38	12	24	2	0	0

10/12/2010	108	13	15	7	27	0	2	0
10/13/2010	110	19	28	12	20	0	1	0
10/14/2010	119	15	17	4	19	2	0	0
10/15/2010	121	16	25	13	24	5	0	1
10/16/2010	130	21	20	13	27	1	0	0
10/17/2010	129	22	38	10	19	2	0	0
10/18/2010	145	14	12	7	19	1		2
10/19/2010	143	30	4	0	23	1	0	0
10/20/2010	117	17	1	0	24	3	1	0
10/21/2010	101	11	10	5	19	5	0	0
10/22/2010	100	12	9	2	18	1	0	0
10/23/2010	97	23	10	6	25	1	0	0
10/24/2010	84	30	33	11	21	5	1	0
10/25/2010	87	10	23	13	23	3	0	1
10/26/2010	100	17	26	10	17	2	0	1
10/27/2010	109	19	28	11	19	1	0	0
10/28/2010	118	10	15	6	17	1	1	0
10/29/2010	123	19	28	10	22	1	1	0
10/30/2010	132	27	33	14	28	5	1	0
10/31/2010	138	21	28	9	21	3	0	0
Total	3,609	554	589	223	679	70	16	8

We can analyse the above data to calculate a few key performance indicators:

Information given

Total patient bed days (sum of midnight head counts for the month)=3,609
Functional beds in the hospital=100
Calendar days=31
Total admissions=589
Total discharges=554
Total number of deliveries= 679
Total number of LSCS=70
Total LAMA=223
Total absconding=8
Total deaths=16

Analysis and calculation of performance indicators:

1. **Bed Occupation Rate (BOR)**= Total patient bed days x 100 ÷ (functional beds in hospital × Calendar days in month)
   Bed Patient days - Sum of daily patient census for whole month.
   3,609 x 100/31 x 100=116.42%

2. **Average Length of Stay (ALOS)=** Total patient bed days in the month (excluding newborn) ÷ Discharges in the month (including death, LAMA, absconding)
   =3,609/554+16+223+8
   =3,609/801=4.5 days,

3) **Bed Turnover Rate (BTR)=** In-patient discharge including deaths, LAMA, and absconding in the month ÷ Functional bed on ground
   =554+16+223+8/100
   =801/100=8.01

4) **LAMA Rate**= Total no. of LAMA cases × 100 ÷ Total no. of admissions
   223 x 100/589=37.8%

5) **LSCS Rate**= No. of LSCS x 100 ÷ No. of total deliveries
   =70 x 100/70+679
   =700/749
   =.93%

Similarly, the data over a period of time, say one year, may be collected and analysed for trend analysis. Any significant or alarming change in the trend requires root cause analysis followed by corrective and preventive actions.

Performance Indicator	Jan	Feb	March	April	May	June	July	Aug	Sep	Oct	Nov	Dec
BOR	116	106	75	86	98	106	88	108	66	88	98	102
ALOS	4.5	5.2	4.2	6.8	3.4	4.6	5.7	8.2	3.9	5.6	5.7	5.6
BTR	7.8	6.7	5.6	6.3	5.6	6.4	7.4	5,.6	8.7	8.3	10.3	5.6
LAMA RATE	39	24	22	18	16	21	18	16	17	18	19	20
LSCS RATE	2	4	6	2	5	6	7	8	9	9	4	3

ISO 9001:2008 Requirements

8 Measurement, Analysis and Improvement

8.5 Improvement

8.5.1 Continual improvement

The organisation shall continually improve the effectiveness of the QMS through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review.

What it means in a hospital setting

Each hospital shall continually seek to improve, rather than waiting for a problem to reveal opportunities for improvement.

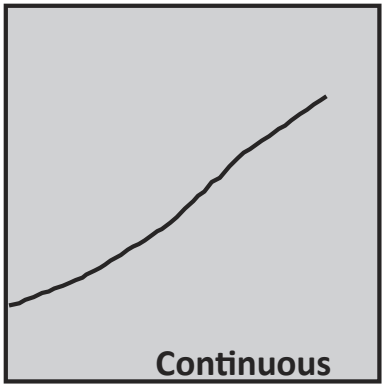
Continual improvement shall be based on relevant information available. Audit results and other data shall be analysed and compared with Quality Policy and Quality Objectives so that corrective and preventive actions can be taken to ensure continual improvement.

Feedback should go to management reviews to enhance this improvement process.

