

**Meeting ISO 9001:2000 quality management system requirements for Healthcare.**



**This document describes many of the documents and processes currently in place that are applicable and/or easily transitioned to ISO 9001 under the NIAHO<sup>SM</sup> Accreditation Program.**

ISO 9001	Applicable documents, processes and related items currently in place or to be transitioned to ISO
4.2.2	<p><b><u>Quality Manual</u></b></p> <p>For healthcare organizations that are currently in the Medicare Program, the Quality Manual may be in the form of the Plan for the Provision of Care or similar document.</p>
4.2.3	<p><b><u>Control of Documents</u></b></p> <p>Control of internal documents would include:</p> <ul style="list-style-type: none"> <li>(a) policies and procedures</li> <li>(b) forms/requisitions</li> <li>(c) patient data</li> <li>(d) previous treatment plans/data</li> <li>(e) work instructions / protocols</li> <li>(f) quality plans / PI Plans</li> <li>(g) quality manual</li> <li>(h) software data</li> </ul> <p>Control of and distribution of external documents would include:</p> <ul style="list-style-type: none"> <li>(a) standard of practice</li> <li>(b) state regulations/Medicare requirements (COP's)</li> <li>(c) DNVHC NIAHO, CARF, CLIA, CAP accreditation standards</li> <li>(d) FDA requirements</li> <li>(e) NFPA (LSC) Requirements</li> <li>(f) OSHA requirements</li> <li>(g) DOH requirements /DEA Requirements, etc.</li> </ul> <p>Is there objective evidence of the control of the distribution of externally generated documents, e.g. ISO 9001:2000, Medicare requirements CMS), Operating Manuals, COP, NIAHO<sup>SM</sup> , CAP, COLA, CLIA etc.</p> <p><b><u>Software Policy</u></b> Information systems (IS) maintains an updated list of supported software w/version levels etc. (i.e., Meditech, [MDS <u>M</u>inimum <u>D</u>ata <u>S</u>et software], etc.)</p> <p><b><u>Hospital Information Systems</u></b> Verify the following areas:</p> <ul style="list-style-type: none"> <li>- Use of Meditech or other patient tracking systems (if applicable)</li> <li>- Password protection</li> <li>- Policies on HIS Department</li> <li>- Confidentiality Statement</li> <li>- Release of Medical Information</li> </ul>
5.2	<p><b><u>Customer Focus</u></b></p> <p>Top Management ensures patient requirements, needs and expectations are determined and achieved to provide patient satisfaction.</p>

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<p><b>5.3</b></p>	<p><b><u>Quality Policy</u></b></p> <p>Healthcare organizations conduct detailed Strategic Planning activities where by the mission, vision and strategy are defined. Normally healthcare organizations use preexisting mission, vision or goal statements as their quality policy. Personnel should be able to articulate the mission statement etc.</p> <p><b>ADDITIONAL NOTE:</b> Definition “Quality Policy”: this term may not be the term staff are used to in the hospital the management can clarify the term used for “Quality Policy” which may be synonymous with the mission.</p> <p>The “Quality Policy” is communicated to all employees in the context of the Mission, Vision, and Values of the organization for example:</p> <ul style="list-style-type: none"> <li>- New Staff Orientation</li> <li>- Departmental Meetings</li> <li>- Imprinting on Employee Badges</li> <li>- Posting throughout facility</li> <li>- Reinforcement via Internal Quality Audits etc.</li> </ul> <p>The organization measures objectives of the “Quality Policy through:</p> <ul style="list-style-type: none"> <li>- Leadership</li> <li>- Measurement of quality health services</li> <li>- Caring for Sick and Injured</li> <li>- Improving Health and Well Being of People</li> <li>- Compassionate Care</li> <li>- Customer Service</li> <li>- Fiscal Responsibility</li> </ul>
<p><b>5.4.1</b></p>	<p><b><u>Quality Objectives</u></b></p> <p>Quality objectives within the organizations should be present at the department/unit level. This may be in the form of PI Plans etc.</p> <p>How are these quality objectives measured? Are they consistent with the quality policy? Are they timely? Are they specific? Are they reasonable? Are they measurable?</p>
<p><b>5.4.2</b></p>	<p><b><u>Quality Management System Planning</u></b></p> <p>How has management defined how the organization plans to:</p> <p>(a) satisfy the needs of its customers (internal and external)</p> <p>(b) meet the requirements of the quality policy, objectives, and system?</p> <p>NOTE: Quality planning involves such things as:</p> <ul style="list-style-type: none"> <li>- Admitting Physician’s Order</li> <li>- Standards of Care documents</li> <li>- Protocols</li> <li>- Nursing Plans of Care</li> <li>- MDS (Minimum Data Sets)</li> <li>- Anesthesia Planning</li> </ul> <p>How does the organization plan for quality?</p> <ul style="list-style-type: none"> <li>- Generating new Standards of Care;</li> <li>- Generating New Protocols and Procedures and revising existing ones;</li> </ul>

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5.5.4	<p><b><u>Internal Communication</u></b></p> <p>Effective communications regarding the quality system can be demonstrated through:</p> <ul style="list-style-type: none"> <li>• regular meetings with management and staff</li> <li>• employees' involvement in corrective action-related activities</li> <li>• periodic employee meetings with administration held for the express purpose of feedback to management level on quality system issues</li> <li>• regular meetings of the Medical Staff including Performance Improvement Committee/Quality Council and Medical Executive Committee</li> <li>• regular meetings of various committees/teams with reports to the Performance Improvement Committee/Quality Council and Board of Directors</li> </ul>
5.6.1	<p><b><u>General - Management Review</u></b></p> <p>Healthcare organizations historically conduct "management reviews" and may call the activity by another name. The hospital may use different nomenclature for "management review":</p> <p>The Performance Improvement Committee/Quality Council currently...</p> <ul style="list-style-type: none"> <li>• key process measures;</li> <li>• results of internal reviews (audits);</li> <li>• status and results of corrective and preventive actions (PI activities);</li> <li>• patient/resident/customer feedback;</li> <li>• follow-up actions from previous management reviews;</li> <li>• competency based evaluations;</li> </ul> <p>Where as some of these activities are done through different committees or departments, these should be include as a part of the role of the Performance Improvement Committee/Quality Council.</p>
6.1	<p><b><u>Provision of resources</u></b></p> <p>The hospital currently adequate resources for the QMS, i.e.:</p> <p>(a) adequate trained personnel assigned for managing the organization, performing the work, &amp; verification activities</p> <p>(b) resources are in place for conducting:</p> <ol style="list-style-type: none"> <li>(1) medical record review</li> <li>(2) review of performance data</li> <li>(3) staff performance appraisals</li> <li>(4) customer satisfaction surveys</li> <li>(5) internal quality review (audits)</li> <li>(6) test and monitoring of treatments</li> </ol> <p>There are defined responsibilities and authorities of all personnel who can affect quality, e.g.:</p> <ol style="list-style-type: none"> <li>(a) Organizational charts</li> <li>(b) Job descriptions</li> <li>(c) Procedures/Operation instructions</li> <li>(d) Change of shift reports</li> </ol> <p>The hospital should be able to demonstrate their commitment, obligation and interface with other providers, major purchasers, insurers, health plans, and /or government authorities?</p>
6.2.2	<p><b><u>Competence, Awareness and Training</u></b></p> <p>Current processes are in place for assessing staff competency, allocating resources for education, and identification of competency, educational needs &amp; ensuring that the needs are met. For the Medical Staff this would include the review of credentials and clinical privileges.</p>



