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Application of a Quality System Model for Medical Imaging Services; Approved Guideline

This document provides a model for providers of medical imaging services that will assist with implementation and maintenance of an effective quality system.

A guideline for global application developed through the NCCLS consensus process.

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Application of a Quality System Model for Medical Imaging Services; Approved Guideline

Abstract

NCCLS document HS5-A—*Application of a Quality System Model for Medical Imaging Services; Approved Guideline* provides the necessary background information and infrastructure to develop a quality system that will meet healthcare quality objectives and be consistent with the quality objectives of each institution. This guideline provides a structure for a comprehensive, systematic approach to build quality into the imaging service's processes, assess its performance, and implement quality improvements. Individual service areas, such as diagnostic radiology, CT, ultrasound, interventional radiology, magnetic resonance imaging (MRI), mammography, and nuclear medicine can apply this model to their respective operations. To provide a practical example of how a quality system is developed and implemented, suggestions for diagnostic radiology are included.

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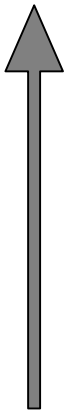
Foreword

In the present environment of limited resources, it is expected by those who fund, receive, and provide imaging services that quality is integral. This document defines a model for those who provide imaging services that will assist organizations with implementation and maintenance of an effective quality system.

This model is consistent with the example provided by the International Organization for Standardization (ISO) for quality standards in business and industry, using terms and concepts more familiar to the healthcare entities.

The model for imaging services is an application of NCCLS document HS1— *A Quality System Model for Health Care*. A working knowledge of HS1 is needed to apply the concepts presented in this document.

Synthesizing the concepts of acknowledged quality experts,[1,2] a hierarchy defining stages of quality[3,4] is described in the table below.



State	Activities Performed
Total Quality Management	Management approach centered on quality, aimed at long-term success through customer satisfaction.
Quality Management	Includes the stages below and also the economic aspects of "cost of quality."
Quality System	**Comprehensive and coordinated efforts to meet quality objectives**.
Quality Assurance	Planned and systematic activities to provide confidence that an organization fulfills requirements for quality.
Quality Control	Operational techniques to fulfill requirements for quality and regulatory compliance.

Using a scheme similar to Maslow's hierarchy of personal needs,[5] an organization can best obtain the next-higher stage by mastery of the preceding one.

In most of the world, healthcare services are operating at or below the stages of quality control and quality assurance. Although some healthcare services are working successfully at the level of quality systems, the need is becoming more apparent for most healthcare organizations to upgrade their quality activities to include quality systems. This document provides guidance to achieve the quality system level in the quality hierarchy as applied in imaging services. **(See shaded grid above.)** The baseline of a quality system, with operations under control, provides a platform for continuous improvement and further movement up the quality hierarchy.

To accomplish the objective of improving operations and services to its customers, the healthcare organization's executive management and respective medical directors must actively support the establishment and maintenance of the quality system. Visible participation of the medical and administrative management in all aspects of the quality system is essential to the successful implementation of the model.

Foreword (Continued)

An integrated quality system provides an opportunity to deliver consistent, high quality, and cost-effective health care in any healthcare organization. In healthcare service areas where regulatory and accreditation compliance applies, a quality system will simplify the process. The model described in this document provides guidance for developing a quality system in healthcare settings that provide imaging services.

Readers will also find the information in NCCLS documents HS1—*A Quality System Model for Health Care* and GP22—*Continuous Quality Improvement: Essential Management Approaches* to be valuable resources.

Key Words

Quality, quality indicators, quality system

Application of a Quality System Model for Medical Imaging Services; Approved Guideline

1 Introduction

The structure described in this document is for a quality system in medical imaging services as described in detail in NCCLS document HS1—*A Quality System Model for Health Care* and is adaptable to any service in a healthcare organization. HS1 origins stem from guidance originally provided to the U.S. blood banking community.[6-9]

For the purposes of the quality system model described in this guideline, quality system essentials are:

- organization;
- personnel;
- equipment;
- purchasing and inventory;
- process control;
- documents and records;
- occurrence management;
- internal assessment;
- process improvement; and
- service and satisfaction.

International guidance is documented as the ISO 9000 family of quality standards.[10] The quality system described in ISO 9001[11] defines 20 quality system elements that any business should use to manage its operations. NCCLS document HS1—*A Quality System Model for Health Care* contains tables that depict the relationship between the ten quality system essentials described in the model and the 20 quality elements used internationally in business and industry.

2 Scope

The quality system model described in this guideline is based on HS1—*A Quality System Model for Health Care* and is applied to medical imaging services. The quality system essentials are universal and thus can be applied to any service's operations, whether simple or complex.

3 Definitions[a]

Accident, *n* **-** An undesirable or unfortunate happening that occurs unintentionally.

Audit, *n* – A planned, independent, and documented assessment to determine whether agreed-upon requirements are being met.[12]

Calibration, *n* - The set of operations that establishes, under specified conditions, the relationship between values of quantities indicated by a measuring instrument or measuring system, or values represented by a material measure or a reference material, and the corresponding values realized by standards.

[a] Some of these definitions are found in NCCLS document NRSCL8—*Terminology and Definitions for Use in NCCLS Documents.* For complete definitions and detailed source information, please refer to the most current edition of that document.

Competence, *n* - The ability of an individual to perform a specific job or task.

Contract review, *n* - Defined activities carried out before entering into a contract agreement to ensure that requirements are adequately defined and understood, and can be achieved.[13]

Corrective action, *n* - Action taken to eliminate the cause(s) of existing problems, defects, or any other undesirable situation in order to prevent recurrence.[13]

Critical control points, CCPs, *n* **-** Groupings of related activities and tasks that must be accomplished effectively to minimize errors in operational processes.

Customer, *n* **-** The recipient of a product or service provided by the supplier.[13]

Document, *n* - Any written item of a factual or informative nature.

Error, *n* - A deviation from truth, accuracy, or correctness; a mistake.

Form, *n* - A paper or electronic document on which information or results are captured; **NOTE:** Once completed, a form becomes a record.

Incident, *n* - An individual occurrence or event.

Key elements, KEs, *n* -The activities and tasks within a critical control point.

Occurrence, *n* - Something that happens; an event, incident.

Policy, *n* - A written statement of overall intentions and directions defined by those in the organization and endorsed by management.[14]

Preventive action, *n* - Action taken to eliminate the cause(s) of potential problems, defects, or any other undesirable situation in order to prevent occurrence. [13]

Preventive maintenance, *n* - Scheduled periodic work on a piece of equipment that is not a result of malfunction or failure and is intended to avert such failure.

Procedure, *n* - A specified way to perform an activity.[13]

Process, *n* - One or more interrelated resources and/or activities that transform inputs (e.g., intent, policies) into outputs (e.g., instruction, procedures).[13]

Quality, *n* - The totality of characteristics of an entity that bear on its ability to satisfy stated and implied needs.[13]

Quality assurance, *n* - Planned and systematic activities to provide adequate confidence that requirements for quality will be met.

Quality control, *n* - Operational techniques and activities that are used to fulfill requirements for quality.[13]

Quality improvement, *n* – A systematic method used to identify opportunities for improvement in clinical and nonclinical systems.[15]

Quality management, *n* - All activities of the overall management function that determine quality policy objectives and responsibilities; and implement them by means such as quality planning, quality control, quality assurance, and quality improvement within the quality system. [13]

Quality plan, *n* – A document or system focused on setting quality objectives and specifying necessary operational processes and related resources to fulfill the quality objectives.[15]

Quality policy, *n* - Overall intentions and direction of an organization with regard to quality (e.g., quality system essentials) as formally expressed by top management. [13]

Quality system, *n* - The organizational structure, resources, processes, and procedures needed to implement quality management. [13]

Quality tools, *n* - Methods and techniques used to generate, analyze, interpret, and present quality data.

Record, *n* - A document that furnishes objective evidence of information obtained, activities performed, or results achieved. [13]

Service, *n* - The result generated by activities at the interface between the provider and the customer and by provider's internal activities to meet the customer needs. [13]

Supplier, *n* - An organization that provides a product or service to the customer. [13]

Traceability, *n* – **1)** A property of the result of a measurement or the value of a standard whereby it can be related to stated references, usually national or international standards, through an unbroken chain of comparisons, all having stated uncertainties; **2)** The ability to trace the history, application, or location of an entity by means of recorded identifications. [13]

Validation, *n* - Action [or process] of proving that a procedure, process, system, equipment, or method used works as expected and achieves the intended result.