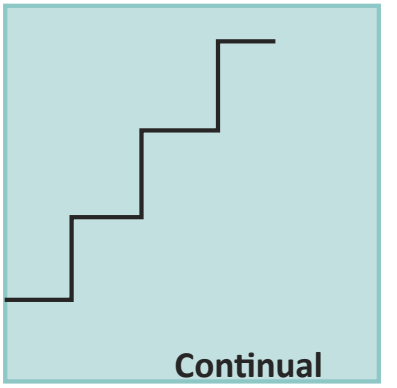
"Excellent firms don't believe in excellence-only in constant improvement and constant change"

- Thomas J. Peters

The difference between continuous and continual improvement: in continuous improvement you improve your performance on a continuous basis without any break, and this is quite impossible to achieve, whereas in continual improvement you improve a bit, sustain the improvement and then go to the next stage, sustain and again improve and so on. Continual improvement is defined as a recurring activity to increase the ability to fulfill requirements. This is graphically presented below:



Improvement



Improvement

Use of continual improvement tools include:

Quality Policy - Top management is required to establish the quality policy and review it for continuing suitability. Changes in services (addition of new department, diagnostics like CT scan), management, technology, QMS standards, etc., may require changes to your quality policy and objectives. As a tool for continual improvement, it requires top management to review and understand these changes; make changes, if necessary, to the quality policy and objectives and use these changes to continue further improvement of the QMS and customer satisfaction.

Audit Results - Audits result usually provide many opportunities to improve QMS effectiveness and efficiency. Opportunities may relate to communications, information systems, processes, controls, use of resources, technology, etc. The management representative must report these opportunities to top management as part of the management review agenda.

ISO 9001:2008 Requirements

8 Measurement, Analysis and Improvement

8.5.2 Corrective action

The organisation shall take action to eliminate the causes of NCs, in order to prevent recurrence.

Corrective actions shall be appropriate to the effects of the NCs encountered.

A Documented procedure shall be established to define requirements for:

- Reviewing NCs (including customer complaints),
- Determining the causes of NCs,
- Evaluating the need for action to ensure that NCs do not recur,
- Determining and implementing action needed,
- Records of the results of action taken (see 4.2.4), and
- Reviewing the effectiveness of the corrective action taken.

What it means in a hospital setting

The standard requires hospitals to have documented procedure to:

- Identify NCs
- Determine the causes of NC
- Evaluate the need for actions
- Determine and implement the actions
- Record results
- Review the effectiveness of action taken.

Other Audits - Besides QMS audits, you might find it very productive to conduct death audits, prescription audits, medical records audit, nursing audits, and financial; information and communication systems audits. You will be amazed at what you will find and improvement opportunities you will uncover.

Performance Indicators to measure the effectiveness of the continual improvement process may include - quality objectives being met sooner than planned, achieving and exceeding quality objectives improved efficiency in use of resources, cost reduction, improved service quality, etc.,

The hospital must establish a system to analyse performance on a defined frequency and prepare to continually improve the effectiveness of QMS. Most quality standards that are set are not necessarily the best possible but what is considered feasible. Achieving nil non-conformity only means that performance targets are not stretched and that we must now raise the bar and aim higher and for this, the quality policy and objectives guide the hospital.

The quality objectives of the hospital should be reviewed at regular intervals to identify the key areas of the hospital where performance has been excellent, good and poor. Accordingly, action plan/s would be required to be developed and implemented. Necessary changes should be made in processes wherever necessary, for continuous quality improvement.

Similarly, internal/external audits should be conducted at predefined intervals. Results of audits are analysed for the root cause of a non-conformity, if so observed and followed by the action Plan (time bound) to close the non-conformities.

The hospital should conduct MRM, preferably once in a month. Hospital data collected by HMIS, reviews and surveys should also be analysed at regular intervals. The results of such reviews should be discussed in MRMs.

Information from MRMs, analysis of data and audits should be analysed for root cause to identify the bottle necks in the structure, processes or outcomes. Based on this, an action plan comprising of corrective and preventive actions is implemented. In this way, the quality of healthcare services delivered can be improved on a continual basis.

8.5.3 Preventive action

The organisation shall determine the action to eliminate the causes of potential non-conformities 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:

- Determining potential non-conformities and their causes
- Evaluating the need for the action to prevent occurrence of non-conformities,
- Determining and implementing action needed
- Recording results of action taken (see 4.2.4)
- Reviewing the effectiveness of the preventive action taken.

What it means in a hospital setting

Actions taken to eliminate the cause of a potential non-conformity or other undesirable potential situation.

The main difference between corrective action and preventive action is that preventive action addresses a potential NC and prevents a gap developing, whereas, corrective action closes a process gap that has developed. Immunisation and adopting healthy life styles constitutes preventive action.

It is better to prevent a problem than to correct a problem. Based on the information available, hospitals must identify way of preventing problems from occurring in the first place.

Corrective action

"The last person to be fired or to quit is responsible for all the errors, until another person is fired or quits."

Definition: Actions taken to eliminate the cause of a *detected* non-conformity or other undesirable situation.

One needs to grasp the difference between correction, which is an immediate remedy, and a corrective action which addresses the root cause. Getting a dirty toilet cleaned or clean sheet put on a bed is correction. But determining the number of sanitary workers needed and making a supervisor arrangement for them or signing a well constructed laundry and linen inventory management system is corrective action.