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7.1 cont'd	<ul style="list-style-type: none"> <li>- Pre-admission Testing</li> <li>- Procedures requested Pre-admission Testing</li> <li>- Consent for Anesthesia</li> <li>- Consent to Procedures</li> <li>- Pre/Post operative documentation</li> </ul> <p><b>Admission of a Patient</b></p> <ul style="list-style-type: none"> <li>- Admission Packet</li> <li>- Identification band (and allergy, falls, etc. band if indicated)</li> <li>- V.S. monitoring equipment</li> <li>- Advanced Directives</li> <li>- Patient Handbook (Patient Rights)</li> <li>- Medical Services consent</li> <li>- Computer (if at bedside or used throughout the patient care unit)</li> </ul> <p><b>Inpatient</b></p> <p>The typical flow for a patient who is admitted to a unit through to discharge:</p> <ul style="list-style-type: none"> <li>- Admissions Process</li> <li>- Triage</li> <li>- Medical Records Review</li> <li>- Assignment of Bed/RN</li> <li>- Treatment Rendered</li> <li>- Status of Care/Wellness of Pt</li> <li>- Universal precautions/BBP</li> <li>- Maintenance of confidentiality (HIPAA)</li> <li>- Control of Valuables/Clothes/Personals</li> <li>- Coordination of support services</li> <li>- Medication Management</li> <li>- Dietary Services – RN/MD interrelationships to ensure patient requirements are met</li> <li>- Handling of infectious/hazardous waste</li> <li>- Maintenance – Life Safety Management program to maintain equipment/records</li> <li>- Inpatient Discharge Process</li> </ul> <p>Typical documentation flow for a patient:</p> <ul style="list-style-type: none"> <li>- Admission</li> <li>- Assessment</li> <li>- Plan of Care (Standard of Care/Practice)</li> <li>- Documentation (Every shift)</li> <li>- Reassessment</li> <li>- Clinical Collaboration/Treatment Intervention</li> <li>- Patient Education/Patient Outcomes</li> <li>- Change in Condition/Assessment: D/C Planning Needs</li> <li>- Discharge Instructions</li> <li>- Discharge Summary</li> </ul> <p><b>Discharging a Patient Protocol</b></p> <p>The following activities occur for d/c patient:</p> <ul style="list-style-type: none"> <li>- Obtain order from physician for D/C</li> <li>- Assist patient in notifying family for transportation</li> <li>- D/C instruction sheet; including meds, Rx, dates of appts with MDs, dates for tests, diet instructions</li> <li>- Home medical equipment/supplies needed</li> <li>- Obtain patient signature as understanding d/c instruct.</li> <li>- Original D/C instruction sheet and copies of meds and diet sheets to patient.</li> <li>- Assist patient in gathering belongings – collect meds or valuables stored in pharmacy/safe</li> <li>- Call admitting dept to communicate patient has been d/c and time of d/c</li> </ul> <p>The following D/C documentation is maintained:</p> <ul style="list-style-type: none"> <li>- Discharge Note in-patient record or on-line in i.e. Meditech, etc.</li> <li>- Complete screens for discharge note, plans for unsolved problems, referral, patient education summary, other education given to patient</li> </ul>

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7.1 cont'd	<p><b>Transfer of a Patient</b></p> <p>There are processes in place for transfer of patients internally:</p> <ul style="list-style-type: none"> <li>- Obtain room assignment (nurse on unit or unit charge)</li> <li>- Inform admitting dept of new room assignment</li> <li>- Call receiving unit to verify bed is ready</li> <li>- Explain to patient reason and process</li> <li>- Collect items including:                             <ul style="list-style-type: none"> <li>Belongings bagged</li> <li>Patient's chart and records</li> <li>Patient's meds/Imprint plate</li> <li>Bed tag/Special equipment in use by patient</li> </ul> </li> </ul> <p><b>Pharmacy</b></p> <p>Pharmacy handles the following activities:</p> <ul style="list-style-type: none"> <li>- Home medications (7.5.4)</li> <li>- Procurement of Pharmaceuticals (7.4.1, 7.4.2, 7.4.3)</li> <li>- Prime Vendor Program (7.4.1)</li> <li>- Drug Distribution (7.5.4)</li> <li>- Unit Dose Cart (7.5.2)</li> <li>- Medication Labeling (7.5.2, 7.5.3)</li> <li>- Floor Stock (6.1, 6.3)</li> <li>- Automated Dispensing Machines (6.1, 6.3)</li> <li>- Unit Dose Packaging (7.5.4)</li> <li>- Expiration of Drugs (7.5.2, 7.5.4)</li> <li>- Dating Sterile Containers (7.5.2, 7.5.4)</li> </ul> <p><b>Operating Room/Recovery Room</b></p> <p>The following activities for OR/RR processes:</p> <ul style="list-style-type: none"> <li>- Schedule Coordination (7.1)</li> <li>- Preparation of Suites (instruments, etc) (6.3, 7.1)</li> <li>- Patient Prep Process (7.1)</li> <li>- Tracking of 'instrument counts' pre/post surgery (6.3, 7.1)</li> <li>- Types of Surgical procedures performed (7.1)</li> <li>- Surgical Equipment/Instruments (6.1)</li> <li>- Calibration labels/records of OR equip (6.3, 7.6)</li> <li>- Recovery Room activities/processes (7.1, 8.2.3, 8.2.4)</li> <li>- Decontamination of room, equipment, instruments; handling of waste (6.4, 7.1)</li> <li>- Medical Records maintained (5.5.7)</li> </ul> <p><b>Central Sterile</b></p> <ul style="list-style-type: none"> <li>- Biological Monitoring (7.5.5, 8.2.3, 8.2.4)</li> <li>- Shelf-Life Expiration (7.5.4)</li> <li>- Storage of Sterile Supplies (7.5.4)</li> <li>- Outdated Supplies (7.5.4)</li> <li>- Recall Central Svc Processed Supplies (8.3)</li> <li>- Packaging Guidelines (7.5.4)</li> </ul> <p><b>Medical Imaging</b></p> <ul style="list-style-type: none"> <li>- Check revision of Guide for Positioning</li> <li>- Film processing process</li> <li>- Mammography Film density</li> <li>- Medical Equipment Management Program</li> <li>- Failure Analysis Equipment</li> <li>- Control of I, M, &amp; T Equipment</li> <li>- Record Control</li> <li>- Types of procedures offered</li> <li>- Referral process if not capable of performing procedure</li> </ul>