Verification, *n* - The confirmation by examination and provision of objective evidence that specified requirements have been fulfilled. [13]

4 Establishing the Quality System in Medical Imaging Services — Diagnostic Radiology as an Example

4.1 Introduction

This section of the guideline uses diagnostic radiology as an example of a medical imaging service for which a quality system can be defined, documented, and implemented. Specific examples of relevant documents (such as policies, processes, procedures, and forms) are provided in the appendixes. The quality system has been defined in NCCLS document HS1—*A Quality System Model for Health Care*.

4.2 Planning for the Quality System

The quality system essentials (QSEs) do not have to be implemented in order. The order suggested below facilitates policy setting, process development, and documentation. Each QSE and related activities are described in further detail in the following sections with relevant examples in the appendixes.

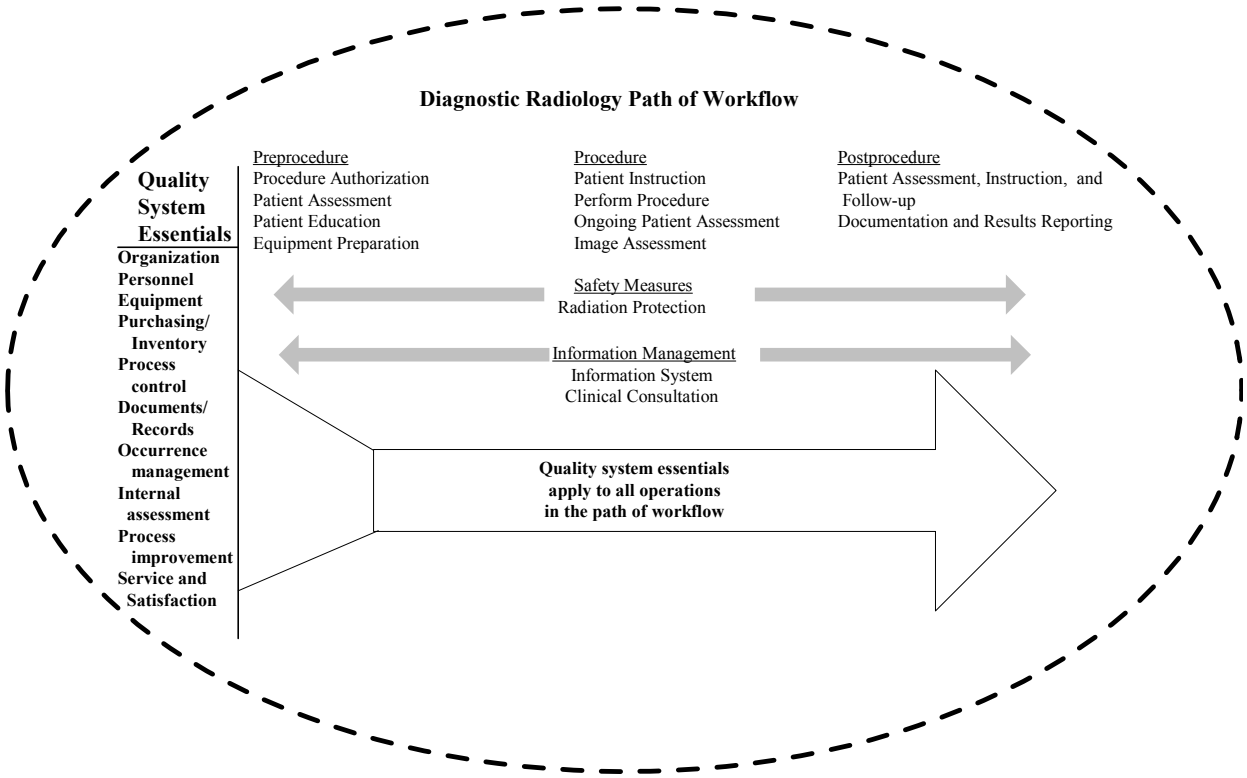


Figure 1. Structure for a Quality System Model for Diagnostic Imaging. Adapted from NCCLS document HS1—*A Quality System Model for Health Care.*

4.3 Phases of Implementation

4.3.1 Initial Phases of Implementation

The following activities set the foundation for quality planning and direct the implementation of the quality system:

- orientation to the quality system;
- confirmation of leadership commitment;
- identification of the diagnostic imaging service's path of workflow;
- development of the quality manual;
- development of an equipment management plan;
- analysis and validation of processes, development of standard operating procedures, and implementation of process controls; and
- development of the document and record control system.

4.3.2 Remaining Phases of Implementation

Teams may be used to develop the processes and procedures for the remaining phases. The use of teams allows these phases to progress simultaneously.

The remaining phases of implementing the quality system essentials include development of the following:

- training and competence assessment programs;
- purchasing and inventory program;
- occurrence management program;
- internal quality indicators and audit programs;
- process improvement program; and
- service and satisfaction program.

4.4 Implementation — Initial Phase

4.4.1 QSE: Organization — Confirmation of Leadership Commitment

To accomplish the objective of improving operations and services to its customers, the healthcare organization's executive management, the imaging services management, and respective medical directors must actively support the establishment and maintenance of the quality system. Visible participation of the medical imaging service's medical and administrative management in setting its quality policy, seeking customer feedback, and receiving and acting upon information derived from quality indicators and occurrence trending is essential to the successful implementation of the quality system.

It is advisable to select a team composed of medical imaging services staff and a staff member knowledgeable in quality process to oversee the implementation of the quality system phases listed in Section 4.3. This team will assign implementation projects, provide support, and track progress in implementing the quality system. Active participation on the part of the management is essential to the successful implementation of the quality system.

A detailed discussion on management commitment to quality through quality planning and actualization is included in NCCLS document GP22—*Continuous Quality Improvement: Essential Management Approaches*. Readers are referred to this document for more information.

4.4.2 Identification of the Path of Workflow

Some preprocedure processes in the path of workflow, such as procedure ordering and patient assessment, cross outside of the medical imaging services arena. Some postprocedure processes in the path of workflow, such as information systems and consultation, extend out of medical imaging services as well. To assure a positive contribution to patient outcomes, the quality system should encompass the entire path of workflow, which extends beyond procedure performance and results reporting. Healthcare settings that provide medical imaging services must be aware that they are but one service in the continuum of providing quality patient care. The quality system for medical imaging services must address how medical imaging services affects and is affected by other services within the system.

The operating systems in the path of workflow are shown across the top of the structure in Figure 1.

Note that in this figure, the path of workflow begins with procedure authorization and related preparatory activities, proceeds through the function-specific activities, and concludes with documentation. Information management is continuous throughout the process.

4.4.2.1 Medical Imaging Path of Workflow – Preprocedure

Elements of the preprocedure phase include:

- Procedure authorization
  - order generation
  - patient instructions
  - procedure scheduling and sequencing
  - verification of procedure for appropriateness
- Patient assessment
  - clinical history/patient signs and symptoms
  - verification of the clinical indication or contraindications for procedure
- Patient education
  - patient instruction regarding procedure
  - assessment of patient compliance with preprocedure instructions
  - procurement of patient approval and consent forms when appropriate
- Equipment preparation
  - gathering equipment and supplies
  - selection of calibration values and standards

4.4.2.2 Medical Imaging Path of Workflow – Procedure

The procedure session should include the following elements:

- Patient instruction
  - procedure explanation and demonstration
  - patient history confirmation
  - assessment of patient understanding
- Implementation procedure
  - adherence to clinical and technical protocols
  - radiation protection/safety implementation
  - consultation where appropriate
- Ongoing patient assessment
  - patient tolerance of procedure
  - patient position and comfort
  - interventions needed

- Image assessment

  - confirmation of diagnostic quality and correctness of image(s)

4.4.2.3 Medical Imaging Path of Workflow – Postprocedure

The postprocedure phase emphasizes the following:

- Patient assessment, instruction, and documentation

  - assessment of postprocedure patient status
  - preparation of correct and accurate documentation as required
  - provision of discharge instructions and document patient understanding where applicable

- Documentation and results reporting

  - generation of report
  - interpretation/report meets applicable regulatory standards
  - report distribution
  - archiving

4.4.2.4 Medical Imaging Services Path of Workflow – Safety

Safety measures include the following elements:

- Radiation protection

  - personnel monitoring
  - shielding
  - A.L.A.R.A.
  - pregnancy screening

4.4.2.5 Medical Imaging Path of Workflow – Information Management

Information management includes the following elements:

- Information system

  - report distribution (printed or electronic)
  - database management
  - systems backup
  - systems security and maintenance
  - archival/storage

