Development of NABH Quality Manual For Hospitals

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Director Programs-AHA
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Introduction

• Documentation is an essential component of NABH accreditation
• NABH standards require documentation
Contd..

• Quality manual is a document in the organization that contains the total quality program of the HCO including general information about organization, its business, its vision mission statements, its quality policy, quality objectives, quality standard applied, departmental & work units policies and procedures, SOPs, forms & formats used by organization, quality monitoring protocols & indicators and the corrective & preventive actions (CAPA) the organization takes to improve quality.

Contd.

• It also includes information about various processes & how various aspects/ clauses of a Quality Management Standard are applied to them.

• It gives an overview of the implemented Quality Management System (QMS) in the HCO.
Why Required?

1. Documentation requirement for NABH & other standards
2. Required by management, internal & external customers to understand how a QMS is applied across organization
3. Objective way to stay on course
4. Reflection of organization’s commitment
5. Can be referred to in case of differences
General Considerations

• Should be standard compliant - Written in the format of the NABH Standard
• Should not be a work copied from another organization’s manual
• Should reflect the systems as they are implemented with minimal additions
• “Say what you do; Do what you say”
• Decision regarding single/multiple manuals

General Considerations

• Page numbering is important:
  – Identifies how many pages there are in a specific section of the document
  – Easy to determine if any pages are missing
• Also determine the procedure for revising the document & accordingly give page numbers, continued numbering for the whole manual or section wise page numbering.
General Considerations

• Quality manual is written in ‘present tense’ - to reflect what is done now & not what will be done
• Better to follow structure of the applied standard
• If the standard’s layout is not followed, then a matrix that cross-references the standard’s clauses to the manual’s layout should be provided
• Header & footer on each page should be provided
**MANAGERIAL ISSUES**

- Management must decide well in advance & assign responsibility of
  - preparing manual
  - reviewing manual
- Top Management before giving their approval to QM must do a final review
- Top Management must ensure that all required resources are available—writing tools (a computer or typewriter), any office appliances, competent person/s
MANAGERIAL ISSUES

• **Information** to be included in QM should be readily & clearly available to those involved in its development.

• Management must **make themselves available for any discussions**.

• They should ensure a thorough **process mapping** as also establish **parameters for Continual Improvement**

• Top Management need to **define how processes are to be monitored**, process of **Internal Quality Audit** & process of **Management Review**

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MANAGERIAL ISSUES

• They must ensure that **Quality Objectives** are established & same are reflected in the QMS as well as in QM

• While Quality Objectives are being established, a **plan** must also be drawn out to achieve them as desired

• Top Management should also decide **scope of QMS & QM**, its **management & distribution parameters**

• The **plan & period for revision of QM** also needs to be decided & documented by top management of HCO
Before starting to write the manual

- HCO owner/ operator or management must take a decision that a quality manual is required
- Commitment of the top management/ owner/ operator of the HCO is important before any quality manual is written
- Collect complete information about the organization’s operations & then decide how to write
- Define Quality Policy, Quality Objectives, process effectiveness criteria & any other areas of improvement
Before starting to write the manual

- **Do process mapping across the organization:**
  - Identify processes across organization clearly defining their operations
  - Determine sequence of the processes & establish areas of their interaction
  - Establish the checkpoints within & outside the processes & determine criteria to measure effectiveness of the processes & product or service (monitoring performance of the processes)

**Process Flow Chart**

Before starting to write the manual

- In planning stage of a quality manual **determine and finalize the procedure for revising** the document and then determine the type of page numbering you want
- **Pagination** can be done as a continuous page numbering of the whole document from front cover page to last cover page or it can also be done section-wise where each section has page numbering starting from one
Types of Quality Manuals and Documents

- Quality manuals are basically of three types depending upon the level at which the manual is applied
- The three types of manuals according to the level of their application are......
Types of Quality Manuals and Documents

**Level-I Quality Manual:**
- This is always one manual that contains the summary of complete QMS as it has been applied to the HCO.
- This manual is QMS Standard Compliant & establishes cross linkages with all other quality manuals & documents of the HCO.