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7.1 cont'd	<ul style="list-style-type: none"> <li>- Contrast/GAD – allergic reactions</li> <li>- Scheduling process</li> <li>- STAT orders</li> <li>- Results reporting</li> <li>- Storage of films/Pulling jackets to compare old films</li> </ul> <p><b>Laboratory</b></p> <ul style="list-style-type: none"> <li>- Protocol for Specimen Labeling</li> <li>- Processing of Samples</li> <li>- Reporting Results (in-range/out-of-range)</li> <li>- STAT prioritization</li> <li>- Infected Blood Products (Look-Back/Notification Process)</li> </ul> <p>Current methods should be in place for the following:</p> <ul style="list-style-type: none"> <li>- Refrigerators, Donor Blood Storage</li> <li>- Freezers, Plasma Component Storage</li> <li>- Blood Products, Storage &amp; Shipment</li> <li>- Blood &amp; Blood Product Inventory</li> <li>- Autologous &amp; Direct Donors</li> <li>- Emergency Issue of Blood</li> </ul> <p><b>Emergency Department</b></p> <p>Patient flow from entry through to admission/discharge of a patient. The following activities that occur:</p> <ul style="list-style-type: none"> <li>- EMTALA Guidelines</li> <li>- Patient Registration</li> <li>- Medical History review</li> <li>- Triage Process</li> <li>- Medical Record Created/Pulled</li> <li>- Assignment of Room/Cubicle</li> <li>- Unit Structure Outline</li> <li>- Assignment of Caregiver(s)</li> <li>- Initial Assessment/Tests Done</li> <li>- Lab/Medical Imaging results reviewed</li> <li>- Diagnosis made</li> <li>- Patient Consent</li> <li>- Treatment/Stabilize Patient</li> <li>- Admission vs. Non-admission</li> <li>- Coordination of Admission if applicable</li> <li>- Treatment</li> <li>- Discharge Procedure</li> </ul> <p><b>OB/Labor/Delivery/Recovery/Nursery</b></p> <ul style="list-style-type: none"> <li>- Infant Identification</li> <li>- Calibration of Scales</li> <li>- Return of Body Parts for religious reasons (placenta)</li> <li>- Patient education</li> <li>- Patient support groups</li> <li>- Departmental Activities/Procedures</li> <li>- Quality Records</li> </ul> <p><b>Patient Care Plans(Long Term Care-Nursing)</b></p> <ul style="list-style-type: none"> <li>- Assigning the Nursing Care of Patients</li> <li>- Nursing Process</li> <li>- Patient Care Plans</li> <li>- Assessment of Patients</li> <li>- Meds Administration</li> <li>- Medication Error Reporting</li> <li>- Discharge Patients from Hospital</li> </ul> <p>Standard nursing documentation includes:</p>

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7.1 cont'd	<ul style="list-style-type: none"> <li>- Coordination with plan of care</li> <li>- Nursing needs assessed by RN on admission</li> <li>- Assessment available to all nursing involved</li> <li>- RN plans patient's care</li> <li>- Entries on Care Plan date and signed</li> <li>- Nursing Goals mutually set with patient/family</li> <li>- Care plans include physiological, psychological, and environmental factors</li> <li>- Patient education and family knowledge documented</li> <li>- D/C instructions noted in medical record</li> </ul> <p><b>Intensive Care Unit</b></p> <ul style="list-style-type: none"> <li>- Admission</li> <li>- Assessment</li> <li>- Plan of Care (Standard of Care/Practice)</li> <li>- Nursing Coordination/Shift Change</li> <li>- Documentation (Every shift)</li> <li>- Reassessment</li> <li>- Clinical Collaboration/Treatment Intervention</li> <li>- Patient Education/Patient Outcomes</li> <li>- Change in Condition/Assessment: D/C Planning Needs</li> <li>- Transfer to med/surg floor</li> <li>- Discharge Instructions</li> <li>- Discharge Summary</li> </ul> <p><b>Center &amp; Social Care Services</b></p> <p>Verify control of activities/processes in the following areas:</p> <ul style="list-style-type: none"> <li>- Home Health, rehab, transfer coordination at D/C</li> </ul>
7.2.1	<p><b><u>Determination of Requirements Related to the Product/Service</u></b></p> <p>Patient needs and/or requirements identified through :</p> <ul style="list-style-type: none"> <li>• patient/ physician/employee/community surveys</li> <li>• clinical outcomes</li> <li>• trends from Occurrence Reports</li> <li>• patient//family interviews upon admission</li> <li>• Patient satisfaction surveys</li> </ul> <p>Patient inputs used to determine key service requirements:</p> <p>Key Requirements consider:</p> <ul style="list-style-type: none"> <li>• Completeness of patient requirements, specifications and expectations</li> <li>• Requirements not specified by patient to achievement of desired outcomes</li> <li>• Regulatory and legal requirements and obligations</li> <li>• Patient requirements related to availability, delivery, and support of the service provided</li> </ul>
7.2.2	<p><b><u>Review of Requirements Related to the Product (Service)</u></b></p> <p>Customer/purchaser/patient and the health care provider know what is being offered &amp; what is being provided?</p> <p>Policies and procedures established &amp; maintained to ensure a thorough understanding of the patient's needs throughout all phases of service delivery</p> <p>Verbal/Telephone orders are order requirements are verified for accuracy</p> <p><b>NOTE:</b> Verbal/Telephone orders are normally documented in patient's chart. Patient services, orders and consents to ensure the provider has reviewed the documents according to documented procedures</p> <p>Processes should be in place by which orders/consents/plans are amended and later communicated defined and</p>