- Clinical consultation

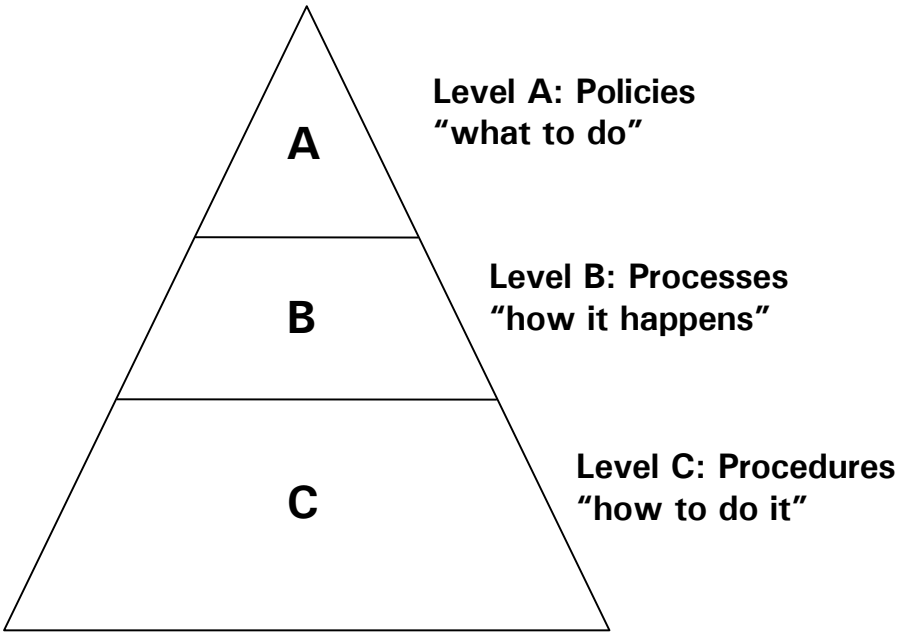
  - application of results to clinical interventions
  - verbal reporting

4.4.3 Documenting the Quality System

Each healthcare service employee should know, understand, and be able to describe the activities for each quality system essential. To accomplish this objective and to fulfill a common requirement for quality systems, the quality system essentials should be documented. This documentation clearly expresses to both employees and customers the healthcare service's intentions for and related activities in each quality system essential.

4.4.3.1 The Document Hierarchy

Usually, three levels of documents are present in a quality system, distinguished as policies, processes, and procedures. Figure 2 depicts a typical quality system document hierarchy.



NOTE: For those familiar with ISO terminology, Level A = policy, Level B = procedure, and Level C = work instructions.

Figure 2. Quality System Model Documentation Hierarchy

4.4.3.1.1 Policies (Level A Documents)

Quality policies state the service's intent regarding the quality system essentials. The service should write one policy for each quality system essential. These policies state what the service does for the elements of each essential. The guidance provided for QSE policy contents can also be found in international quality standards and guidelines, national healthcare regulations, and accreditation requirements in countries where they exist. Thus, the service's written quality policies become the commitment to meet applicable requirements.

The compilation of written policies for quality system essentials becomes the service's quality manual. The service's staff should become familiar with its quality policies. The quality manual can be shared with customers, external assessors or other authorities, and employees to familiarize them with the service's quality system.

4.4.3.1.2 Processes (Level B Documents)

Quality system processes describe how the quality policies are carried out. These documents are descriptions of the processes for implementing the quality system essentials in a given healthcare service. In flowchart or text format, these documents describe:

- who is responsible;
- what the action is; and
- what the expected results are.

Technical processes describe how the service's operations are carried out. These documents are descriptions of the service's processes in its path of workflow. In flowchart or text format, these documents describe:

- who is responsible;
- what the action is; and
- what the expected results are.

4.4.3.1.3 Procedures (Level C Documents)

These documents are the work instructions. For example, instructions for laboratories are the standard operating procedures; for nursing, the nursing manual; and so forth, that have been traditionally used to give instructions to personnel for performing particular tasks.

There should be instructions for critical process steps in each quality system essential. There should also be instructions for critical process steps for each of the operations in the service's path of workflow.

Quality system documentation also includes forms used to record information or results from performing procedures. Forms are the blank pages or computer screens on which information is recorded. After completion, a form becomes a record.

4.4.3.2 Quality System Essentials: Policies, Processes, and Procedures

The following pages provide guidance for developing policies, processes, and procedures for the quality system essentials. This guideline contains minimum suggestions compatible with international requirements. Users should adapt these suggestions according to the details of their particular services.

The quality manual provides guidance to all members of the medical imaging service for the policies and processes necessary to assure the quality of procedure results and services. The quality manual describes the service's commitment to the quality system.

4.4.4 Development of the Quality Manual

The team should adopt the project of developing the quality manual by setting the policies for the quality system essentials. There should be a written policy for each quality system essential. Each policy should state the goals of the policy and identify the parties or functions responsible for implementing the goals. See Appendix A for a sample policy on documents and records. Guidance for what to include in policy statements is given in NCCLS document HS1—*A Quality System Model for Health Care*. Additional

guidance specific for diagnostic imaging can be found in Appendix B. This appendix reflects key elements based on a review of regulatory and accreditation requirements.[b]

In addition to writing policies for the quality system essentials, the team should also describe the activities that transform the intent into action. This description should include the actions to be taken, the responsible parties or functions, and any supporting documents used or generated. Appendix C describes a process for the Quality System Essential: "Personnel." This process is applied to all operations across the entire path of workflow. Tables and flowcharts are the best methods for understanding and documenting the quality process. These formats provide visualization of how the activities progress across time. The sample process description for QSE: "Personnel" in Appendix C is provided in the table format.

The quality manual should minimally contain the policies for all the quality system essentials. The manual may also include descriptions of the quality processes. The quality manual communicates the structure and detail of the quality system to imaging services management, staff, physician, customers, and external accreditation organizations.

4.4.5 QSE: Equipment — The Equipment Management Plan

There should be a medical imaging equipment management plan, so that all instruments and equipment are properly selected, installed, calibrated, and their functions verified.

4.4.5.1 Equipment Selection

To ensure proper equipment selection, the management plan should include the following:

(1) Development of a list of acceptable vendors based on the defined equipment needs and required specifications;
(2) Development of a product-evaluation comparison matrix;
(3) Evaluation of selected equipment—equipment should meet or exceed minimum equipment performance standards;
(4) Determination of acceptable limits of accuracy and precision;
(5) Performance of site evaluation for the equipment; and
(6) Provision for vendors to supply operator guidelines.

4.4.5.2 Equipment Installation

There should be a plan for installing all new pieces of equipment to verify proper function. The plan should verify that the facilities have adequate electricity, ventilation, temperature, and meet other environmental conditions. Verification activities should be documented and the installation process should include:

- provision (by the vendors) of appropriate installation and operators' manuals;
- equipment validation performed by the manufacturer;
- equipment validation performed by the imaging staff; and
- biomedical safety checks performed by an internal or external biomedical department or included in the preventive maintenance provided by the manufacturer.

[b] In the U.S., the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) and the American College of Radiology (ACR), for example.

The requirements for calibration, quality control, maintenance, and adjustments should be determined. Schedules for calibration, QC, and maintenance should be derived, documented, and followed. When problems occur, there should be documented processes to follow for troubleshooting, repair, and post-repair recalibration or revalidation. Standard operating procedures for all calibration, maintenance, quality control, and performance monitoring activities should be defined.

A comprehensive equipment management plan could include a master list of all equipment with respective identifying information, calibration, and maintenance schedules, as well as persons designated to review the plan and respective records at defined intervals.

4.4.6 QSE: Process Control—Process Analysis and Validation, Development of Standard Operating Procedures, and Implementation of Process Controls

4.4.6.1 Developing Flowcharts for Imaging Services Processes

Ideally, management and staff should flowchart the process for each section of the path of workflow specific to their institution. This can be accomplished manually or by using any of several available software programs. Process flowcharts identify steps where standard operating procedures are needed to complete specific tasks. Once a process is outlined on a flowchart, problems that cause redundancies, inefficiencies, and rework can be identified. Revised processes and procedures can then be implemented to improve or correct performance.

Appendixes D1 and D2 describe a process in the path of workflow for the process of an X-ray examination of the lumbar spine. This process, presented in two formats (Appendix D1: Manual, Appendix D2: Table), describes the responsibilities, actions, and documents needed for selection and reporting of an X-ray examination of the lumbar spine. This process lists standard operating procedures for specific tasks that must be properly performed for the process to be successfully accomplished.

4.4.6.2 Process Validation

Validation consists of a plan for medical imaging services personnel to challenge and document the results of new or modified processes or procedures to assure that the processes or procedures work as expected before actual implementation. Whenever a change is necessary, the new process or procedure should be validated to assure that the results will continue to meet the service's needs and expectations, and those of its customers. When developing the standard operating procedures to be used in the process, those for calibration, maintenance, and QC must also be included. Appendix E provides a sample validation protocol.