**Level-II Quality Manuals:**
- These manuals are policy documents for different quality standards as they are applied to the HCO.
- There are policies for medication, diagnostics, CPR, care of patients, care of vulnerable patients, care of surgical patients, patients rights & responsibilities, consent, human resource, safety, sentinel event & near miss reporting, equipment management, provision of resources & logistics, patient & family education, grievance redressal of internal & external customers, information management, handling & archiving of medical records, continuous quality improvement, maintain regulatory compliances & valid licenses, reporting to outside agencies, infection control & handling of Biomedical waste, surveillance for infection control etc.
Types of Quality Manuals and Documents

Level-II Quality Manuals Contd...

- These manuals are prepared as per the NABH standards applicable to the HCO and cover all these areas.
- These manuals have cross linkages with level-I manual.

Level-III Quality Manuals:

- These are SOPs, work instructions, training manuals, flow charts, standard treatment guidelines as per the requirement of the HCO.
Types of Quality Manuals and Documents

Other Manuals/ Documents:

- Then there are forms both for Clinical use & administrative purposes, records of quality monitoring & CAPA, information & education material, pamphlets, displays etc.
Contents of Quality Manual

- Different types or levels of quality manuals have a common structure that has been described in previous discussions.
- Areas where they differ are presented now.
Level-I quality manual or Apex quality manual

- **Cover Page:** The presentation, designing & other components of this page are at the discretion of the HCO making this quality manual, but some mandatory & advisable matter on this page includes:
  - Name of the organization/ HCO
  - Address of the organization/ HCO
  - Phone numbers and other contact information of the organization/ HCO
  - The name of the QMS that has been applied in the HCO
  - Name of the document i.e. about the matter it contains e.g. for apex manual this can be “Apex Quality Manual”.
  - The year of issue of the manual.
  - The document number that has been allocated to this manual as per the numbering system evolved by the organization/ HCO. This is the unique id of the manual.
  - Copy number for distribution control.

Level-I quality manual or Apex quality manual

- The **color scheme** of the cover page can be put to use for differentiating different manuals in the HCO and also for ease of their distribution
- One may continue with the same cover page design for all quality manuals in the HCO but broadly different color schemes can be selected and applied for Level-I, Level-II and Level-III quality manuals
Level-I quality manual or Apex quality manual

- **Matrix** in tabulated form on the first page after the cover page. This is a very important page and gives a brief about administrative aspects of the manual. A sample of this matrix is given next..

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**Level-I quality manual or Apex quality manual**


<table>
<thead>
<tr>
<th>Version No.</th>
<th>Date Of Issue: 20th May, 2013</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name of Service</td>
<td>Patient Rights and Education</td>
</tr>
<tr>
<td>Name of Policy</td>
<td>Policy for Patient and Family Rights and Responsibilities</td>
</tr>
<tr>
<td>Policy No.</td>
<td>MAGHH/PRE/01/A</td>
</tr>
</tbody>
</table>
| Purpose | • To define and document patient and family rights and to put up a system in place to inform them about their responsibilities during care  
  • To ensure that the patient and family rights support individual beliefs, values and to involve the patient and family in decision making processes |
| Scope | All patients and their families that are provided care at MAGHH |
| Responsibility | All staff members of MAGHH: Medical staff, Nursing staff, Technical staff, Pharmacy staff, Physiotherapy and Rehabilitative services staff, Medical records, Registration/ admission/ discharge/ transfer staff, security personnel, management personnel etc. |
| Prepared by | Designation: Chairperson PRE Committee, MAGHH  
Signature: |
| Approved by | Designation: Managing Director, MAGHH  
Signature: |
| Issued by | Designation: Hospital Chief Quality Coordinator, MAGHH  
Signature: |
| Responsibility for updating | Designation: Chairperson PRE Committee, MAGHH  
Signature: |
Level-I quality manual or Apex quality manual

• Table of Contents (Index):