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<p>7.2.2 cont'd</p> <p>7.2.2 cont'd</p>	<p>documented?</p> <p>Patients are informed of treatments, changes of condition and supporting documentation is in place</p> <p>Patient records should confirm how changes to the Plan of Care are correctly carried out</p> <p><b>Advance Directive / Patient Information</b> Processes are in place to verify the existence of an Advance Directive and durable power of attorney upon admission: <b>NOTE:</b></p> <ul style="list-style-type: none"> <li>- If such exists, it should become part of patient's medical record and form should be completed and signed by patient or the patients representative</li> <li>- If not admitted through normal process, form is completed on the inpatient floor</li> <li>- If patient is unable or unwilling to sign, this is documented in medical record</li> <li>- If patient does not have an existing advance directive, written info shall be provided if requested re: patient' rights under applicable State law</li> <li>- Nondiscrimination with execution of advance directive</li> </ul> <p><b>Care of the Dying Patient (Review of Customer Requirements)</b> Verify patients rights to:</p> <ul style="list-style-type: none"> <li>- Make decisions re: his/her care</li> <li>- Designate a representative/medical durable power of attorney policy</li> <li>- Reasonable response to his/her requests and needs</li> <li>- Consideration to psychosocial, spiritual, cultural variables that influence care/death</li> <li>- Optimized comfort through primary/second symptom treatment</li> <li>- Access to Ethics committee re: treatment issues</li> <li>- All rights defined in patient rights policy</li> <li>- DNR orders</li> </ul> <p><b>Physician Medical Staff Contracting/Credentials &amp; Privileges</b></p> <p><b>7.2.2 Credentials &amp; Privileges (C&amp;P) Process (Delineation of Privileges)</b></p> <ul style="list-style-type: none"> <li>- Services that may be needed such as: medical director for a specific clinical service, physician services for a clinical specialty, or physician services required by law;</li> <li>- When potential staff is selected, verification of Credentials, medical staff review if applicable, letters of recommendation etc.</li> <li>- Objectives defined by department director or admin.</li> <li>- Objectives discussed with respective administrator</li> <li>- If objectives valid, review of reimbursement market and development of contract</li> <li>- Administrative approval of contract</li> <li>- Verify items listed in procedure that will appear in physician contracts</li> <li>- Evaluation/reporting of physician's ability to meet defined duties</li> <li>- Job description required for practitioners contracted for specific services such as medical director</li> <li>- Contract, job description, remuneration, and measurement must be approved by Admin Staff</li> <li>- Request, job description, and duties sent to each active member of the Medical Staff</li> <li>- VP/Pres/Board interview candidates and select</li> <li>- If approved, a letter is sent to MD along with contract and job description</li> <li>- Contract signed by both parties, letter sent to medical staff informing them of contracted MD</li> <li>- Original contract/job description/measures kept in Admin.</li> </ul> <p>This review should include, but not limited to:</p> <ul style="list-style-type: none"> <li>• Consents for treatment</li> <li>• Physician orders</li> <li>• Resident Contracts</li> <li>• Allied Health Professional Agreements</li> <li>• Contracts for services</li> </ul>

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7.2.3	<p><b><u>Customer Communication</u></b></p> <p>Methods of customer communication address the following aspects:</p> <ul style="list-style-type: none"> <li>• Information about healthcare services provided and impact of such services;</li> <li>• Information related to modification of any service to be provided;</li> <li>• Information related to patient complaints, grievances and actions in response to nonconforming service;</li> <li>• Patient/customer feedback about acceptability of service.</li> </ul> <p>Methods for communicating with patients/customers should include, but are not limited to:</p> <ul style="list-style-type: none"> <li>• patient/ /physician/employee/community surveys?</li> <li>• Patient individual interviews upon admission</li> <li>• Patient satisfaction surveys</li> </ul>
7.3	<p><b><u>Design and Development</u></b></p> <p><b>In most healthcare organizations, design and development under clause 7.3 is excluded as this applies to other requirements under the QMS.</b></p> <p><b>Teaching organizations and others that perform clinical trials or design and develop medical procedures, etc. should consider including 7.3 as a part of the scope of the ISO quality management system.</b></p>
7.4.1	<p><b><u>Purchasing Process</u></b></p> <p>There should be a system in place for communicating supplier performance to Materials Management (Purchasing) if problems arise after purchased product reaches points of use</p> <p>If problems arise with a supplier, what is the process to request a new supplier within the (VHA contract or other mass supply contractors) that provides approved medical supplies. <b>NOTE:</b> Evaluate the communication link to ensure any problems with an approved vendor are addressed.</p> <p>Suppliers should be selected on the basis of their ability to meet expectations for:</p> <ul style="list-style-type: none"> <li>- Quality</li> <li>- Delivery</li> <li>- Technical requirements and/or specifications</li> <li>- Cost competitiveness</li> </ul>

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7.4.2	<p><b><u>Purchasing Information</u></b></p> <p><u>Standing Purchase Orders</u></p> <p>PO requisitions, PO #s, and completed PO are maintained by Materials Management</p> <ul style="list-style-type: none"> <li>- Standing order generated departmentally</li> <li>- Dir of Materials Mgmt or Materials Mgmt Specialist negotiates with vendor and dept head</li> <li>- Order entered in computer system as items are shipped by vendor</li> <li>- Receiving clerk receives items on computer system and delivers to user dept</li> </ul> <p><b>**Note:</b> Procedure reference types of receiving inspection activities that occur or the verification that received items match PO. Verification processes should be in place for requisitions purchase requests</p> <p>There should also be a requisition process for pharmaceuticals:</p> <ul style="list-style-type: none"> <li>- Prescription vs. Intravenous Medication</li> <li>- Pharmacy processes for procurement and oversight</li> <li>- Materials received &amp; visually inspected for usability</li> <li>- Materials stocked in secure area</li> </ul> <p>There should be a process in place when material is not satisfactory, how the vendor contacted, item returned, record defective item and vendor</p> <p>For purchasing good/services, the hospital should provide subcontractors/suppliers with precise details of the order to ensure item/services are purchased correctly in the first place</p>

