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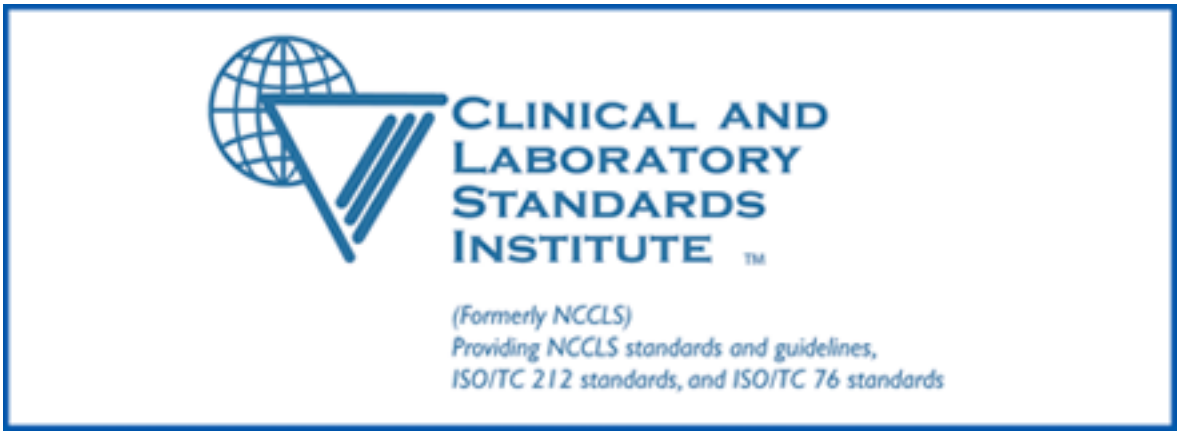
Application of a Quality System Model for Respiratory Services; Approved Guideline



This document provides a model for providers of respiratory 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 Respiratory Services; Approved Guideline

Abstract

NCCLS document HS4-A—*Application of a Quality System Model for Respiratory 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 respiratory service's processes, assess its performance, and implement quality improvements. Individual service areas, such as respiratory therapeutics, pulmonary diagnostics, or sleep diagnostics can apply this model to their respective operations. To provide a practical example of how a quality system is developed and implemented for respiratory services, suggestions for the pulmonary diagnostic laboratory and respiratory therapeutics are included.

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Application of a Quality System Model for Respiratory Services; Approved Guideline

Volume 22 Number 23

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Contents

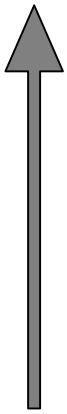
Foreword

In the present environment of limited resources, it is expected by those who fund, provide, and receive healthcare services that quality is integral. This document defines a model for those who provide respiratory 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, though the terminology and concepts used are more familiar to the healthcare entities.

The model for respiratory services is an application of NCCLS document HS1— *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.

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 needed, it is becoming more apparent that healthcare organizations need 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 respiratory 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.

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 providing respiratory 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 Respiratory Services; Approved Guideline

1 Introduction

HS4 is one document in a quality series designed for healthcare service managers who wish to improve their programs through quality management activities. This companion document provides specific guidance for the application of the quality system model to respiratory services. This guideline is intended to be used together with the comprehensive program of quality improvement described in NCCLS publication HS1—*A Quality System Model for Health Care*. These guidelines provide users with a complementary set of quality system resources designed to assist any healthcare organization in establishing or fortifying its quality system infrastructure.

The structure described in this document is for a quality system in respiratory 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. NCCLS HS1 stems 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 (QSEs) are:

- Organization
- Personnel
- Equipment
- Purchasing and inventory
- Process control
- Documents and records
- Occurrence management
- Internal assessment
- Process improvement
- Service and satisfaction
- Information Management
- Facilities and Safety

Concurrently with the development of the rudiments of a quality system for blood banking, there has also been a growing awareness of the existence of the international guidance for quality being used in the manufacturing and service industries. International guidance is documented as the ISO 9000 family of quality standards.[10] The subcommittee has considered the following documents in the drafting of this guideline: ISO 9001:1994 *Quality Systems — Model for quality assurance in design, development, production, installation and servicing*[11]; ISO/DIS 15189, *Quality management in the clinical laboratory* [12]; and ISO/IEC DIS 17025, *General requirements for the competence of testing and calibration laboratories,*[13]*;* ISO 9004:2000, *Quality management systems—Guidelines for performance improvements*.[14] 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 twelve 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 NCCLS Document HS1—*A Quality System Model for Health Care* and is applied to respiratory 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 - An undesirable or unfortunate happening that occurs unintentionally.

Audit - A planned, independent, and documented assessment to determine whether agreed-upon requirements are being met (American Society for Quality (ASQ), Quality Audit Division[15]).

Calibration - 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 (VIM93-6.11[16]).