<table>
<thead>
<tr>
<th>Sr. No.</th>
<th>CONTENTS</th>
<th>Pages</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Introduction</td>
<td>4-9</td>
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<tr>
<td></td>
<td>Organogram</td>
<td>10-10</td>
</tr>
<tr>
<td></td>
<td>About NABH</td>
<td>11-11</td>
</tr>
<tr>
<td></td>
<td>MAGHH Quality Plan</td>
<td>12-15</td>
</tr>
<tr>
<td></td>
<td>Authority and Accountability</td>
<td>15-18</td>
</tr>
<tr>
<td></td>
<td>Organizational Structure of MAGHH Quality Team</td>
<td>19-21</td>
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<td></td>
<td>MAGHH Quality Management Council</td>
<td>22-22</td>
</tr>
<tr>
<td></td>
<td>Chapter 1. Access, Assessment and Continuity of Care</td>
<td>23-40</td>
</tr>
<tr>
<td></td>
<td>Chapter 2. Care of Patients</td>
<td>41-69</td>
</tr>
<tr>
<td></td>
<td>Chapter 3. Management of Medications</td>
<td>70-84</td>
</tr>
<tr>
<td></td>
<td>Chapter 4. Patient Rights and Education</td>
<td>85-94</td>
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<td></td>
<td>Chapter 5. Hospital Infection Control</td>
<td>95-108</td>
</tr>
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<td></td>
<td>Chapter 6. Continuous Quality Improvement</td>
<td>109-122</td>
</tr>
<tr>
<td></td>
<td>Chapter 7. Responsibility of Management</td>
<td>123-130</td>
</tr>
<tr>
<td></td>
<td>Chapter 8. Facility Management and Safety</td>
<td>131-145</td>
</tr>
<tr>
<td></td>
<td>Chapter 9. Human Resource Management</td>
<td>146-156</td>
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<tr>
<td></td>
<td>Chapter 10. Information Management System</td>
<td>157-166</td>
</tr>
<tr>
<td></td>
<td>Glossary</td>
<td>167-174</td>
</tr>
<tr>
<td></td>
<td>Reference guide on sentinel events</td>
<td>175-176</td>
</tr>
</tbody>
</table>

• This Quality Manual has been formulated as per the third edition of the NABH Accreditation Standards for Hospitals

Level-I quality manual or Apex quality manual

• Introduction: This shall contain following aspects about HCO:
  – General facts and history of the HCO
  – Mission statement of the HCO
  – Vision statement of the HCO
  – Quality policy statement of the HCO
  – Detailed quality policy
  – Quality objectives of the HCO
  – Quality plans of the HCO
  – Organization chart (Organogram) of the HCO with responsibility and accountability matrix
  – Authority and accountability of major functionaries of the HCO towards quality
  – A brief about the NABH, its organization, objectives and NABH standards
  – Scope of NABH QMS at the HCO
  – Continuous quality improvement program of the HCO
  – Goals of continuous quality improvement of the HCO
Level-I quality manual or Apex quality manual

- **HCO’s Quality Management Council**: A list of all persons included in the quality management council of the HCO and their roles is prepared and attached here.
- This is an important structure for development, implementation and monitoring of QMS.
- The rules for conduct, functions & meetings of this council are finalized and documented.
- A sample list of such committee is given next....
- The HCO might have lesser/ more staff & in that case the membership can be accordingly changed.

<table>
<thead>
<tr>
<th>S.N.</th>
<th>Designation</th>
<th>Names</th>
<th>Position</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Director MAGHH</td>
<td>Chairperson</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Medical Superintendent MAGHH</td>
<td>Invited Member</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Hospital Administrator</td>
<td>Member</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Hospital Chief Quality Executive MAGHH</td>
<td>Member</td>
<td>Secretary</td>
</tr>
<tr>
<td></td>
<td>Chairperson AAG Committee</td>
<td>Member</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Chairperson COP A Committee</td>
<td>Member</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Chairperson COP B Committee</td>
<td>Member</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Chairperson MOM Committee</td>
<td>Member</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Chairperson PRE Committee</td>
<td>Member</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Chairperson HIC Committee</td>
<td>Member</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Chairperson CQI Committee</td>
<td>Member</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Chairperson ROM Committee</td>
<td>Member</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Chairperson FMS Committee</td>
<td>Member</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Chairperson HRM Committee</td>
<td>Member</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Chairperson IMS Committee</td>
<td>Member</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Chairperson Medical Audit and Review Committee</td>
<td>Member</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Intensivist</td>
<td>Member</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Nursing Personnel</td>
<td>Member</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Nursing Personnel</td>
<td>Member</td>
<td></td>
</tr>
</tbody>
</table>

Membership of MAGHH Quality Management Council
Level-I quality manual or Apex quality manual

- From here after all Ten chapters of “NABH standards for Hospital” are documented
- Each chapter starts with a description of intent of that chapter & how HCO envisions fulfilling the same
- A list of the documents/ manuals that have been prepared to meet the requirements of the chapter is also produced here
- Indicators that HCO has planned to measure & monitor also need to be mentioned in this part
- Then standards & objective elements of the chapter along with document numbers of those manuals that fulfill & address those particular objective elements are documented in a tabular form
- In a soft version of the quality manuals & documents these can then be hyperlinked with the respective documents