4.4.6.3 Identifying and Writing Standard Operating Procedures

There should be written standard operating procedures for critical steps in the quality system essentials. There should also be standard operating procedures for critical steps in medical imaging processes in each operating system throughout the entire path of workflow. As mentioned previously, medical imaging service's staff should collaborate with other healthcare providers that impact the imaging service's path of workflow. For example, the imaging service may wish to consider providing patient instruction and order forms for procedures performed in an office practice.

Guidance for developing procedures for the QSEs is given in NCCLS document HS1—*A Quality System Model for Health Care*.

Standard operating procedures should be easy to read, use, and follow. In the appendixes, note how the use of columns, bullets, and tables simplifies these documents and provides necessary information in a visually pleasing format.

4.4.6.4 Process Control

Once a quality system is put into place, each operation must be monitored to ensure that it is functioning as designed and that it contributes to achieving the goals and objectives stated in the quality manual. Tools available for monitoring imaging services processes include:

- a quality control program that reflects the internal needs of the imaging service and meets minimum regulatory requirements (see Section 4.4.6.4.1);
- proficiency testing programs that offer an assessment of process output (see Section 4.4.6.4.2);
- occurrence logs which itemize and characterize problems with process or product output (see Section 4.5.3);
- statistical techniques which help imaging services personnel to understand process performance and analyze trends (see Section 4.4.6.4.3); and
- development and implementation of quality indicators with thresholds that cause imaging services staff to review the process (see Section 4.5.5).

4.4.6.4.1 Quality Control (QC)

Quality control is a vital part of assuring the quality of the medical imaging services procedure methods. The written policy for the QSE "Process Control" should state that the QC program considers government regulations, accreditation requirements, manufacturer's recommendations, and imaging services needs.

4.4.6.4.2 Proficiency Testing for Medical Imaging Services (Quality Assessment)

The written policy for QSE "Process Control" should state that the medical imaging service participates in a program of quality assessment to meet regulatory or accrediting standards. There should be a written description of the process that minimally includes:

- enrollment in appropriate programs;
- the imaging service's protocol for execution of specific procedures;
- tracking of performance;
- evidence of meeting requirements; and
- investigation and corrective action for unacceptable results.

Guidance for investigating unacceptable results can be found in the current edition of NCCLS document GP22— *Continuous Quality Improvement: Essential Management Approaches.*

4.4.6.4.3 Use of Quality Tools

Quality tools have been described and used for controlling processes. See Appendix F for a listing of frequently used tools.

4.4.7 QSE: Documents and Records —Development of the System for Controlling Documents and Records

4.4.7.1 Document Control

Document control is a means to ensure that only the latest versions of approved documents are being used by medical imaging services staff. The medical imaging service should appoint someone with the vested responsibility for overseeing the document control system. Document control includes:

- document identification (numbering/coding);
- version identification;
- change control;
- master file maintenance;
- master index maintenance;
- distribution; and
- archiving.

4.4.7.1.1 Document Identification (Numbering/Coding)

The medical imaging service should develop a numbering system that includes all documents. The numbering system should identify the type of document (quality policy, quality process, quality procedure, operating policy, operating process, and operating procedure), its respective code number, and the version. The medical imaging services section may be identified in the code number. Although there is no one correct way to code documents, a combination of alpha and numeric characters has been found to be useful.

Example # 1: This is an example of a document identification number for a quality policy.

QP201/02
Where QP = Quality Policy
201 = Policy document number 201 (QSE #2, Personnel)
/02 = second version

4.4.7.1.2 Version Identification

Version identification helps assure that only that latest approved version of a document is in use. Versions can be identified with numbers or letters. The display of an effective date on the document, or the uses of colored paper or stamps are other examples of version identification.

4.4.7.1.3 Change Control

In a quality system, a formal means of change control assures that only authorized changes are made to approved documents, that all changes are reviewed and approved prior to being placed into use, and that all copies of the document in use reflect the change. Appendix G is an example of a document change request form commonly used in quality systems to request changes to approved documents. Departments must also determine how changing one document could affect needed changes in other documents and how the input of all those affected by the change will be obtained and considered.

4.4.7.1.4 Master File for a Document

Each document should have a master file that contains the current and all previous versions. Either or both electronic and hard-copy versions of master documents can be filed. Copies of the document change request form with review and approval signatures should also be kept in the master file. The master file serves as the historical record of a particular document from its inception to the present and provides a means to look back in time should there ever be a need to do so.

4.4.7.1.5 Master Index

The master index is a listing of all documents currently in use, functioning like an extended table of contents of all policy, process, and procedure manuals. Whenever a document is changed and updated to a new version, the master index should also be updated. The master index provides all staff with the means to identify exactly which version of a particular document they should be using in their work. The master index should include:

- document name;
- document number;
- version designation;
- effective date; and
- document location(s).

Appendix H contains a sample master index. Software applications for personal computers, such as spreadsheets and databases, are also useful for maintaining the master index.

4.4.7.1.6 Distribution

The document master file and index should indicate each location where active copies of a document are placed. For example, copies of a technical procedure may be placed in the supervisor's office and at one or more work areas where the procedure is performed. Therefore, where there is more than one active copy of the procedure, each location should be listed on the master index. The master file and master index should list the locations of all documents. Document locations may be added or deleted as needed by the imaging service departments.

4.4.7.1.7 Archiving

The current version of a document (policy, process description, procedure, or form) is stored in its respective master file. When a document is changed, old working copies must be destroyed and replaced with the new version.

Document master files must be stored in a manner to prevent loss or damage and to promote easy retrieval. Regulations or accreditation requirements for imaging services or a specific modality, as well as the organization's business requirements, may define duration of retention.

4.4.7.2 Records Management

4.4.7.2.1 Records Review

Reviews of records should be performed according to regulations and accreditation requirements for the imaging service's own policies and procedures. All reviews should be documented with the review date and the reviewer's name/initials.

4.4.7.2.2 Archiving

Records must be stored in a manner to prevent loss or damage and to promote easy retrieval. Regulations or accreditation requirements for imaging services and the organization's business requirements may define duration of retention.

4.5 Implementation — Remaining Phases

4.5.1 QSE: Personnel

4.5.1.1 Job Qualifications and Descriptions

The responsibility for specifying job qualifications and descriptions should reside within the facility. Resources for developing job qualifications and descriptions can be obtained through professional associations, as well as certifying and regulatory bodies.

4.5.1.2 Development and Documentation of Training and Competency Assessment Programs

Orientation, training, and competency assessment should be provided to ensure compliance with internal policy.

4.5.1.2.1 Orientation and Training

The written policy for QSE "Personnel" should state that it provides staff with orientation and training. The policy should include, but is not limited to:

- code of ethics;
- organizational requirements (such as those found in the organization's employee handbook);
- imaging services orientation and general imaging service requirements;
- safety training;
- computer training;
- job-specific tasks; and
- the organization's and imaging services quality system, the employee's role, and the use of continuous improvement tools and techniques.

Appendix I is a more detailed listing of the components of orientation and continuing education. There should be a written description of the process when:

- new employees are hired;
- new procedures/technologies have been implemented;
- procedures are changed; and
- retention, remediation, or a periodic reverification of competency is required.

4.5.1.2.2 Guidelines for Education

Guidelines for education are useful in conveying important information to employees and include the rationale for particular actions in a procedure. Guidelines for education provide instructions to assure that each employee receives the same information every time. See Appendix J for sample contents.

4.5.1.2.3 Competency Assessment

Employers should ensure that a formal competency assessment program is established. This should include required skills and a timeframe for reassessment.

4.5.1.2.4 Documentation of Education and Competency Assessment

All education and competency assessments must be documented. When assessments fail to meet expectations, re-education must be initiated and documented.

A system should be developed to document and track employee education and competency assessment.

4.5.2 QSE: Purchasing and Inventory

4.5.2.1 Purchasing

Quality system policies should ensure that purchased goods or services conform to specified performance and/or regulatory requirements. Suppliers should be assessed, purchasing data should be clear and accurate, and purchased products should be verified to ensure that they are the items received.

Documented procedures should be established and maintained to ensure that purchased items and services conform to specified requirements and are purchased only from approved suppliers.

4.5.2.1.1 Suppliers, Contractors, and Consultants—Qualification and Approval

Suppliers should be selected based on their ability to meet specified requirements. Qualifications should include a system of evaluation of the supplier using appropriate quality system and/or process assessments, supplier surveys, inspections, and evaluation techniques for items supplied. As appropriate, the assessment of a supplier's quality management system should be performed and included in the assessment. A listing of all suppliers, contractors, and consultants should be maintained. The listing should grade the suppliers' ability to meet specific requirements.