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7.5.1	<p><b>Control of Production and Service Provision</b></p> <p>Each patient care process is subject to the following:</p> <ul style="list-style-type: none"> <li>- Policies/Procedures/Clinical Guidelines/Competencies</li> <li>- Correct tools/equipment in suitable environment</li> <li>- Compliance with stated care plans and industry standards (OSHA, HEDIS, NCQA, DNVHC NIAHO<sup>SM</sup> )</li> <li>- Patient care is monitored real time (patient assmts)</li> <li>- Preventive maintenance (safety logs, infection control)</li> </ul> <p>Department/Unit specific policies and procedures may be in place for standard items such as:</p> <ul style="list-style-type: none"> <li>- Standards of Care Manuals</li> <li>- Unit Education Notebooks</li> <li>- Nursing Policy Manuals</li> <li>- Procedure Manuals</li> <li>- Fire and Disaster Manuals</li> <li>- Infection Control Manuals</li> <li>- Emergency Medications</li> <li>- Oxygen Supply for emergency</li> <li>- Suction supply for emergency</li> <li>- Code carts</li> </ul> <p><b>NOTE:</b> The BioMed department may hold the inventory list of equipment and this is comprehensive, current, accurate and followed.</p> <ul style="list-style-type: none"> <li>- preventive maintenance of equipment schedules</li> <li>- training programs for equipment users and maintenance personnel</li> <li>- ongoing program in place to ensure that the building and grounds are suitable to the nature of services provided (e.g. clean grounds, well-lit, auditory and visual privacy during tx, etc.)</li> <li>- frequency, maintenance, inspection and testing of fire alarms</li> <li>- frequency of maintenance, inspection, and testing of portable fire extinguishers</li> <li>- Systems in place at the hospital for activation of fire alarms or fire detection systems that dampers or designated fans are closed or opened to control smoke</li> </ul>
7.5.1 cont'd	<p>The organization should have procedures in place that establish checking mechanisms to ensure standards and procedures are met from initial MD order through to delivery and completion of all services</p> <p>Receiving inspections such as:</p> <ul style="list-style-type: none"> <li>- Purchased products inspected upon receipt or at points of use</li> <li>- Cert. of Analysis may be required for "certain items"</li> <li>- Patient assessment for general admission vs. Emergency Room.</li> <li>- Documented physician orders to establish care needs before services commences</li> <li>- Medicines checked against prescriptions when delivered to an inpatient floor/clinical area</li> </ul> <p>Checks are carried out to facilitate monitoring of performance against established criteria in order to verify critical tasks are performed and oversight of care, safety, effectiveness, efficiency are in place. Consideration should also be taken for inspection and testing methods that ensure criteria related to customer requirements, regulatory requirements, or specific insurer requirements are incorporated.</p> <p>Checking mechanisms facilitate monitoring of performance against established criteria:</p> <ul style="list-style-type: none"> <li>- Critical quality tasks are performed</li> <li>- Oversight of care</li> <li>- Oversight of safety</li> <li>- Oversight of effectiveness</li> <li>- Oversight of efficiency in place</li> <li>- Oversight of regulatory compliance (DNVHC/NIAHO<sup>SM</sup> , CMS)</li> </ul>

**Meeting ISO 9001:2000 quality management system requirements for Healthcare.**

ISO 9001	Applicable documents, processes and related items currently in place or to be transitioned to ISO
	<p>All incoming products and services are verified prior to use.</p> <p>There should be a process in place for checking expiration dates of supplies in stock rooms</p> <p>For active patients, there should be in-process checks (patient assessment sheets) such as:</p> <ul style="list-style-type: none"> <li>- Progress notes indicate monitoring of daily/weekly patient needs</li> <li>- Test results reviewed to aid in diagnosis/pt. Progress</li> </ul> <p>Final checks at the end of course of treatment should be in place to ensure all reviews, assessments, tests have been carried out and results demonstrate conformance to planned arrangements (sample medical records of discharged patients here).</p> <p>Documentary evidence of checks and reviews completed (e.g. treatment histories, diagnostic information, compiled data such as outcome reports/analyses)</p> <p>When processes fail, there should be procedures in place for control of nonconforming service</p> <p>Necessary signatures, stamps, and initials should be present on the medical records to identify assessment authority</p> <p><b>NOTE:</b> In most cases, health providers satisfy this clause through adequate documentation of customer care, routine vital signs, results of tests, adequate labeling, pathology records, pharmacy records, dating of drugs/expiration, etc.</p> <p><b>NOTE:</b> Other examples that should be checked are:</p> <ul style="list-style-type: none"> <li>- <i>Food:</i> Labeled with dates in freezer using a rotation system (first in/first out)</li> <li>- <i>Medications:</i> procedure to check for and remove expired medicines and segregate new meds until inspected</li> <li>- <i>Supplies:</i> note expiration dates and remove from stock when expired</li> <li>- <i>Equipment:</i> Calibration labels indicate status</li> <li>- <i>Linen:</i> sorted into different colored bags (marked zones for dirty, infectious, or clean linen)</li> <li>- <i>Infection Control:</i> Labeling and segregation of infectious areas.</li> </ul>