Level-I quality manual or Apex quality manual

<table>
<thead>
<tr>
<th>Access, Assessment and Continuity of Care (AAC)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>AAC.13.</strong> The organization has a documented discharge process.</td>
</tr>
<tr>
<td>a. The patient’s discharge process is planned in consultation with the patient and/or family.</td>
</tr>
<tr>
<td>a. Documented procedures exist for coordination of various departments and agencies involved in the discharge process (including medico-legal cases)</td>
</tr>
<tr>
<td>a. Documented policies and procedures are in place for patients leaving against medical advice</td>
</tr>
<tr>
<td>a. A discharge summary is given to all the patients leaving the organization (including patients leaving against medical advice)</td>
</tr>
</tbody>
</table>
Level-I quality manual or Apex quality manual

- After all the ten chapters of the NABH standards have been elaborated, a *glossary guide for reference* to this quality manual is prepared and attached
- This facilitates clear understanding of the definitions and context of various terms and terminologies that have been used in the quality manual
- This needs to be preferably in *alphabetical order*

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Level-I quality manual or Apex quality manual

- A *Reference guide on sentinel events* may then be annexure in the apex quality manual as the organization’s commitment to safety of all users of the HCO
Level-II quality manual or policy & procedures documents

- Have something in common with the ‘Apex Quality Manual’ & many new aspects specific to that function or activities are also documented
Contents of Quality Manual Contd..

- Introduction
- Quality Policy
- Quality Objectives
- Scope of Services/Dept.
- Organizational Structure of the service/Dept.
- Duties & Responsibilities of key functionaries
- Physical Facility Provided
- Special equipments/ environment, if any
- Procedures/SOPs: Along with the responsibility of each step/process
- Departmental Standards
- Indicators monitored & with what periodicity
- Records generated, in what format & with what periodicity

Level-II quality manual or policy & procedures documents

- **Cover Page**: All the features and specifications for the cover page of the level-II manuals is same as for the Apex Quality Manual, save for the name of the document e.g. for the Patients Rights and Education Manual, the name can be “Policy for Patients and Families Rights, Responsibilities and Education”

- The document number shall be having the same uniform number of characters as were planned earlier e.g. “MAGHH/PRE/01/A”

- The presentation, designing & other components of this page are at the discretion of the HCO
Level-II quality manual or policy & procedures documents

- **Matrix** in tabulated form on the first page after the cover page
- This as in the apex quality manual is a very important page and gives a brief about administrative aspects of this manual
- A sample of this matrix for Level-II quality manual is given next

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<table>
<thead>
<tr>
<th>Name of Service</th>
<th>Hospital Infection Control</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name of Policy</td>
<td>Policy for Hospital Infection Control</td>
</tr>
<tr>
<td>Policy No.</td>
<td>MAGHH/HIC/01/A</td>
</tr>
<tr>
<td>Purpose</td>
<td>To ensure that the hospital has an infection control program with its administrative structure in the form of a multi-disciplinary infection control committee and designated infection control nurse(s). The infection control programme is supported by the management and includes training of staff.</td>
</tr>
<tr>
<td>Scope</td>
<td>All patient care areas at MAGHH with special stress on ICU, OTs, SNCU, Emergency, Procedure rooms, Endoscopy Room, Dialysis unit, Dressing rooms and all wards.</td>
</tr>
<tr>
<td>Responsibility</td>
<td>All members of medical, administrator, nursing, technical, paramedical, housekeeping and support services staff</td>
</tr>
<tr>
<td>Prepared by</td>
<td>Designation: Chairperson HIC Committee, MAGHH Signature:</td>
</tr>
<tr>
<td>Approved by</td>
<td>Designation: Medical Director, MAGHH Signature:</td>
</tr>
<tr>
<td>Issued by</td>
<td>Designation: Hospital Chief Quality Coordinator, MAGHH Signature:</td>
</tr>
<tr>
<td>Responsibility</td>
<td>Designation: Chairperson HIC Committee, MAGHH Signature:</td>
</tr>
<tr>
<td>for updating</td>
<td><a href="mailto:drashishgupta@blueoceanconsultants.in">drashishgupta@blueoceanconsultants.in</a> 09811114879</td>
</tr>
</tbody>
</table>