4.5.2.1.2 Purchasing Data

All commitments to purchase should be documented in accordance with procedures. Purchasing documents should describe the product being ordered and contain relevant information to that order, including specification references and, when appropriate, any traceability requirements.

4.5.2.1.3 Verification of Purchased Products

Periodic verification is intended to ensure that purchased products and services are accurately represented by the vendor and meet stated performance claims as required. Verification or inspection requirements should be agreed to with the client and the supplier, and are related to the supplier's performance record, if applicable.

4.5.2.2 Inventory

The quality system requirements for the handling, storage, packaging, preservation, and delivery of products and equipment should be defined. Inventory control procedures apply to all operational sites associated with the maintenance of quality, from receipt of materials/components to delivery of the finished product to the customer.

4.5.2.2.1 Handling

Documented procedures should be established for the handling of materials, products, and equipment to prevent damage and deterioration. The methods for handling must ensure that product integrity is maintained throughout the procedure.

4.5.2.2.2 Storage

As appropriate, materials and products should be stored in designated storage areas within the facility. Storage methods should be designed to prevent damage and deterioration to the product prior to use or delivery. Where special storage conditions are required to prevent deterioration, e.g., temperature units, procedures will be in place to ensure conditions are adequately controlled and maintained.

4.5.3 QSE: Occurrence Management — Development of an Occurrence Management System

4.5.3.1 Uniform Document for Capturing Information

An internal system should be developed to capture and report any and all occurrences when a process or procedure did not or might not have the expected outcome (e.g., "near-miss"). Examples include: reporting of occasions when other services did not follow established policy, therefore affecting the imaging service's ability to meet its customers' expectations; all occasions of verbal or written customer complaints; communication failures within the medical imaging service and to outside customers; and problems with technical operations. An occurrence report form should minimally include space for a tracking number, date/time of occurrence, description, and resolution. Appendix K provides an example of a quality system-oriented occurrence report form.

4.5.3.2 Immediate Action and Investigation

The employee who discovers the problem should take steps necessary to resolve the immediate issue and document what was done on the occurrence report form. The form is given to the designated person who logs the occurrence; the investigation then begins. The occurrence log can be a hard-copy document; Appendix L provides an example. Alternatively, electronic spreadsheets and databases can be used.

4.5.3.3 Investigation and Corrective Action

Awareness of a problem carries the responsibility that something will be done to remove its cause and prevent recurrence. A plan of corrective action should be devised, implemented, and documented, including the method for assessing its effectiveness. See Section 4.5.5 for a discussion on the continuous improvement process.

4.5.4 QSE: Internal Assessment — Internal Quality Indicators and Audit Programs

4.5.4.1 Mapping Current Quality Indicators to the Medical Imaging Services Path of Workflow

Medical imaging services are encouraged to map their current clinical quality indicators to the quality system framework. This can be accomplished by listing the name of the indicator under the respective column of the path of workflow that best represents what the indicator measures. An example is provided in Appendix M. The results of such mapping will show the areas in the path of workflow that are not currently monitored. To assure that all processes function as needed and expected, one or more quality indicators should be monitored in each operating system or each section of the path of workflow. Each medical imaging service has been encouraged to identify its own high-risk, high-cost, and problematic issues.

4.5.4.2 Internal Auditing

An internal auditing program should be established to review the facility's quality system. The program assesses the appropriateness of the quality system in place, and evaluates compliance with internal policy statements and applicable regulatory requirements.

4.5.4.2.1 The Quality Audit[c]

The auditor assesses the intent, implementation, and effectiveness of the facility's quality system. The purpose is to verify that a quality system exists, is being followed, and is effective in maximizing the quality of procedures and services to the customer.

To evaluate the intent, the auditor examines whether or not the facility has stated in writing its intent to fulfill the quality system requirements. This intent is manifested in the policies for the quality system essentials as outlined in the quality manual.

To evaluate implementation, the auditor examines whether or not the facility has defined its processes and procedures, and communicated them adequately to its employees. The auditor also determines whether employees are following the quality system.

To evaluate effectiveness, the auditor examines the facility's records to see whether or not the procedures and services rendered from the stated processes and procedures meet the stated intent, any applicable regulations or requirements, and the customers' needs.

4.5.4.2.2 Auditors

Individuals performing quality system audits should receive special education in the audit function. Whenever possible, auditors should be from areas that are different from those being audited.

4.5.4.2.3 The Audit Report

At the conclusion of the audit, the auditor issues a report to management that describes any discrepancies between the documented quality system and what the auditor found in the records review, interviews, and observations. The report is written in a way to help management understand the impact of the discrepancies on the quality of its procedures and services to its customers.

An example of a systematic surveillance report can be found in NCCLS document GP22— *Continuous Quality Improvement: Essential Management Approaches.*

4.5.5 QSE: Process Improvement

Process improvement policies should describe problem resolution processes and quality improvement tools used to improve the quality of its services. The need for improvement exists inherently in all processes and does not necessarily come in response to a problem. Sources include:

- staff feedback;
- customer feedback;
- internal assessments (information from quality indicators and audits of the quality system);

[c] More information on quality system auditing can be found in Arter DA. *Quality Audits for Improved Performance*. 2nd ed. Milwaukee, WI: ASQC Press; 1994; and in Russell JP, Regel T. *After the Quality Audit: Closing the Loop on the Audit Process.* Milwaukee, WI: ASQC Press; 1996.

- external assessments (regulatory, accreditation);
- analysis of occurrences, including cases and trends;
- reports from other areas in the organization; and
- the difference between customer needs and the services provided (gap analysis).

4.5.5.1 Quality Improvement Process

Quality improvement plans include:

- problem identification, prioritization, and selection;
- determination of the root cause of the problem;
- analysis of the current process and collection of data;
- generation of ideas for improvement;
- development of an action plan;
- implementation of the plan;
- evaluation of effectiveness of actions;
- revision of the plan as needed; and
- documentation of activities.

When the need for improvement is identified, a multidisciplinary team approach may be appropriate.

Additional guidance for continuous quality improvement can be found in the current edition of NCCLS document GP22— *Continuous Quality Improvement: Essential Management Approaches.*

4.5.5.2 Periodic Reporting

Progress should be reported to the organization's management at predefined intervals.

4.5.6 Customer Satisfaction

Customer satisfaction is an effective measure of quality system performance. Customer satisfaction requires identification of customers, determination of customer needs, and procedures to meet these needs. Management should solicit customer feedback to determine if the needs are being met.

Customers include both internal and external groups. External to the medical imaging services are customers such as patients, physicians, outreach clients, industry, and regulatory bodies or accrediting agencies. Internal customers include physicians, imaging services staff, therapists, nurses, and other caregivers in the organization. Mechanisms should be developed to measure the satisfaction of the different customer groups, survey the customers, and analyze the results of the survey efforts. Where feedback indicates the need for improvement, corrective actions should be taken. Marketing, public relations, or quality management departments may provide guidance for the development and measurement of customer satisfaction.[16]

5 Application of Path of Workflow Across the Continuum of Care

An individual may enter the continuum of care at any point (see Figure 3). Within the continuum of care there are multiple areas such as:

- emergent care (e.g., ambulance services, emergency departments, emergency visits, transport);
- acute care (e.g., hospital setting external to critical care);
- critical care (e.g., adult intensive care units, burn units, neonatal intensive care units, pediatric intensive care units, transport, trauma intensive care units);
- postacute care (e.g., community care, home care, hospice, long-term care, palliative care, physical therapy, skilled nursing facility (SNF), subacute care);
- wellness and prevention (e.g., community care, occupational/environmental services, physical therapy); and
- primary care (e.g., diagnostic services, educational services, therapeutic services).