Corrective action is taken to eliminate the cause of a detected non conformity to prevent recurrence, whereas, preventive action is taken to eliminate the cause of a potential non-conformity or other undesirable situation, to prevent recurrence.

Improvement does not happen without implementing changes. This requirement is related to ensuring that actions are identified, taken and verified for implementation/ effectiveness. If a problem occurs, action needs to be taken to ensure that the problem is corrected and that it does not recur. This involves finding the cause of the problem, recording the results of the action taken and verifying that the action was effective. The intent of this requirement is to have a disciplined approach for making sure that action takes place and is effective.

"One of the tests of leadership is the ability to recognise a problem before it becomes an emergency."

"The more we sweat in peace, less we bleed in war."

Preventive action

There many management methodologies to identify causes of potential NCs. These include risk analyses, trend analyses, statistical process control, fault tree analysis, failure modes and effects and criticality analyses etc.

The sources of information and the processes of decision making are similar to those for corrective action. Preventive action can have considerable financial outlay and in a public hospital setting, may require considerable advocacy and persuasion to raise resources for.

Preventive actions often become closely related to the concept of continual process improvement.

Model questions and review of ISO 9001:2008

1. What are indicators for Indoor Patient Department (IPD)? Calculate Bed Occupancy of your hospital for the preceding calendar year.
2. What are indicators for monitoring of the House Keeping Services at the Hospital?
3. What are indicators for monitoring laundry services at the hospital?
4. There has been an electrical short circuit at the main distribution box of the male ward. What corrective and preventive actions could be taken for this occurrence?
5. You notice that post-operative infection rate is high in women, undergoing LSCS. Undertake a root cause analysis of high post operative infection among LSCS.
6. How will you introduce death audit at your hospital?
7. During course of analysis, you notice that there is high wastage of X-ray films in radiology department. What probable corrective action could be taken?
8. True/False
    - High LAMA rate (Left against medical advice) suggests that patients are not satisfied with the hospital services. (True/False)
    - Employees Perception survey is not an important activity of hospital. (True/False)
    - Hospitals' main job is to provide medical care to dependent population. They are not required to undertake complaint redressal. (True/False)

CHAPTER 9

Road Ahead

Steps to Establish and Strengthen Quality Management System

STEP 1: Status Assessment through *As-Is Survey*

1. Set up an implementation team for QMS

The committee members should include the In-charge of the hospital, at least two clinical HODs, Accounts Head, Hospital Administrator, Senior Pathologist and Matron. This committee for driving QMS initiative is different from RKS. Some of the advantages of working through committees are:

- Members of the committee can exchange views and information to bring collective wisdom, group deliberation and judgement to bear upon subjects of discussion or task.
- Committees generate ideas for change and overall quality improvement.
- A well organised and responsible committee enables its members to perform at a high level of cooperation and commitment. It promotes success through delivery rather than conformity.

2. Awareness training for committee members

The hospital management shall arrange training for committee members on QMS before initiating the process.

3. Organise first meeting of committee

Organise the first committee meeting and discuss the QMS development and implementation milestone.

4. Appoint an MR to lead the implementation team of QMS who is responsible to establish, implement and maintain QMS.

- The top management should appoint an MR, who in addition to his/her vocational responsibility shall be hold the responsibility of MR. For public hospital, the top management refers to chairperson of RKS.

- The MR, after his/her appointment on the position, nominates:
  - A Training In charge
  - A Document Control Incharge (DCI)
  - A internal Quality In-charge
  - An Alternate Management Representative or Dy. MR
- Organise training for MR, Dy. MR, DCI, Training In-charge and Internal Quality In-charge for their roles, responsibility and function.

5. Organise a meeting with the implementation team

The MR organises one meeting with the implementation Team regarding the *As-Is survey* and QMS Implementation Programme and gives a clear direction to all team members how they can achieve QMS certification in the hospital.

6. Organise a Workshop for all Employees

The MR and implementation team members should organise in convenient batches one "Awareness and Introduction workshop for all employees of the hospital for better understanding. This is to make everyone aware of QMS to manage the quality of different processes.

7. Conduct an *as*-is *survey* including observation, documentation and review of manpower, equipment, infrastructure, training and capacity building activities, services and eacilities provided, legal compliance status etc.

The MR and Implementation Team members organise a comprehensive ***"As-Is Gap Survey"*** which includes general observations through interview methodology, documentation and review of manpower, equipment, infrastructure, processes including training and capacity building activities, services and facilities provided, legal compliances etc. The gaps need to be elucidated against FFH requirements, as the issues enclosed are is the FFH format. Besides the above points, the format for the "Facility Survey" available in IPHS guidelines (specific to the number of beds hospital) must be logically filled and captured in *"As-Is Gap Report".* This includes all support processes including nursing, housekeeping and laundry services, security services, dietary services and information support services etc. The team must have the back up information sheet carrying the sources of each such information furnished in the *As-Is report.*

8. Identify resource and process gap in the hospital

In the above *"As-Is Gap Survey",* The Implementation Team identifies and explains their statement with rationales and take relevant photographs of the identified gaps. These photographs shall be included in the *As-Is Gap Report* for better presentation and clear understanding.