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8/31/2014
Level-II quality manual or policy & procedures documents

- **Table of Contents (Index):** This is important for rapid access to different parts of the quality manual by the readers

- The index is planned before the manual is written and is finalized after the contents of the manual have been documented

Level-II quality manual or policy & procedures documents

- **Responsibility for Implementation:** This is a very important page as here the individual responsibilities for different aspects of implementation of the policies and procedures as mentioned in that manual are clearly defined and delegated

- Without this there is always a lot of ambiguity regarding who will undertake what responsibilities for the manual

- Please note that this is not a SOP for any activity but a description about responsibilities of different persons for ensuring that the policy that follows is applied

- An example of this part is given next....
E.g.

– The patient and family rights to be displayed in the form of bilingual display boards in the OPD waiting area and any other suitable area in the HCO as required, but having good illumination. The display boards use font size and contrast so that all persons can read it with ease in even low light. The responsibility for such display and its upkeep is with the Nurse In-charge of OPD Services.

– The patient and family rights are published as patient information booklets and employee information booklets and distributed to them. All the employees of HCO are oriented to all aspects of patient and family rights and responsibilities. The responsibility for such activities is with the MS of the HCO.

Level-II quality manual or policy & procedures documents

• Parameters for Quality Assurance: The following text defines various indicators that would be used in monitoring different aspects of this policy. Indicators are variables related to structure, processes and outcomes of the care whose quantification provides a measure of quality, quantity or cost. To the extent possible, these indicators are based on scientific evidence or, when scientific evidence is unavailable, on expert consensus. Indicators may be administrative or clinical.
Level-II quality manual or policy & procedures documents

- The indicators monitored for performance of QMS are of either Clinical or administrative types:
  - **Administrative Indicators**: Variables related to resource utilization and costs of the services and personnel management.
  - **Clinical Indicators**: Variables related to Clinical care processes, Clinical outcomes, perceptions of care or patient functional status (e.g., adherence to guidelines and standards, intermediate and long-term results of care, patient satisfaction and functional status surveys sensitive to short-term changes).
- A sample indicator measurement for a *Policy for Imaging Services* is given next.

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<table>
<thead>
<tr>
<th>Sr. No.</th>
<th>Quality Objectives</th>
<th>Performance Indicators</th>
<th>Responsibility</th>
<th>Measurement Criteria</th>
<th>Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>Service Level</td>
<td>Staff availability</td>
<td>HOD, Imaging Dept.</td>
<td>Duty Roster / Attendance Record</td>
<td>Monthly</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Staff skills</td>
<td>HOD, Imaging Dept.</td>
<td>Staff job description and staff resumes</td>
<td>Half yearly</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Investigation time</td>
<td>HOD, Imaging Services</td>
<td>Imaging department patient registration record Imaging department procedures record</td>
<td>Monthly</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Coordination between all staff</td>
<td>Chairperson XYZ HCO Quality Committee</td>
<td>Patient feedback form</td>
<td>Monthly</td>
</tr>
<tr>
<td>2</td>
<td>Quality control</td>
<td>Internal Quality Control Processes</td>
<td>HOD, Imaging Services</td>
<td>Quality Control Records</td>
<td>Monthly</td>
</tr>
<tr>
<td></td>
<td></td>
<td>External Quality Control</td>
<td>HOD, Imaging Services</td>
<td>Quality Control Records</td>
<td>Half yearly</td>
</tr>
<tr>
<td>3</td>
<td>Customer Satisfaction</td>
<td>Courtesy level</td>
<td>Chairperson XYZ HCO Quality Committee</td>
<td>Patient feedback form</td>
<td>Monthly</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Wait time and Convenient reports collection</td>
<td>Chairperson XYZ HCO Quality Committee</td>
<td>Patient feedback form</td>
<td>Monthly</td>
</tr>
</tbody>
</table>
Level-II quality manual or policy & procedures documents

- **Amendment Sheets**
  - Blank sheets two in number with header and footer for future amendments.
  - It is required to reflect any amendments made in the copy and signatures of the person making those changes in a particular copy during the period before the next version is printed.
  - No cutting overwriting is allowed in the printed copies.