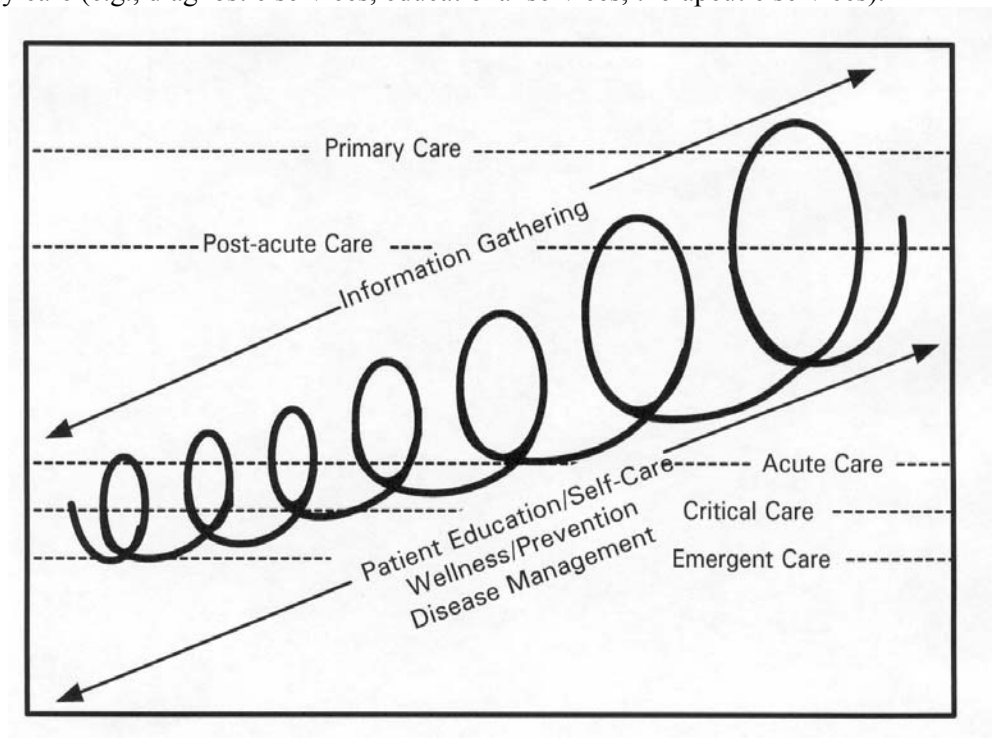


Figure 3. The Continuum of Care

The spiral represents the frequency of assessment and intervention by the medical imaging personnel as the patient moves through the continuum of care. As the individual moves, the frequency of the professional assessment and intervention decreases as the patient/client ownership and ability for self-care increases, thus requiring fewer professional assessments and interventions by medical imaging personnel.

The ability for the decrease in professional intervention is accomplished by educating the individual/significant others, and the assessment of their ability to implement interventions.

In a quality system, the QSEs and path of workflow for medical imaging services apply across the continuum of care.

6 Staff Involvement

Staff involvement in organization-wide quality improvement is required. At a minimum, all employees should receive education on the quality system and their responsibilities in the education, occurrence management, and data collection/indicator monitoring processes. Staff should participate in flowcharting

their respective work processes, identifying where standard operating procedures are needed, and recommending changes for improvement.

7 Conclusion

Health care must expand its view of quality beyond the departmentalized quality control and quality assurance activities of the last decades to keep pace with the growing role of total quality management in today's competitive environment. Quality systems are being used successfully in the world's manufacturing and service sectors, and there is reason to believe that quality systems will benefit healthcare services as well.

Each healthcare service in an organization can use the same quality system essentials to manage its specific path of workflow. In so doing, the healthcare organization's management can develop one set of policies for the quality system essentials that apply to all the services in the entire organization. The processes and procedures for implementing the quality policies can also become more uniform and streamlined, which removes costly discrepancies, conflicts, and struggles for limited resources among the many services. Using the same quality system essentials for each healthcare service integrates the quality system across the entire continuum of care.

This guideline presents a working model that will enable champions for change to take the first steps in improving quality in healthcare services specific to medical imaging services.

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Canadian Association of Medical Radiation Technologists (CAMRT)	http://www.camrt.ca
Canadian Association of Radiologists (CAR)	http://www.car.ca
Canadian Council on Health Services Accreditation (CCHSA)	http://www.cchas.ca
United States Environmental Protection Agency (EPA)	http://www.epa.gov
International Commission on Radiological Protection (ICRP)	http://www.icrp.net
International Society of Radiographies and Radiological Technologist (ISRRT)	http://www.isrrt.org
United States Nuclear Regulatory Commission (NRC)	http://www.nrc.gov
United States Occupational Safety and Health Administration (OSHA)	http://www.osha.gov

Appendix A. Sample (Level A) Medical Imaging Services Quality Policy

QSE Policy: Documents and Records

Policy

The management of (facility name/function) ensures that only controlled documents are used to describe and implement the quality system; and that images/records are generated, reviewed, and retained in accordance with government regulations and accreditation requirements for medical imaging institutions.

Purpose

This element ensures our customers that our staff members have the current documents concerning work processes, that changes to those documents are controlled, and that the records generated from using the documents are managed appropriately.

Responsibility

The (responsible function name) is responsible for establishing and maintaining the document control system.

Managers and supervisors are responsible for:

- ensuring that staff have current copies of the documents they need to perform their work;
- promptly removing outdated documents from the workplace; and
- storage and retrievability of all required records/images.

Document Creation

A standardized format is used for creating all types of documents to assure consistent and effective representation of all requirements.

Review and Approval

- Staff who are familiar with the subject matter of a given document are assigned to review and approve new documents before they are released.
- Staff who are familiar with the original document review and approve changes to a document.

Document Availability and Storage

Controlled copies of documents are:

- available to staff as required;
- maintained, stored and retrievable; and
- compliant with all applicable standards for retention.

Continued on next page

Appendix A. (Continued)

QSE Policy: Documents and Records

Document Master List and Numbering System	• The (responsible function name here) maintains a master list that shows the current revision levels of documents and the current issue levels of documents in our quality system so that staff know if they are using the correct document. • Each document is uniquely identified to ensure traceability throughout the document life cycle.
Review and Issue	• Controlled documents are reviewed on a scheduled basis and reissued after significant changes are made.
Records: Reviews, Retention, Storage, and Retrieval	• Managers and supervisors review records according to established schedules. • Records are retained for periods mandated by government regulations, and for accreditation requirements for the organization's policies. • Records are stored in a manner that maintains integrity and facilitates retrieval.
Supporting Documentation	The following is a list of documents that support this quality system essential: • QP-XX Creation, Review, and Approval of New Documents • QP-YY Master Document Index • QP-ZZ Making Changes to Controlled Documents

End

Appendix B. Key Elements (KEs) of Quality System Essentials for Medical Imaging Services

QSE: Organization

KE-1 Medical imaging planning
KE-2 Provision of services
KE-3 Conformance with regulatory requirements
KE-4 Program for monitoring quality and appropriateness

QSE: Personnel

KE-1 Job qualifications
KE-2 Job descriptions
KE-3 Personnel files
KE-4 Orientation and training
KE-5 Competency assessment
KE-6 Continuing education
KE-7 Performance appraisal

QSE: Equipment

KE-1 Use of standard devices, materials
KE-2 Equipment selection
KE-3 Installation
KE-4 Equipment acceptance standards
KE-5 Calibration
KE-6 Maintenance of all equipment, hardware and software
KE-7 Documentation review and reporting

QSE: Purchasing and Inventory

KE-1 Supplier/Vendor/Contractor qualification
KE-2 Purchasing agreements
KE-3 Pharmacology and radiopharmacology selection
KE-4 Supplies management

QSE: Process Control

KE-1 Adequate and safe work environment
KE-2 Design of effective processes
KE-3 Equipment and process validation
KE-4 Supply use and control
KE-5 Written procedures
KE-6 Quality control program

QSE: Documents and Records

KE-1 Uniformity of written procedures and forms
KE-2 Document revision and control
KE-3 Document and records management

QSE: Occurrence Management

KE-1 System to detect errors
KE-2 Internal occurrence reporting
KE-3 Correction of problems
KE-4 External occurrence reporting

QSE: Internal Assessment

KE-1 Performance measurement and assessment for compliance (QSE and operations)
KE-2 Benchmarking
KE-3 Schedule for internal assessments
KE-4 Corrective actions where needed
KE-5 Reporting

QSE: Process Improvement

KE-1 Planned systematic performance improvement
KE-2 Use of quality tools, where indicated