9. Conduct patient and employee satisfaction survey

The Implementation Team conducts one ***"Employee Satisfaction Survey" (ESS) and "Patient Perception Survey" by simple random sampling method*** among all employees and OPD and IPD patients respectively and analyse the low scoring areas. The analyses of both surveys also form a part of the *As-Is Gap Report* as annexure.

10. Preparation of detailed *"As-Is Survey" report* which includes all gaps, process flows, patient satisfaction data, manpower status as per IPHS

The MR and his team prepare a detailed *As-Is Gap Report,* which shows all the positive and negative aspects of the hospital. Process flows of each department, equipment and manpower detail, as per IPHS standard, shall be incorporated under each process head.

11. Gaps are divided into nine categories as follows:

1. Safety, Security and Dignity
2. Regulatory Compliance
3. Administrative Process
4. Clinical Process
5. Support Process
6. Human Resources
7. Infrastructure
8. Reproductive, Child and Health Related
9. Tools, Tackle and Equipment

12. Submit *As-Is Gap report* to appropriate authority for implementation

The MR submits a detailed *As-Is Gap* report to the top management for action, along with preparing and presenting a detailed power point presentation of the gaps, along-

with SWOT analyses to the top management for better clarity of achieving excellence in the hospital. On the basis of the report and presentation, the top management should raise funds from the state government for upgradation of the hospital and plan to eliminate all gaps identified in the report. From the point of view of traversing gaps, it is placed in three groups:

- Gaps where local action is required.
- Gaps where district administration's action is required.
- Gaps where higher level intervention is required.

STEP 2: Quality Management System Training

13. Identify the training need for all members of the hospital

Identify the competence gap for personnel working in the hospital on the basis of their roles and responsibilities and their present skill sets.

14. Preparation of an annual training plan with steering committee members as per competence gaps

Based on the skills gaps elicited amongst employees and on the general understanding of QMS, the training modules can be prepared, planned and subsequently imparted to the selected staff members by the implementation team. The MR and Training In-charge may take help of the external domain expert and faculty for imparting such training as desired. Some examples of the trainings is detailed below:

- Quality An Introduction
- Design of a Good QMS
- FFH requirements
- ISO 9001:2008 Clause Review/Implementation
- Document and Data Control
- SMART Objectives
- All Mandatory, Clinical and Administrative Procedures

15. Conduct training as per the training plan

- **Training provider/faculty**

  The ability of the trainer to communicate effectively and innovatively to the trainees is critical to the success of programme. Besides having adequate knowledge of the subject matter, the trainer needs to make the training delivery effective, through good quality communication and a friendly non-threatening environment. A participative and interactive approach and hands-on exercise goes a long way in making learning easy and lasting.

- **Training support**

  Such facilities essential for the training delivery includes:
  - Proper training room
  - Facilities viz: OHP, LCD Projector, a laptop or a computer system, audio system, a white board flip, charts, markers, dusters, pointers etc.

- **Conclusion of training**

  It will include:
  - Evaluation, assessment and/or feedback from trainer
  - Obtaining structured feedback from trainees
  - Post training activity/exercise if any.

STEP 3: Quality Management System Development

16. Establishing quality policy

Hospital Management ensures that the quality policy is appropriate to the purpose of the hospital, it includes a commitment to comply with requirements and continually improve the effectiveness of the services provided by it. During developing a Quality Policy, it is vital to take inputs from all employees and stakeholders of the hospital to ensure their commitment in its implementation. The quality policy is communicated throughout the hospital and provides a framework for establishing hospital objectives.

17. Gaps filling through action planning

- Respective process owner is designated to be the responsible person to find a solution and close the gaps, this is finally supervised by the MR who verifies and validates the solution and also ensure the gap shall not arise in future, by taking corrective and preventive action for the same.
- The timelines for action plan must be identified.

18. Design and development of adequacy manual named as Apex Quality System Manual, meeting QMS requirements

Apex Quality System Manual includes the scope of the QMS, reference of all clinical and non clinical procedures and interaction between the processes of QMS. Quality System Manual describes all the clauses in ISO 9001:2008 standards and explains its interpretation in terms of means of fulfilling patient requirement needs of a FFH.

19. All Processes are documented in the form of SOPs/flow charts/guidelines as per the hospital working. Templates for the documentation are available in the implementation guide book.