**Meeting ISO 9001:2000 quality management system requirements for Healthcare.**

ISO 9001	Applicable documents, processes and related items currently in place or to be transitioned to ISO
7.5.2	<p><b><u>Validation of Processes for Production and Service Provision</u></b></p> <p><b><u>(This is also Covered under 7.2.2 but also applies in 7.5.2)</u></b></p> <p><b>Physician Medical Staff Contracting/Credentials &amp; Privileges</b></p> <p><b>Credentials &amp; Privileges (C&amp;P) Process</b></p> <ul style="list-style-type: none"> <li>- Services that may be needed such as: medical director for a specific clinical service, physician services for a clinical specialty, or physician services required by law;</li> <li>- When potential staff is selected, verification of Credentials, medical staff review if applicable, letters of recommendation etc.</li> <li>- Objectives defined by department director or admin.</li> <li>- Objectives discussed with respective administrator</li> <li>- If objectives valid, review of reimbursement market and development of contract</li> <li>- Administrative approval of contract</li> <li>- Verify items listed in procedure that will appear in physician contracts</li> <li>- Evaluation/reporting of physician's ability to meet defined duties</li> <li>- Job description required for MDs contracted for specific services such as medical director</li> <li>- Contract, job description, remuneration, and measurement must be approved by Admin Staff</li> <li>- Request, job description, and duties sent to each active member of the Medical Staff</li> <li>- VP/Pres/Board interview candidates and select</li> <li>- If MD approved, a letter is sent to MD along with contract and job description</li> <li>- Contract signed by both parties, letter sent to medical staff informing them of contracted MD</li> <li>- Original contract/job description/measures kept in Admin.</li> </ul>

**Meeting ISO 9001:2000 quality management system requirements for Healthcare.**

ISO 9001	Applicable documents, processes and related items currently in place or to be transitioned to ISO
7.5.3	<p><b>Identification and traceability</b></p> <p><b>NOTE:</b> Hospitals are required to identify their patients, subcontractors, facilities, and products provided, so as to be able to trace them through the organization. Ex: clothing (name tags), files, patient notes, medicines, staff, etc.</p> <p>All care/treatment should be traceable to the patient and caregiver.</p> <p>Identification should be adequate during all stages of care and treatment including examples such as:</p> <ul style="list-style-type: none"> <li>- Medication administration/dosage and times/administered by</li> <li>- Patient charts</li> <li>- Therapy traceable to corresponding patient/clinician</li> <li>- Specimen labels should identify the patient</li> <li>- X-ray exposure</li> <li>- Treatment regimens</li> <li>- Investigations</li> <li>- Education</li> </ul> <p>A process should be in place regarding each patient and any belongings, samples, and specimens bear name or identification #.</p> <p><b>NOTE:</b> Federal, state, or local laws requiring identification/traceability of medical devices, pharmaceuticals, etc. may also be required.</p> <p>Identification should be recorded and records maintained</p> <p><b>NOTE:</b> Inpatients are identified and tracked throughout the health care service delivery processes by:</p> <ul style="list-style-type: none"> <li>• the use of first, middle, and last names for patients</li> <li>• identification banding of patients</li> <li>• the assignment of a medical record number that identifies each patient;</li> <li>• the use of social security number or equivalent identification?</li> </ul> <p><b>NOTE:</b> Outpatients are identified and tracked throughout health care service delivery processes by:</p> <ul style="list-style-type: none"> <li>• the use of first, middle, and last names for patients</li> <li>• the assignment of a medical record number that identifies each patient</li> <li>• the use of social security number or equivalent identification</li> </ul> <p><b>NOTE:</b> Customers at the fitness / PT center are identified by:</p> <ul style="list-style-type: none"> <li>• First and last names?</li> </ul>

ISO 9001	Applicable documents, processes and related items currently in place or to be transitioned to ISO
7.5.4	<p><b>Customer Property</b></p> <p><b>NOTE:</b> Patient data/medical history records (e.g. imaging studies, treatment histories) provided by a patient or other customer (e.g. physician) are controlled and personal information is kept confidential.</p> <p><b>NOTE:</b> Control mechanisms should be in place for the following types of customer-supplied products:</p> <ul style="list-style-type: none"> <li>- Patient owned medications</li> <li>- Banked blood</li> <li>- Donated organs</li> <li>- Babies</li> <li>- Cadavers</li> <li>- Body parts returned to patients for religious reasons</li> <li>- Personal effects</li> <li>- Physician owned instruments/equipment</li> </ul> <p><u>Control of Patient Valuables</u></p> <p><b>NOTE:</b> Personal items for patients are identified and maintained during patient stay including::</p> <ul style="list-style-type: none"> <li>- Prosthetic appliances at bedside/in closets</li> <li>- Denture cups labeled with patient names</li> <li>- Items transferred with patient from one unit to another</li> </ul>
7.5.5 cont'd	<p><b>Preservation of Product</b></p> <p>Procedures should be available that describe the control of product handling, storage, packaging, e.g.:</p> <ul style="list-style-type: none"> <li>- Medicines</li> <li>- Medical supplies</li> <li>- Food</li> <li>- Linen</li> <li>- Clothing</li> <li>- Cleaning materials</li> <li>- Medical waste</li> <li>- "Sharps"</li> <li>- X-ray film</li> </ul> <p>The hospital should have methods and means of handling that prevent damage been provided, for example:</p> <ul style="list-style-type: none"> <li>- Specimens</li> <li>- Transfer of patients</li> <li>- Packaging of sterile supplies</li> <li>- Special lifting techniques</li> </ul> <p>There should be methods in place for preventing damage caused by:</p> <ul style="list-style-type: none"> <li>- Poor technique</li> <li>- Inappropriate method</li> <li>- Wrong container</li> <li>- Inadequate training</li> <li>- Contamination</li> </ul> <p>The hospital should have a process in place for handling equipment periodically checked and serviced</p> <p>There should be a designated storage area of stock rooms, to prevent damage or deterioration of product, pending use or delivery</p> <p>Note: shelf life limitations may apply, and there should be a system in place to ensure that controls are effective</p> <p>Storage control of hazardous materials/products meet statutory requirements should be in place</p> <p>The hospital should have controls in place for packaging items such as specimens, x-rays, sterile supplies, medications.</p>