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

Contract review - Defined activities carried out before entering into a contract agreement to ensure that requirements are adequately defined and understood, and can be achieved (ISO 8402, 3.10[17]).

Corrective action - Action taken to eliminate the cause(s) of existing problems, defects, or any other undesirable situation in order to prevent recurrence (ISO 8402, 4.14[17]).

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

Customer - The recipient of a product or service provided by the supplier (ISO 8402, 1.9[17]).

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

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

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

Incident - An individual occurrence or event.

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

Medical error - Any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in control of the health care professional, patient, or consumer. Such events may be related to professional practice, health care product, procedures and systems, including prescribing; order communication; education; monitoring; and use.[18]

Occurrence - Something that happens; an event, incident.

[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.

Policy - A written statement of overall intentions and directions defined by those in the organization and endorsed by management (AABB[19]).

Preventive action - Action taken to eliminate the cause(s) of potential problems, defects, or any other undesirable situation in order to prevent occurrence (ISO 8402, 4.13[17]).

Preventive maintenance - 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 - A specified way to perform an activity (ISO 8402, 1.31[17]).

Process - One or more interrelated resources and/or activities that transform inputs (e.g. intent, policies) into outputs (e.g., instruction, procedures) (ISO 8402, 1.2[17]).

Proficiency testing/External quality assessment/PT//EQA - A program in which multiple specimens are periodically sent to members of a group of laboratories for analysis and/or identification; whereby each laboratory's results are compared with those of other laboratories in the group and/or with an assigned value, and reported to the participating laboratory and others.

Quality - The totality of characteristics of an entity that bear on its ability to satisfy stated and implied needs (ISO 8402, 2.1[17]).

Quality assurance - Planned and systematic activities to provide adequate confidence that requirements for quality will be met (ISO 8402, 3.5[17]).

Quality control - Operational techniques and activities that are used to fulfill requirements for quality (ISO 8402, 3.4[17]).

Quality management - 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 (ISO 8402, 3.2[17]).

Quality policy - Overall intentions and direction of an organization with regard to quality (e.g., quality system essentials) as formally expressed by top management (ISO 8402, 3.1[17]).

Quality system - The organizational structure, resources, processes, and procedures needed to implement quality management (ISO 8402, 3.6[17]).

Record - A document that furnishes objective evidence of information obtained, activities performed, or results achieved (ISO 8402, 3.15[17]).

Service - 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 (ISO 8402, 1.5[17]).

Statistical tools - Methods and techniques used to generate, analyze, interpret, and present data.

Supplier - An organization that provides a product or service to the customer (ISO 8402, 1.10[17]).

Traceability - 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 (VIM93-6.10); 2) The ability to trace the history, application, or location of an entity by means of recorded identifications (ISO 8402, 3.16[17]).

Validation - Action [or process] of proving that a procedure, process, system, equipment, or method used works as expected and achieves the intended result (ISO 8402, 2.18[17]).

Verification - The confirmation by examination and provision of objective evidence that specified requirements have been fulfilled (ISO 8402, 2.17[17]).

4 Introduction to the Path of Workflow

In healthcare organizations, there are multiple units providing various services. Each of these units can apply the organization's quality systems to their operational activities. Mapping these unit activities creates a "path of workflow" to accomplish the assigned tasks. The path of workflow describes the operational aspects that define how a particular service or product is provided. ISO 9000 describes this concept as the "process model." It represents the sequence of activities from the initiation of a request for the healthcare service's products or services through the provision of those products or services, and any necessary follow-up. The activities may cross functional boundaries.