QSE: Service and Satisfaction

KE-1 Customer satisfaction
KE-2 Obtaining feedback

Appendix C. Sample Quality Process Description for QSE: Personnel

QSE Process: Personnel Management

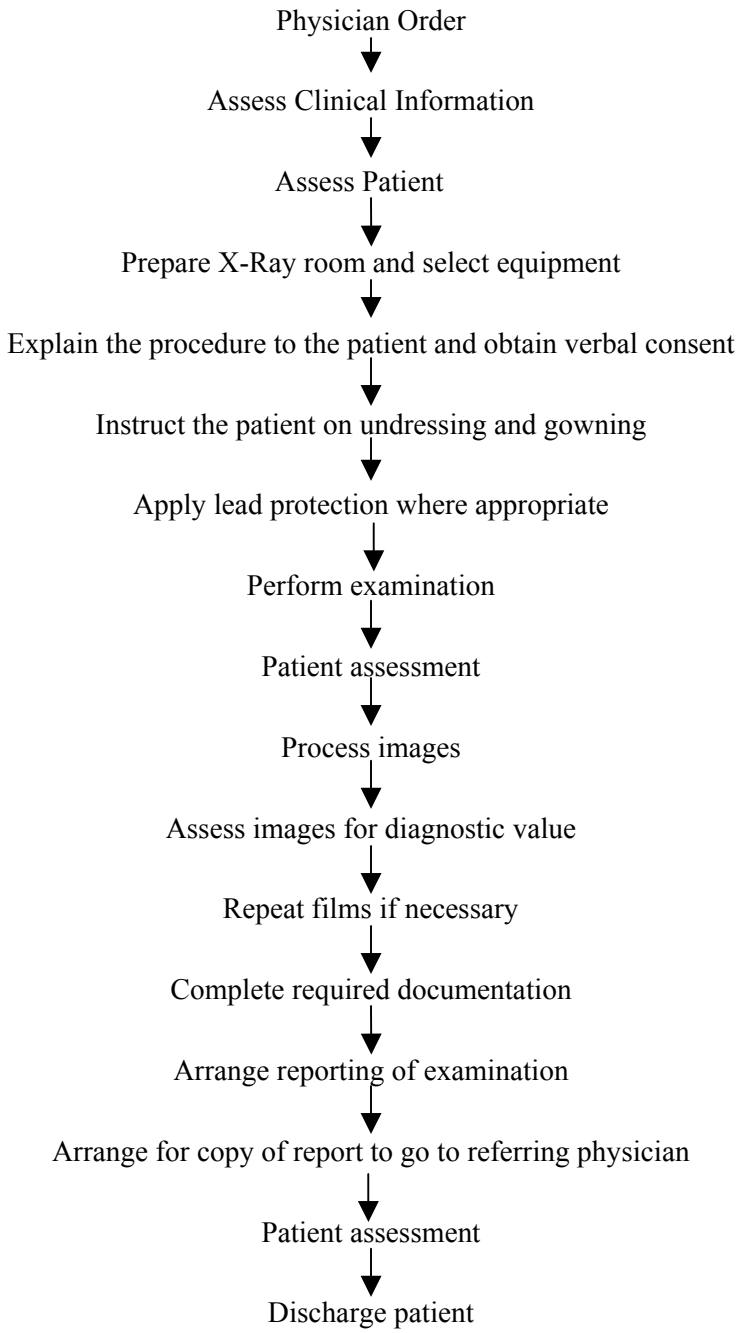
Purpose	To ensure that employees for (facility name/function) are selected consistently and are educated and assessed in a standardized format.
Process	This process is supported by the steps and documents in the table that follows:

What Happens	Who's Responsible	Results: Documents
1. Determines requirements for each job 2. Prepares job description	Medical imaging supervisor	• Job descriptions
3. Develops competency system	Human resources/ Medical imaging supervisor	• Competency documents
4. Conveys organizational knowledge	Human resources	• Employee handbook • Organization checklist • Staff meeting minutes
5. Conveys quality information	Quality coordinator or designee	• Quality manual • CQI, TQM, QC, other, as needed • Quality checklist
6. Communicates departmental information 7. Communicates job-related general knowledge 8. Provides job-specific education (new employee and/or new/revised procedure)	Manager/Supervisor	• Departmental policy manual and checklist • Departmental safety manual and checklist • Standard operating procedures and checklist
9. Completes required education	Employee	• Educational guides • Checklists • Competency documents
10. Evaluates completed education/competency assessment documents 11. Approves employee for job task performance 12. Files completed documents	Manager/Supervisor	• Completed documents

Expected Results: Competent personnel.

Appendix D1. Sample Process Description (Level B) in Medical Imaging Services: X-Ray Examination of Lumbar Spine — Manual Flowchart Format

Operating Process: **X-Ray Examination of Lumbar Spine**



End

Appendix D2. Sample Process Description (Level B) in Medical Imaging Services: X-Ray Examination of Lumbar Spine— Table Format

Operating Process: **X-Ray Examination of Lumbar Spine**

Purpose: To describe the process for radiographic examination of the lumbar spine

Process: The steps and documents in the table that follows support this process

Process/What Happens	Who's responsible	Documents
1. Physician writes order and signs request for lumbar spine X-ray examination	Physician	Standard Operation Procedures for: Medical imaging request for consultation
2. Assess clinical information on request; ensure appropriateness of clinical information with regard to the examination requested	Technologist	Standard Operating Procedures for: Utilization of ionizing radiation Protocols for imaging examinations
3. Assess patient's condition	Technologist/ Appropriate Personnel	Standard Operating Procedures for: Infection control standards Care of patients with special needs Excluding the possibility of pregnancy
4. Prepare X-ray room and select equipment	Technologist	Standard Operating Procedures
5. Explain the procedure to the patient and obtain verbal consent 6. Proceed with examination	Technologist	Standard Operating Procedures for: Consent to treatment
7. Assess patient	Technologist/ Appropriate Personnel	Standard Operating Procedures
8. Instruct the patient on undressing and gowning	Technologist	Standard Operating Procedures
9. Apply lead protection where appropriate	Technologist	Standard Operating Procedures for: Protection of the patient from ionizing radiation
10. Perform examination	Technologist	Standard Operating Procedures for: A.L.A.R.A. principle
11. Process image	Technologist/ Support Staff	Standard Operating Procedures for: Processing equipment performance
12. Assess image for completeness of examination, diagnostic value, correct identifiers	Technologist/ Radiologist	Standard Operating Procedures
13. Repeat films if necessary	Technologist	Standard Operating Procedures for: Repeating of medical image
14. Complete required documentation	Technologist	Standard Operating Procedures for: Documentation
15. Arrange reporting of examination	Technologist/ Radiologist	Standard Operating Procedures for: Report on diagnostic imaging examination
16. Provide copy of report to referring physician	Technologist/ Support Staff	Standard Operating Procedures for: Availability of report
17. Assess patient	Technologist/ Appropriate Personnel	Standard Operating Procedures
18. Discharge and inform patient on how to obtain results	Technologist/ Support Staff	Standard Operating Procedures for: Report generation

Expected Results: Accurate and reliable procedure results.

End

Appendix E. Sample Validation Process Checklist

Process Validation Checklist (Attach documentation to support the following activities):

I. Purpose of Validation

II. Description of the System to be Validated

III. Responsibilities

A. Installation qualification
   1. Performed by
   2. Reviewed by
B. Maintenance and calibration
C. Support services provided by
D. Validation
   1. Performed by
   2. Reviewed by

IV. Validation Protocol

A. Requirements
   1. Standard operating procedures to be used
   2. Personnel to perform
   3. Equipment needed
   4. Material to be used
B. Procedure to be used
C. Data to be collected
D. Acceptance criteria
E. Protocol
   1. Prepared by
   2. Reviewed by
   3. Approved by

V. Validation Activity

VI. Conclusion

A. Validation results
B. Comments/actions
C. Signatures
   1. Performed by
   2. Approved by
   3. Medical director review
   4. Quality function review
D. Results acceptable?
   1. Yes or no
   2. Comments

End

Appendix F. Quality Tools

The following is a list of commonly used quality tools. It is not intended to be a complete list.

- Run and control charts can measure the effect of a process change or variation in processes and outcomes.

- Pareto charts can help determine changes that are most likely to have the greatest effect in reaching the goal.

- Histograms can show how much effect each change had.

- Selection grids and multivoting are specific tools that identify priorities for improvement.

- Brainstorming is an unstructured discussion used for generating ideas on a specific subject or problem.

- Flowcharting is used to identify all steps in a process from start to finish, including all activities performed, decisions made, delay or waiting points, and documentation needed.

- Cause-and-effect diagrams show the many causal relationships between various actions or events leading to a certain outcome.

More information can be found in publications such as:

Tague N. *The Quality Tool Box.* Milwaukee, WI: ASQC Press; 1995.

Wilson PF, et al. *Root Cause Analysis: A Tool for Total Quality Management.* Milwaukee, WI: ASQC Press; 1993.

Appendix G. Sample Document Change Request Form

Change #: _____

DOCUMENT CHANGE REQUEST FORM

Document Name:	
Document Number:	Requestor:
Revision Number	Date:

DESCRIPTION OF CHANGE

RATIONALE FOR CHANGE

RELATED PROCEDURES AFFECTED? _____Yes _____No
IF YES, LIST:

VALIDATION AFFECTED? _____Yes _____No
WHY OR WHY NOT?