20. Identify the core clinical processes and support processes

Clinical processes

- Out Patient (OPD) Management
- In-Patient (IPD) Nursing Care Management
- Medical Emergency Management
- Family Planning Management
- OT Management
- Hospital Diagnostic Management
- Blood Bank Management
- Hospital Infection Control and Sterilisation Management
- Hospital Referral Management
- Nursing Care Management
- Hospital BMW Management
- Management of Death

Administrative Processes

- Patient Registration, Admission & Discharge Management
- Medicine Stores and Inventory Management
- General Stores and Inventory Management
- Procurement and Outsourcing Management
- Hospital Transportation Management
- Hospital Security, Safety and Disaster Management
- Hospital Finance and Accounting Management
- Hospital Infrastructure Maintenance Management
- Hospital housekeeping and General Upkeep Management
- Human Resource Development and Training Management
- Dietary Management
- Laundry Management

Mandatory Procedures

- Control of Documents
- Control of Records
- Internal Audit
- Service Non-Conformity
- Corrective Action
- Preventive Action

21. The MR and his team members incorporate all working documents into SOPs and freeze the individual department SOPS with the respective HODs. The SOP should carry all information pertaining to the actual working methodology of the department. While approving SOP, the MR takes care of minimum system adequacy for any department with regard to its functional requirements and requirements of standards.

22. Prepare a Master List of Documents

The MR collects one copy of each format/register which is either already used or planned to be used in the departments and maintains one master format file reference. More documents/formats may arise during the development of QMS, which further also incorporated in the master list of documents.

23. The MR finalises the quality objectives with the implementation committee members

The MR shall ensure performance objectives (CQI-Continuous Quality Improvement) are finalised with the top management, including meeting the requirement of service. The quality objectives are measurable and consistent with the quality policy.

These may include 30 indicators such as:

1. BOR	16. Biological Indicator Failure Rate in CSSD
2. ALOS	17. Ward Indent Satisfaction Percentage
3. Gross Death Rate	18. Patient Complaint Rate
4. LAMA Rate	19. Percentage of Total Patient BPL IPD
5. SSI Rate	20. Total Hospital Waste in kg
6. Operation Cancellation per week	21. Percentage of Infectious Waste
7. Post Operative UTI	22. OT/Ward Linen Stock out Incidence
8. IV Reaction Rate	23. Stock-out Incidence of Life Saving Drugs
9. Casualty Response Time	24. Ward Indent Satisfaction Percentage
10. Average Transfer Time Casualty to Ward	25. Near Expiry Drug <90 days
11. Blood Transfusion Reaction Rate	26. Down Time Critical Equipment
12. MP Positive Rate	27. Unserviceable Needle Destroyer
13. Calibration Failure Incidence	28. Patient Satisfaction Survey
14. Sputum Positivity Rate	29. Staff Satisfaction Survey Score
15. BMW Bag stock out Incidence	30. Percentage of Total Patient BPL OPD

24. Collect data on the quality objectives for review

The MR determines, collects and analyse appropriate data to demonstrate suitability and effectiveness of the QMS.

25. Approval and dissemination of documents to all staff members for proper implementation of documented procedures and guidelines with the help of controlled copy holders

After finalisation of documents, all documents are approved prior to issue. Before issuing the documents, the MR has to check that all documents are legible and readily identifiable.

26. Setting up display boards including the quality policy, citizen's charter and directional signages

A detailed signage plan should be prepared covering indoor and outdoor signages. Its implementation is then ensured through a selected external agency. Quality policy should be displayed at all prominent locations.

27. Approval and dissemination of Quality System Manual to identified recipients for that manual

The Quality System Manual is approved by the MR and issued by the DCI as per the controlled copy holders' list attached in the manual itself.

STEP 4: Implementation

28. The MR organise training for internal auditors

The Training In-charge and the MR identify competent people within the hospital who understand QMS and who can conduct internal audits after a formal training. The Training In-charge organises a three-day training to all identified staff members and certifies those who qualify those test at the end of the workshop. A formal certificate is issued by authorised agencies to ***"Certified Internal Quality Auditors"*** to enable them to do audit.

29. Conduct internal audit with identified and trained internal auditors

Identified and certified internal auditors conduct internal audits initially at monthly intervals and later every three months to determine whether the QMS conforms to the planned arrangements and to effectively implemented or not.

30. Conduct management review with top management and implementation committee members and discuss the agendas as per the procedure

The top management reviews the QMS and its effectives at planned intervals, preferably every two months, to ensure its continuing suitability, adequacy and effectiveness.

31. Action planning in management review and closing all gaps

All defined agendas namely:

- Results of Audit
- Customer Feedback
- Process Performance and Service Conformity
- Status of Preventive and Corrective Action
- Follow up Actions from Previous Management Reviews
- Change that could affect the QMS
- Recommendations for improvements are discussed in management review meetings and records of management review meetings are circulated to all concerned employees of the hospital for necessary action, besides sending a copy to the Top Management, who in the case of Hospitals is the Chairman, RKS.