**Meeting ISO 9001:2000 quality management system requirements for Healthcare.**

ISO 9001	Applicable documents, processes and related items currently in place or to be transitioned to ISO
	<p>There should be a system in place to ensure product marking is labeled and sealed in a legible, durable, traceable manner.</p> <p>There should be a process in place for preservation/segregation methods, e.g.:</p> <ul style="list-style-type: none"> <li>- Cleaning and preservation</li> <li>- Moisture elimination</li> <li>- Protective clothing</li> <li>- Wrapping</li> <li>- Oxygen elimination</li> <li>- Refrigeration</li> </ul> <p><b>Hazardous Materials</b></p> <p><b>NOTE:</b> There should be documentation of materials listed by MSDS sheets as hazardous or any ignitable, corrosive, reactive, or extraction procedure toxic materials are received and stored per procedure:</p> <ul style="list-style-type: none"> <li>- MSDS sheets received by senior buyer – new/updated sheets distributed</li> <li>- Storage of inventoried materials in flammable room by receiving clerk; all others in designated dept. areas</li> <li>- Bills of lading, packing slips, forms filed in packing slip file by PO # in receiving</li> <li>- Shipments not left on loading dock for more than 1 day</li> <li>- Shipping out materials – manifests and labels completed.</li> </ul>

# Meeting ISO 9001:2000 quality management system requirements for Healthcare.

ISO 9001	Applicable documents, processes and related items currently in place or to be transitioned to ISO
7.6	<p><b>Control of Measuring and Monitoring Devices</b></p> <p>The BioMed/Clinical Engineering Department normally maintains the calibration and maintenance program of equipment deemed critical to the quality and safety of the patients including examples such as:</p> <ul style="list-style-type: none"> <li>- Defibrillator equipment</li> <li>- Blood Pressure</li> <li>- EKG</li> <li>- Imaging equipment</li> <li>- Lab equipment</li> <li>- OR equipment</li> <li>- Scales in OB</li> <li>- Ventilators</li> <li>- Fetal Monitors</li> </ul> <p><b>Note:</b> not all equipment may need calibration – a simple functional check may be adequate for items such as a clinical thermometer used for patient temp.</p> <p><b>NOTE:</b> Equipment deemed non-critical may only be a part of the hospital's preventive maintenance program. Ensure that the difference between PM and Calibration is understood.</p> <p>The system should contain all appropriate equipment that should be addressed.</p> <p>The system should address test hardware and software used to verify the condition of the patient, results of test, the status of measurements</p> <p>A process should be in place to ensure that all new or repaired equipment is calibrated/recalibrated before use</p> <p>Where calibration is performed by an external supplier, there should be procedures in place to monitor and track this.</p> <p>The hospital needs to ensure that personnel using calibrated equipment are adequately trained in its use</p> <p>There should be procedures in place to provide for the recall of equipment when it is due for calibration</p> <p>Equipment should be identified, where appropriate, with an indicator to show calibration status</p> <p>Calibration status should show date calibrated, next calibration date, by whom, calibration limitations</p> <p><b>NOTE:</b> a maintenance management system should be in place to record, track, and schedule all repair, maintenance, and calibration activity.</p> <p>This system should address validity of previous results is verified if equipment is found out of calibration,</p> <p>The hospital should retain history of calibrations and adjustments and kept on file and records are available for review &amp; analysis.</p>

ISO 9001	Applicable documents, processes and related items currently in place or to be transitioned to ISO
8.2.4	<p><b><u>Measuring and Monitoring of Product (Service)</u></b></p> <p>The hospital applies types of statistical techniques that may be applied to analyze performance indicators for any aspect of health care service delivery.</p> <p>Consideration should be made if statistical techniques are applied due to:</p> <ul style="list-style-type: none"> <li>- Outside benchmark quality indicators</li> <li>- Internal benchmarks</li> <li>- Contractual requirements</li> <li>- Regulatory requirements</li> <li>- Internal requirements (determined by quality policy, or quality planning)</li> </ul> <p>Procedures should be in place to describe:</p> <ul style="list-style-type: none"> <li>- the need for statistical data</li> <li>- what statistical and data collection methods are used</li> <li>- how the results of statistical analysis are intended to be used.</li> </ul> <p><b>NOTE:</b> Examples of the types of data in a health organization in place, but not limited to:</p> <ul style="list-style-type: none"> <li>- Incident Reports</li> <li>- Infection Control</li> <li>- Patient waiting times</li> <li>- Volume statistics</li> <li>- Referral patterns</li> <li>- Discharges</li> <li>- Diagnoses</li> <li>- Complications</li> <li>- Patient Satisfaction rating</li> </ul>
8.3	<p><b><u>Control of Nonconforming Product (Service)</u></b></p> <p>In the event of inadequate or unsatisfactory /service is prevented from inadvertent use. (Patient records, maintenance of support services &amp; equipment records)</p> <p>Examples of nonconforming service includes, but is not limited to:</p> <ul style="list-style-type: none"> <li>- Wrong supplies received</li> <li>- Recall of Central Supply items</li> <li>- Defective/damaged equipment</li> <li>- Not following procedures</li> <li>- Ineffective treatment plan</li> <li>- Medication or Care Error</li> <li>- Incomplete record keeping</li> <li>- Out-of-date shelf life material</li> <li>- Patients respond poorly or worsen, requiring a change in care/treatment</li> </ul> <p><b>NOTE:</b> A process should be in place for decisions/actions taken as a result of any type of abnormality found in support materials, equipment, activities, or in a tx/care plan</p> <p><b>NOTE:</b> If nonconformance appears in a treatment regimen, the process for review/disposition of the service should address e.g.:</p> <ul style="list-style-type: none"> <li>▪ Reconsider/amend care plan</li> <li>▪ Restart or delay care</li> <li>▪ Change care plan</li> <li>▪ Discontinue care plan</li> </ul> <p><b>NOTE:</b> If nonconformance is due to support materials, there should be a process in place for removal or replacement e.g. contaminated bedding, furniture, protective clothing, expired medical supplies</p>