Level-II quality manual or policy & procedures documents

- Now the main text of the quality manual is documented as per the chapter/standards which the document represents. This shall contain the following aspects about the HCO:
  - Introduction of the chapter/service in general and as it is applied to the HCO.
  - Objectives of the service/unit with regards to quality.
  - Scope of services/details of services offered for this aspect of activity that is included in the manual.
  - Any compliance with regulatory requirements/legal requirements/statutory requirements/certification requirements, ethical requirements that are required by the service offered for this aspect of activity that is included in the manual or its infrastructural requirements.
Level-II quality manual or policy & procedures documents

- **Infrastructure** provided at the HCO for such services/activities. This includes:
  - Building structure, space etc
  - Equipment
  - Logistics
  - Consumables
  - Staff: Number and training
  - Support structure and logistics like special environment needs, stationary, technology, computers etc

- **Hierarchy** of staff including their reporting relationships

- **Job specifications** and **job descriptions** of all functionaries of the services that are included in the manual

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Level-II quality manual or policy & procedures documents

- **Detailed explanation on each** of the aspects of the service unit’s **policy**. This should also explain how the HCO is applying these standards to its processes and how the HCO ensures that these quality objectives are met by the HCO and its staff. This forms the major part of the quality manual

- **Continuous quality improvement** program of the HCO

- **Goals** of continuous quality improvement of the HCO

- List of all **procedures and processes** that are included in the mentioned services in the manual and the persons/staff responsible of each of such processes.
Level-III Quality manual or SOPs, work instructions and other documents

Level-III quality manuals and documents can be in the following formats:

- Complete SOPs Manuals
- *Loose individual sheets of paper* each containing pertinent information or work instructions and placed in a *file cover* for process owners to rapidly access desired information in brief
- Training manuals
- Display material for important and frequently used instructions and SOPs
- New forms and data collection sheets
Level-III Quality manual or SOPs, work instructions and other documents

The Level-III manuals have the following plan of presentation and contents:

- **Cover Page** with all information as for the apex quality manual, complete with the document number
- There is **no table matrix** that is required to be placed in this manual as these manuals are for free distribution to all process owners and are for training purpose.
- **Index/ table of contents** is required where the number of pages is more than five

Contd..

- In the **Header** we can have the name of the HCO or its Logo
- In the **footer** we need to have page numbering in the same style as before i.e. page 3 of 56
- The **main body** will have the SOPs, work instructions, Dos and Don’ts
- The **annexure** shall contain new forms, data collection material, display material used
OTHER ISSUES CONCERNING QUALITY MANUALS

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Number of Manuals to be Printed

- The HCO needs to decide number of quality manuals & documents that it needs to print for use in the HCO or for distribution to others concerned

  Broadly speaking one need to follow the following basic principles in deciding on this issue:

- **Level-I quality Manual or Apex quality manual** is required by the top management & HCO Quality manager only & accordingly **Four copies** can be made

- One each for the top management, HCO Quality manager, one for the NABH assessors who would come for assessment surveys and one reserve copy
Number of Manuals to be Printed

- **Level-II quality manuals** would be required by many people.
- Number shall depend upon size of HCO & number of staff & functional units.
- It would also depend upon whether HCO is a part of a larger healthcare/business network.
- Broadly speaking **for a small HCO** One copy each for each of the nursing station, administrative heads, respective committee chairperson, library, assessors and some reserve copies for replacement.
- **For larger HCOs** number of copies would accordingly increase as they are required by many process owners.
- **Library index boxes** that are color coded can be used for keeping the quality manuals at user end.

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Number of Manuals to be Printed

- **Level-III quality manuals** would also be required by many people and especially all process owners.
- **For a small HCO** one each for each nursing station, Administrators, departmental heads, respective committee chairpersons, library, reserve copies for replacement.
- **For larger HCOs** the number of copies would accordingly increase as they are required by many process owners.
- One can use **flip cover folders** for keeping loose SOPs and work instructions at user end.
Number of Manuals to be Printed

- Display material, work instructions, forms & data collection sheets would be prepared as per the need of the HCO
- The whole idea in deciding number of documents is that each & every person in the HCO or those related with the QMS must have free access to these quality manuals

Conclusion

- Documentation of QMS as it has been applied to the HCO is reflected in the QMs that are produced by the HCO
- Every effort needs to be put up by the HCO to have properly & accurately customized QMs as per its scope of services & requirements
- Should not be a work that has been copied from other organization’s work
- Manuals need to be specific, to the point & easy to comprehend
- Process owners should not be burdened with any sort of information overload
- A good quality manual is backbone of quality program & is very important document for quality management
Questions?

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