STEP 5: QMS Certification

32. Preliminary intimation to certification body

Once the MR is confident on the basis of results of internal audits that the hospital is ready for the certification audit, he coordinates with certification bodies and intimates the agency about the certification requirement.

33. Application to selected certification body and finalisation of pre audit date

After finalising the certification body, the MR fills the application form for getting pre audit dates.

34. Pre Audit by third party agency

The MR informs all staff members of the hospital about pre audit from third party agency and on the day of audit, the MR facilitates the pre audit with auditors. At the end of the day MR organises the closing meeting for discussing gaps identified in pre audit in front of the Top Management.

35. Close all pre audit gaps/NCs

The MR and his team work on the identified gaps and send the corrective action report to the certification body and ask for the final audit date.

36. Certification audit

A team of auditors come for the certification audit and the MR facilitates them for audit, as per the schedule given by them. At the end of the audit the MR arranges the closing meeting, and in the presence of the Auditor's team briefs them about their findings.

37. Closure of final audit observation

The MR ensures, with his team members that all final audit observations are closed.

38. Send corrective action report to certification body on observed points

The MR sends the corrective action report to the certification body, if some NCs occur.

39. The certification body takes a call on the award of ISO compliance certificates on the basis of its findings in the audits.

STEP 6: Handholding

40. Plan QMS handholding for one year and so on

The hospital shall plan a handholding milestone for one year, after successful certification to ISO 9001: 2008 standards and monitors the QMS progress on a continuous basis.

41. Improvement in SOPs and manuals

If there is any change in the hospital is working, on the basis of that the MR amends the procedures.

42. Conduct internal audits as per the defined annual plan

Identified internal auditors conduct internal audits at planned intervals to determine whether the QMS conformed to the planned arrangements and effectively implemented or not. The internal audit will be pre planned and core clinical processes will be taken into account.

43. Close all audit gaps

The MR gives the audit report to all HODs for necessary corrective and preventive action. HODs are responsible for taking corrective action without any undue delay to eliminate detected non NCs and their causes.

44. Conduct trainings as per the plan and post effectiveness of training for all employees

The Training Manager conducts trainings as per the annual training plan and intimates all trainees from time to time.

45. Conduct management review

Continuous reviews are conducted to set the ball rolling for continual improvement. The important thing is that the implementation should be effective and there should be a visible change happening in infrastructure, patient satisfaction, employee satisfaction and hospital visibility.

ANNEXURE

NHSRC Quality Improvement Project

Monthly Report Format for District/Sub-District Hospital Ver. 2.0		
VOLUME INDICATORS		
NAME OF THE HOSPITAL:		
CS/MS:		
Hospital Manager:		
On Site Consultant:		
Month & Year:		
Stage of Project:		
Sr. No.	**Title**	**Value**
(A) HOSPITAL STATISTICS		
1	Total OPD Attendance	
1 (a)	Old	
1 (b)	New	
2	BPL OPD Attendance	
2 (a)	Old	
2 (b)	New	
3	Total IPD Admissions	
4	BPL IPD admissions	
5	Patient Bed Days (Cumulative total of midnight head count of all days of the month)	
6	No. of Deaths	
7	No. of patients attended in Emergency	
8	No. of Sanctioned Beds by the State Government	

9	No. of functional Beds on ground	
10 (a)	No. of functional ambulances available	
10 (b)	No. of trips made by ambulance for transferring patients	
(B) OPERATION THEATRE		
11	No. of Minor Surgeries	
12	No. of BPL Patients underwent Minor Surgeries	
13	No. Major surgeries Done	
14	No. of BPL Patients underwent Major Surgeries	
(C) MATERNAL & CHILD HEALTH		
15	No. of Normal Deliveries in Hospital	
16	Number of Normal Deliveries-(BPL Category)	
17	No. of C-Section Deliveries	
18	No. of C-Section Deliveries-(BPL)Category	
19	No. of Maternal Deaths	
20	No. of Neonatal Deaths including still births.	
21	No. of MTP Conducted	
(D) BLOOD BANK		
22	No. of Blood Units Issued	
23	No. of units Demanded by Hospital	

(E) LABORATORY SERVICES		
24	No. of Lab tests done	
25	No. of Lab test done - (BPL Category)	
(F) RADIOLOGY		
26	No. X-Ray Taken	
27	No. of X-Ray taken - (BPL Category)	
28	No. of ultrasound Done	
29	No. of ultrasound Done - (BPL Category)	
(G) DEPARTMENT WISE STATISTICAL DATA		
OPD ATTENDANCE		
30	Medicine	
31	Surgery	
32	Paediatrics	
33	Orthopaedics	
34	Obstetrics and Gynaecology	
35	Dental	
36	Ophthalmology	
37	Skin and VD	
38	T.B.	
39	E.N.T.	
40	Psychiatry	
41	ICTC	
42	Others (if any)(STI)	
43	Others (if any)(RTI)	
	TOTAL OPD ATTENDANCE	