5 Path of Workflow

5.1 Pulmonary Diagnostics

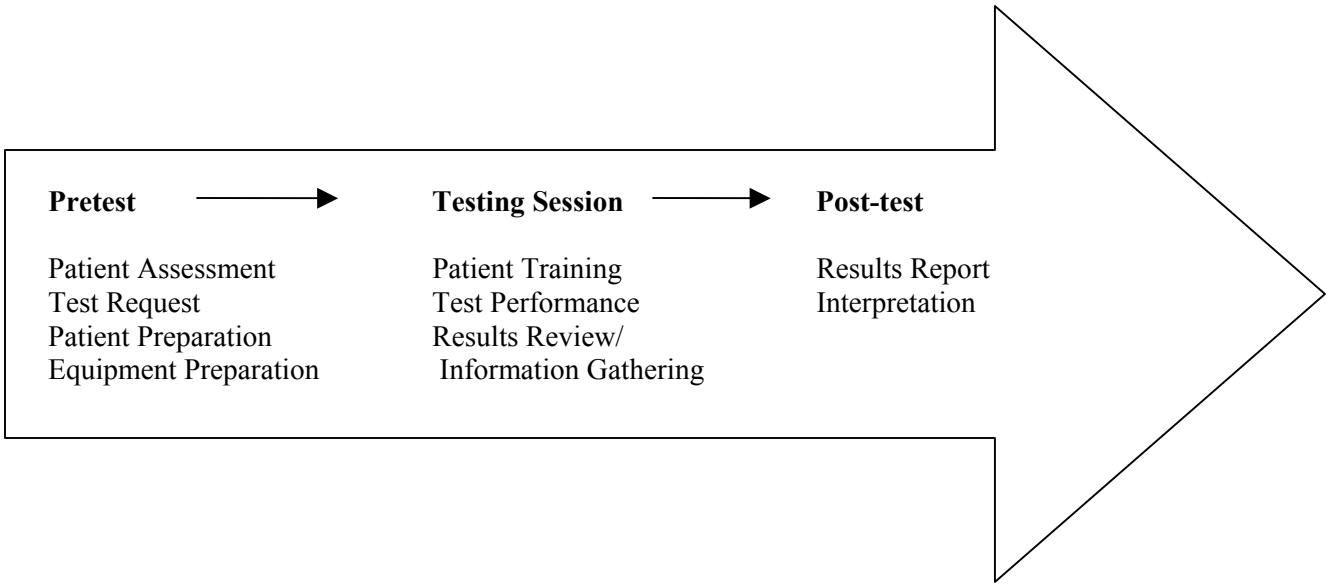


Figure 1. Path of Workflow for Pulmonary Diagnostics. Adapted from NCCLS document HS1—*A Quality System Model for Health Care.*

QSEs apply to all operations across the path of workflow. The operating systems in the path of workflow are shown within the structure in Figure 1.

5.1.1 Pretest Phase

Elements of the pretest phase include:

Patient Assessment

- clinical history
- patient signs and symptoms

- other indicators that guide the physician or practitioner to make recommendations related to appropriate testing
- standardized ordering format may guide the process

Test Request Process

- generating the order
- patient instructions
- scheduling
- sequencing of test performance may impact test results

Patient Preparation

- specific demographic and history information from the patient (e.g., questionnaires, height and weight)
- assessing patient compliance with pretest instructions
- verifying the clinical indication or contraindications for testing
- consent forms when appropriate

Equipment Preparation

- calibration and gathering equipment and supplies
- selection of reference values

5.1.2 Testing Session

The testing session should include the following elements:

Patient Training

- procedure explanation and demonstration

Test Performance

- according to best clinical practice guidelines[20-32]
- patient understanding and ability to perform the test
- recognition of equipment or test performance errors

Results Review and Selection

- conformance to laboratory, and best clinical practice guidelines[20-32]
- data and graphic review and selection
- therapist/technologist comments

Patient Assessment for Further Testing

- utilization of patient-driven protocols
- correlation of results with the patient's clinical presentation

5.1.3 Post-test Phase

The post-test phase emphasizes the following:

Results Report

- quality review
- report generation

Interpretation

- conformance to laboratory and best clinical practice guidelines[20]