SIGNATURE APPROVAL: (As defined in the document control process)

Document Author: _____ Date _____

Supervisor: _____ Date _____

Medical Director: _____ Date _____

ISSUE DATE: _____ EFFECTIVE DATE: _____

End

Appendix H. Sample Master Document Index

Master Index

Document Control Number and Version	Document Name	QSE	Effective Date	Location(s)
MIS4231	**Image Archival/Retrieval**		**1/15/90**	**MIS File Room**
MIS4233	**Preprocedural Preparation**		**2/1/95**	**MIS Administrative Offices**
MIS4233.01	**Upper GI Series Preparation**		**2/1/95**	**MIS Administrative Offices/Procedure Rooms**

End

Appendix I. Components of Orientation and Continuing Education

Component	Contents

Organizational knowledge	• Mission statement
	• General orientation
	• Conditions of employment (employee handbook)
	• Employee benefits
	• Facility tour
	• General safety
	  • hazard communication – general
	  • fire preparedness
	  • disaster preparedness

Departmental knowledge	• Departmental mission
	• Area tour
	• Departmental terminology
	• Departmental rules and policies
	• Dress requirements
	• Safety
	  • general safety and equipment
	  • infection control
	  • hazard communication – medical imaging services-specific

Quality knowledge	• Code of ethics • Organization's and department's quality system • Employee's expected roles

Job-related knowledge	• Standard operating procedures
	  • computer access
	  • recordkeeping
	  • occurrence reporting, etc.
	  • quality system procedures
	  • troubleshooting procedures

Appendix J. Sample Contents for Education Guides

Education Guide Content	Function
Current standard operating procedures	Serves as outline for each procedure
Annotated standard operating procedures	Standard Operating Procedures with notes inserted for use during demonstrations and practice
Required reading	Used by employee to define the required reading to achieve didactic knowledge to achieve competency
Orientation guidelines	Used by employee and educator to define the required knowledge to achieve competency
Learning objectives	Used by employee to evaluate self after practicing the standard operating procedures Used by the educator to assess whether training has been successful Used for periodic ongoing competency assessment to assure skills have been retained Used after remedial education to assure demonstration of required skills
Direct observation checklist	Used by employee to evaluate self after practicing the standard operating procedures Used by the educator to assess whether education has been successful Used for periodic ongoing competency assessment to assure skills have been retained Used after remedial education to assure demonstration of required skills
Quiz or written test	Questions written to assess knowledge of the procedure in areas of: • procedure theory • procedure technique • interpretation • problem solving
Education checklist	Used to assure completeness of education and outcome
Education documentation records	Tracks education and competency over time

Appendix K. Sample Occurrence Report Form (side 1)

(Contributed by Exempla-St. Joseph Hospital Laboratory, Denver, Colorado and adapted to imaging services)

Occurrence Report Form

Department Employees: Complete this section only and return to:		
Initiated by:	Date	Time
Brief description of occurrence: (Do not use names of employees or patients)		
Immediate action taken (short-term solution):		
Time spent on occurrence resolution:		
Was hospital incident report completed?	___ Yes	___ No

DEPARTMENT SERVICE

- ☐ Administration
- ☐ Bone density
- ☐ Cardiac catheterization lab
- ☐ CT
- ☐ Dept. archiving system
- ☐ Dept. computer system
- ☐ Hospital computer system
- ☐ Mammography
- ☐ Medical Ultrasound
- ☐ Medication
- ☐ MRI
- ☐ Nuclear medicine
- ☐ Operating room
- ☐ Orthopedic clinic
- ☐ Other
- ☐ Outpatient surgery
- ☐ Preliminary/final report
- ☐ Radiation therapy
- ☐ Radiology
- ☐ Safety
- ☐ Transport

OCCURRENCE CLASSIFICATION

- ☐ Accident
- ☐ Communication
- ☐ Complaint
- ☐ Delay
- ☐ Equipment malfunction
- ☐ External dept.
- ☐ Injury
- ☐ Medication error/adverse drug reaction
- ☐ Nonpatient-related
- ☐ Patient-related
- ☐ Personal deviation
- ☐ Physician related
- ☐ QC documentation
- ☐ Report error

QUALITY SYSTEM ESSENTIAL

- ☐ Organization
- ☐ Personnel
- ☐ Equipment
- ☐ Purch/Inventory
- ☐ Process Control
- ☐ Documents & Records
- ☐ Occurrence Management
- ☐ Internal Assessment
- ☐ Process Improvement
- ☐ Services & Satisfaction

Continued on reverse side

Appendix K (Continued). Sample Occurrence Report Form (side 2)

OPERATING SYSTEM-MEDICAL IMAGING SERVICES

☐ *PREPROCEDURE*	☐ Patient assessment ☐ Equip prep	☐ Request	☐ Patient prep
☐ *PROCEDURE SESSION*	☐ Patient education ☐ Patient reassessment	☐ Procedure session	☐ Review
☐ *POSTPROCEDURE*	☐ Reporting	☐ Interpretation	☐ Info mgmt

STANDARD OPERATING PROCEDURES INVOLVED

_____

INVESTIGATION OF OCCURRENCE:

Supervisor: _____ Date_____
Quality Coordinator: _____ Date_____

INSTRUCTIONS:

Staff	Complete all sections in the box on the front and return to supervisor.
Section supervisor	Complete the remainder of the form and submit to quality coordinator for entry into the occurrence log database. • Check box for department function. • Classify occurrence: — **planned deviation from standard operating procedures**: approved by supervisor or medical director: — **personal deviation from standard operating procedures**: unapproved deviation from standard operating procedures. — **complaint**: dissatisfaction with any elements of the service. — **QC documentation**: failure to appropriately document QC or any comments associated with QC. — **accident**: nonpreventable occurrence. — **mislabel**: any type of image labeling exclusion or error. — **communication**: lack of optimal exchange of information. — **results report error (A/B/C)**: A= error available to all users. B= error available only in the department. C= cosmetic correction, does not change result. — **external department**: source of occurrence is external to the service or department. — **equipment malfunction**: malfunction not related to deviation from standard operating procedures. — **other**: Describe when none of the above apply. • Choose a quality system essential, where applicable. • Choose the operating system involved in the occurrence. • Identify any standard operating procedures(s) involved. • Determine what factors caused the variance.
Quality coordinator	• Review all occurrence report forms. • Enter all information into the occurrence log database. • Retrieve information for trending information, periodic reports, and identification of quality improvement projects.

End

Appendix L. Sample Occurrence Log

Occurrence Number	Reported By	Occurrence Type	Operating System Involved	Occurrence Source	Corrective Action Completed Date	Corrective Action Verified (Yes or No)	Finalized and Closed Out (date)

Appendix M. Examples of Quality Indicators by Operating System and/or QSE

Procedure Authorization

- Correct reason for procedure
- Complete patient information

Preprocedure Patient Assessment

- Documented patient clinical history
- Adherence to preprocedure instructions

Image Assessment

- Repeat rate
- Reason for repeat

Documentation and Results Reporting

- Report turnaround time
- Accuracy of reporting

QSE: Personnel

- Competency evaluation
- Employee retention
- Radiation monitoring

QSE: Equipment

- Scheduled preventative maintenance
- Equipment availability
- Up-time measures

QSE: Occurrence Management

- Incidents

QSE: Internal Assessment

- On-site inspections/assessments
- Self-inspections/assessments

QSE: Service and Satisfaction

- Telephone response time
- Customer satisfaction surveys
- Complaints/compliments

Related NCCLS Publications*

GP2-A4 **Clinical Laboratory Technical Procedure Manuals—Third Edition; Approved Guideline (2002).** This guideline addresses design, preparation, maintenance, and use of technical procedure manuals in the clinical laboratory.

GP6-A **Inventory Control Systems for Laboratory Supplies; Approved Guideline (1994).** This document contains recommendations for inventory control systems to ensure the availability of reagents and supplies in the laboratory.

GP21-A **Training Verification for Laboratory Personnel; Approved Guideline (1995).** This document provides background and recommends an infrastructure for developing a training verification program that meets quality/regulatory objectives.

GP22-A **Continuous Quality Improvement: Essential Management Approaches; Approved Guideline (1999).** This guideline considers continuous quality improvement (CQI) as a system of managerial programs addressing actualization, quality anticipation, and quality assessment and improvement.

HS1-A **A Quality System Model for Health Care; Approved Guideline (2002**). This document provides a model for healthcare service providers that will assist with the implementation and maintenance of effective quality systems.

NRSCL8-A **Terminology and Definitions for Use in NCCLS Documents; Approved Standard (1998).** This document provides standard definitions for use in NCCLS standards and guidelines, and for submitting candidate reference methods and materials to the National Reference System for the Clinical Laboratory.

* Proposed- and tentative-level documents are being advanced through the NCCLS consensus process; therefore, readers should refer to the most recent editions.

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