IPD/ADMISSIONS/DEATHS/REFERRALS		Total Admissions	BPL	Discharge	Referred
44	Male Medical ward				
45	Female Medical ward				
46	Male Surgical Ward				
47	Female Surgical Ward				
48	Paediatric ward				
49	Gynaecology ward				
50	Obstetric ward				
51	Eye ward				
52	Emergency ward				
53	ICCU				
54	NICU				
55	ENT				
56	BURN Ward				
57	Any other ward				
58	Isolation Ward				
	TOTAL				

Monthly Report Format for District/Sub-District Hospital Ver. 2.0 PERFORMANCE INDICATORS					
NAME OF THE FACILITY:					
CS/MS:					
Hospital Manager:					
On Site Consultant					
Month & Year:					
Stage of the Project					
Sr. No.	**Title**	**Metric**	**How**	**Calcula-tions/Ex-planations**	**Values (Numbers Only)**
(A) HOSPITAL STATISTICS					
1	Bed occupancy Rate (BOR)	Rate	Total Patient Bed Days x 100 ÷ (Functional Beds in Hospital × Calendar Days in month) Bed Patient days- Sum of daily patient census for whole month.		
2	Bed Turnover Rate (BTR)	Rate	Inpatient discharge including deaths in the month ÷ Functional Bed on Ground		
3	Average Length of Stay (ALOS)	Rate	Total Patient Bed Days in the month (excluding New Born) ÷ Discharges in the month (including Death, LAMA, absconding)		
4	Lama Rate	Rate/100 Adm	Total No. of LAMA cases × 100 ÷ Total No. of Admissions		

(B) PATIENT CARE					
5	Nurse to Bed ratio	Ratio	Total Hospital Beds/Total No. of Nurses (including ANM)		
6	Percent of Cancelled surgeries	Percent	surgeries Cancelled x 100 ÷ Total surgeries performed		
7	Total No. of death on Operation Table and Postoperative Deaths	Numbers	Count		
8	Anaesthesia related mortality	Numbers	Count		
(D) MATERNAL & CHILD HEALTH					
9	LSCS Rate	Rate	No. of CS delivery x 100 ÷ No. of Total delivery		
10	Percentage of mothers leaving hospital in less than 48 hrs.	percent	no. of mothers leaving hospital in less than 48 hrs of delivery x 100 ÷ Total No. of delivery		
11	Percentage of mothers getting JSY benefits within 48 hours of delivery	Percent	No of institutional deliveries, receiving JSY benefits within 72 hrs. of delivery × 100 ÷ Total no. of mothers entitled		
(E) DISPENSARY					
12	No of drugs expired during the month	Number (Volume and Type)	Count		
13	Percentage of drugs available	Percent	No. of drugs available in the dispensary x 100/No. of drugs as per essential drug list for the facility		

(F) Blood Bank					
14	Blood Bank Turnover	Ratio	No. of unit issued/No. of units collected (including replacements)		
15	Validation of test results by external laboratories	Numbers	Number of validation per month		
16	Sputum Positive Rate	Rate	No. of slide found positive in AFB x 100 ÷ Total slide Prepared for test		
17	M P Positive Rate	Rate	No. of slide found positive for Malaria Parasite x 100 ÷ Total slide Prepared for test		
18	Cycle Time for Diagnostic Reporting	Hours	Sum of total time in delivering reports ÷ Total Reports **measure at least for five patients in a month that includes-* *OPD-2* *Male Ward-1* *Female Ward-1* *Emergency-1*		
(H) RADIOLOGY					
19	Cycle time for X-Ray Reporting	Minutes/ Hours	Measure		

(I) HOUSEKEEPING *for every YES give 1 for every NO give 0,* *add scores of all 10 attributes to get the final score*					
20	Hygiene Score	Score of 0-10 (*for every YES give 1 for every NO give 0, add scores of all 10 attributes to get the final score)*	Availability of running water		
			Availability of functional Cisterns		
			Clean toilets		
			No broken seats, cistern, tiles.		
			No water logging		
			No water leakage fro taps/ overhead tanks		
			Clean wards/corridors		
			No clogged/overflowing drains		
			No over grown weed shrubs in the premises.		
			toilets meant for patients not locked from outside.		
21	Number of Culture Surveillance conducted	Number	Number of Culture Surveillance with details of departments in which they are conducted. ***Reports of Surveillance to be attached***		
22	Down Time Critical equipments	In Hours/ Days	Total time critical equipments cannot be used because of being out of order		
23	No. of Instrument Calibrated	Numbers	Count		