**Meeting ISO 9001:2000 quality management system requirements for Healthcare.**

ISO 9001	Applicable documents, processes and related items currently in place or to be transitioned to ISO
8.3 cont'd	<p><b>NOTE:</b> If nonconformance is due to equipment, there should be a process in place to ensure that equipment is replaced, repaired, discarded – prevented from inadvertent use.</p> <p><b>NOTE:</b> Other examples could be:</p> <ul style="list-style-type: none"> <li>- If a patient falls and fractures a leg, there will be immediate action taken, an incident report written, and f/u to prevent from occurring again</li> <li>- Equipment needed repair is logged in a maintenance book to record the repair and then checked off and signed when repair is completed.</li> </ul> <p><b><u>Medical Device Tracking</u></b></p> <p><b>NOTE:</b> Procedures should be in place to ensure that all medical devices defined in Safe Medical Devices Act (SMDA) of 1990 are identified, tracked and reported.</p> <p><b>NOTE:</b> Materials Management and Surgery Departments should identify and maintain required documentation, flag the device as a tracked device prior to in-house distribution and report all subject devices to the manufacturer as per procedures.</p> <p><b>NOTE:</b> Procedures should be in place to verify ID &amp; maintenance of records for devices such as:</p> <ul style="list-style-type: none"> <li>- Vascular graft prostheses</li> <li>- implantable pacemaker pulse generator</li> <li>- Replacement heart valves</li> <li>- Implantable infusion pumps</li> <li>- Continuous ventilator</li> <li>- DC-defibrillator and paddles</li> <li>- Silicone breast prosthesis</li> </ul> <p><i>Variance Reporting Procedure</i></p> <p><b>NOTE:</b> There should be a process in place to ensure that variances and major nonconformances are reported within 24 hours of identification:</p> <ul style="list-style-type: none"> <li>- Variance = event having adverse effect or potential adverse effect on patient, visitor, employee, medical staff or hospital itself. (e.g. complaints by patients, family members, or visitors)</li> <li>- Adverse Event = unexpected occurrence involving death or serious physical or psychological injury, or the risk thereof. Serious injuries include loss of limb or function</li> </ul> <p><b>NOTE:</b> Examples of variances captured and verified may include, but not limited to:</p> <ul style="list-style-type: none"> <li>- Reported with Variance Reporting Form by any Medical Center staff member</li> <li>- CAR plan developed &amp; approved within a specified timeframe</li> <li>- Nonconformities identified during IQA internal reviews (audits) should be documented on Internal Audit Findings Summary forms / reports or similar documents.</li> </ul> <p><i>Clinical Monitoring/Evaluation (8.3, 8.5.2, 8.4)</i></p> <p><b>NOTE:</b> There should be a process in place for monitoring, reporting and analysis of data, this includes, but not limited to:</p> <ul style="list-style-type: none"> <li>- Medical staff monitoring</li> <li>- Risk Management</li> <li>- Infection Control</li> <li>- Communicable Disease Reporting</li> <li>- Employee Health</li> <li>- Isolation Procedures</li> <li>- Utilization Review Plan</li> <li>- Medical Records Review</li> <li>- Discharge Planning</li> </ul> <p><b>NOTE:</b> The hospital should use data collected to measure and improve the system.</p> <p><b>NOTE:</b> A documented system for CAR/PAR occurs (where appropriate) in trended problem areas.</p> <p><i>Medical Device Reporting</i></p>

# Meeting ISO 9001:2000 quality management system requirements for Healthcare.

ISO 9001	Applicable documents, processes and related items currently in place or to be transitioned to ISO
	<p><b>NOTE:</b> A process should be in place for reporting of a device causing or contributing to death within a required timeframe to FDA and device manufacturer</p>
<p><b>8.4</b></p>	<p><b><u>Analysis of Data</u></b></p> <p>Clinical data should be reviewed and analyzed for:</p> <ul style="list-style-type: none"> <li>• Effectiveness, Efficacy, Appropriateness, Safety, Timeliness, Accessibility/availability, respect and caring, continuity of services</li> <li>• Efficiency levels of service</li> <li>• Patient/ /customer/employee/physician satisfaction?</li> <li>• Process/practice trends and patterns?</li> <li>• Characteristics of services?</li> </ul>
<p><b>8.5.2</b></p>	<p><b>Corrective Action</b></p> <p><b>NOTE:</b> The hospital should have a system in place to document Corrective Action (CA)/Preventive Action (PAs) from the following sources, but not limited to:</p> <ul style="list-style-type: none"> <li>- Variance Reporting System</li> <li>- Customer Complaints/Patient Grievances</li> <li>- Internal Quality Reviews (Audits)</li> <li>- Noncompliance with documented QMS or ISO</li> </ul> <p>A process should be in place to ensure that corrective/preventive action taken will prevent actual nonconformity appropriate to the magnitude of the problem and risks associated with it</p> <p>The hospital should implement and record any changes to the procedures resulting from CA/PAs?</p> <p>Procedures for investigation should include :</p> <ul style="list-style-type: none"> <li>- Cause of the nonconformities relating to treatments</li> <li>- Violations against CMS requirements for Medicare/Medicaid Conditions of Participation, DNVHC/NIAHO<sup>SM</sup></li> <li>- Procedures and Quality System</li> <li>- Corrective Action needed to eliminate cause</li> </ul> <p><i>Patient Complaints/Grievances</i></p> <p><b>NOTE:</b> Handling of complaints/grievances are handled as per procedure and requirements:</p> <ul style="list-style-type: none"> <li>- Notification process</li> <li>- Variance Report Form or similar document completed</li> <li>- Management involvement/investigator</li> <li>- Timeframe for response by phone or mail</li> <li>- Right of patient to contact Administration or designee at any time</li> </ul> <p><b>NOTE:</b> The hospital should have a tracking system for CA/PAs – and how these CA/PAs are opened, traced and eventually closed</p>

# Meeting ISO 9001:2000 quality management system requirements for Healthcare.

ISO 9001	Applicable documents, processes and related items currently in place or to be transitioned to ISO
8.5.3	<p><b><u>Preventive Action</u></b></p> <p>The hospital should consider appropriate sources of information for identifying/analyzing Preventive Action (PAs) e.g.:</p> <ul style="list-style-type: none"> <li>- Clinical Indicators</li> <li>- MD Hospital Assoc. Quality Indicator Project</li> <li>- MI Hospital Assoc. MI Patient Outcome Measures</li> <li>- CMS</li> <li>- Patient Satisfaction Surveys</li> <li>- Quality Dashboard</li> </ul> <p>The hospital should conduct “trend analysis” reviews (e.g. statistics of accidents, infection control levels, treatment effectiveness) to detect, analyze, and eliminate nonconformities. Examples of methodology applied may include, but not limited to:</p> <ul style="list-style-type: none"> <li>- Process characterization analysis</li> <li>- Patterns and trends over time</li> <li>- Clinical outcome analysis/improvement</li> <li>- Morbidity and mortality analysis</li> <li>- Proactive benchmarking activities</li> </ul>