(L) LAUNDRY SERVICES					
24	Linen/day/bed	Rate	Total no of bed sheets washed/Bed Complement		
(M) SECURITY SERVICES					
25	Total No. of guards available per day	Number	Count		
(N) BIOMEDICAL WASTE MANAGEMENT *for every YES give 1 for every NO give 0,* *add scores of all 10 attributes to get the final score*					
26	BMW Score	Scale 1-10	Availability of colour coded Bins at point of BMW generation		
			Availability of coloured liners		
			Display of work instructions at the point of segregation		
			Segregation of BMW at point of generation		
			availability of sharps pit and disposal of sharps as per rules.		
			Availability of deep burial pit and disposal of placenta and other anatomical waste as per rule		
			Availability of PPE(Personal Protective Equipments) with biomedical waste handlers		
			Availability of sodium hypochlorite solution and puncture proof boxes		
			Mutilation and disinfection of plastic waste before disposal		
			Authorisation under BMW management rules 1996.		

(O) TRAINING					
27	No. of trainings conducted	count	Attach a note on training that includes- 1. Topic 2. No. of trainee 3. Name of trainer 4. Schedule		
(P) PATIENT RIGHTS AND INFORMATION *for every YES give 1 for every NO give 0,* *add scores of all 10 attributes to get the final score*					
28	Patient Information Score	Scale 1-10	Citizen Charter available and prominently displayed		
			Emergency signage prominently displayed		
			Help Desk/Enquiry counter with dedicated person available		
			User Charges (OPD/IPD/ Diagnostics/blood bank/ others) prominently displayed		
			Availability of drugs prominently displayed (at dispensary and IPD)		
			Departmental Signage prominently displayed		
			Display of mandatory information (under PNDT/ RTI etc.		
			Complaint/Suggestion box prominently placed		
			Safety/Hazard and caution sign prominently displayed.		
			Consent Practiced (OT/IPD/MTP/HIV testing)		

(Q) SECURITY SERVICES					
29	Total No. of guards available per day	Number	Count		
(R) PATIENT SATISFACTION					
30	Patient Satisfaction Survey Score for OPD	Scale 1 TO 5	Survey ** Reports to be attached*		
31	Patient Satisfaction Survey Score for IPD	Scale 1 TO 5	Survey ** Reports to be attached*		
32	Waiting time taken for OPD registration	In minutes	Duration for which Patient has to wait for OPD registration		
33	No. of Complaints/ Suggestions Received	Numbers	Count		
34	Waiting time for OPD Consultation	In minutes	Survey		
35	Consultation Time	In minutes	Survey		
36	Waiting time at Dispensary	In minutes	Survey		
37	Staff Satisfaction Survey Score	Scale 1 TO 5	1. Survey 2. Analysis 3. Action Plan on Analysis ** Reports to be attached*		

* Patient Satisfaction Survey to be conducted Quarterly. Data Analysis, Root Cause Analysis and Action plan for Patient Satisfaction Survey to be attached.
* Staff Satisfaction Survey to be conducted once in SIX months
Tools for deciding Sample Size will be sent to you shortly.
* Work instructions for conducting patient satisfaction survey are attached with this format.

(S) COMMUNITY PARTICIPATION (RKS)					
38	Number of RKS meeting held in the month	Number	Count		
39	Utilisation of RKS funds	Rs.	1. Opening Balance of RKS account for Month 2. Expenditure in the Month 3. Funds Received/Income in the month		
40	Funds raised through NGO/ PRI/Corporate/ sources other than state government.				
(T) INTERNAL, MEDICAL AUDIT AND DEATH AUDIT					
41	Internal Audit conducted during the month (Yes/No)	Yes/No	1. Details to be attached including report, if audit conducted 2. If Internal Audit not conducted in this month then specify the due date for the same.		
42	Death Audit conducted during the month (Yes/No)	Number	Medical Audit Conducted - YES/NO Number of cases discussed ?		
43	Medical Audits conducted during the month/Number of cases discussed	Number	Medical Audit Conducted - YES/NO Number of cases discussed ?		

(T) MANAGEMENT REVIEW MEETING					
44	MRM conducted during the month	Number	1. MRM Conducted - YES/NO 2. MOM to be attached. 3. Action plan to be attached		
(U) ANY FUND RELEASE/ARCHITECTURAL DEVELOPMENT/REPAIR DONE DURING THIS MONTH					
45	Any Fund Release/ Architectural Development/ Repair done during the month	Details	Attach details if any		
46	Any other Major Events/Remarks	Details	Attach details if any		

Human Resource Report							
S.No.	**Category**	**Sanctioned Post**	**IPHS Norms**	**Posted in**	**Posted Out**	**Net Strength**	**Remarks**
	Duty Doctors						
	Specialists Doctors						
	Ayush Doctors						
	Staff Nurses						
	ANMs						
	Technicians						
	Paramedics						
	Pharmacist						

National Rural Health Mission
Ministry of Health & Family Welfare
Government of India