Clinical Consultation

- application of results to clinical interventions
- verbal reporting

5.2 Respiratory Therapeutics

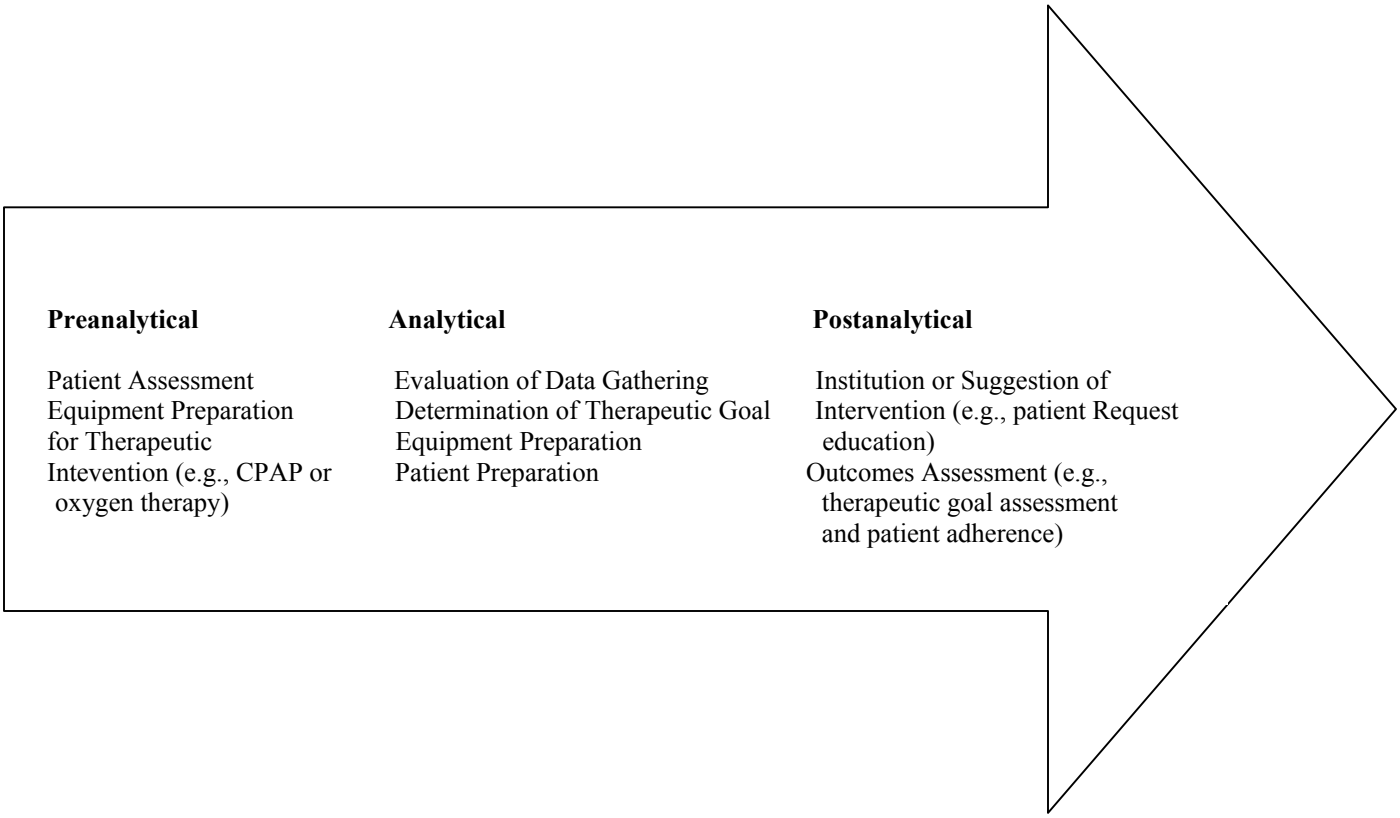


Figure 2. Path of Workflow for Respiratory Therapeutics. Adapted from NCCLS document HS1—*A Quality System Model for Health Care.*

5.2.1 Preanalytical Phase

The preanalytical phase encompasses the following elements (see Figure 2):

Information Gathering:

- chart review (e.g., advance directives, test results, physician progress notes)
- review of chest x-ray
- consultation with other care providers

Patient Assessment:

- clinical history
- patient signs and symptoms
- allergy information
- physical assessment
- standardized ordering formats and care paths (Protocols may guide the process.)

Equipment Preparation:

- calibration and gathering of equipment and supplies (e.g., peak flow meter, oximeter)

Request for Therapeutic Intervention:

- scheduling and/or sequencing of interventions

Patient Preparation:

- creating an environment for patient or significant others' participation in the applications of respiratory services

5.2.2 Analytical Phase

The analytical phase addresses the following elements (see Figure 2):

Evaluation of Data Gathering:

- patient assessment
- information gathering

Determination of Therapeutic Goals:

- conferencing with other providers
- clinical indications versus contraindications
- efficacy
- desired outcome
- utilization of patient-driven protocols

Equipment Preparation:

- calibration and gathering of equipment and supplies for therapeutic intervention

Patient Preparation:

- explain procedure to patient or significant other
- assess patient compliance
- complete consent forms, where appropriate

5.2.3 Postanalytical Phase

The following elements are considered during the postanalytical phase (see Figure 2):

Institution or Suggestion of Intervention:

- conformation to best clinical practice guidelines

Outcome Assessment:

- therapeutic goal assessment
- correlation of results with patient's clinical presentation
- utilization of patient-driven protocols

Clinical Consultation:

- application of results and/or clinical intervention
- verbal reporting

5.3 Integration of Therapeutic and Diagnostic Paths of Workflow

In some instances, the path of workflow that begins as one process will integrate with a second path of workflow. This can best be illustrated looking at sleep disorder testing and treatment, as depicted in Figure 3, on the following page.

The typical path of workflow begins as pulmonary diagnostics with the pretest requirements completed. The movement to the testing session is the location that the path of workflow may become an integrated path of workflow with respiratory therapeutics.

In the testing session, many sleep centers, utilizing a protocol, may initiate a split-night sleep study. The treatment begins with the initiation of CPAP based on pre-established criteria. The patient then moves from the pure diagnostic path to a path for therapeutic intervention. In this case, the path of workflow will follow the respiratory therapeutic flow beginning with preanalytical stage and move to the analytical stage. As the treatment proceeds with CPAP adjustments, the interventions will remain therapeutic. Once the treatment criteria are established, the path of workflow reverts to the pulmonary diagnostics flow at the post-test level, and the path is completed.

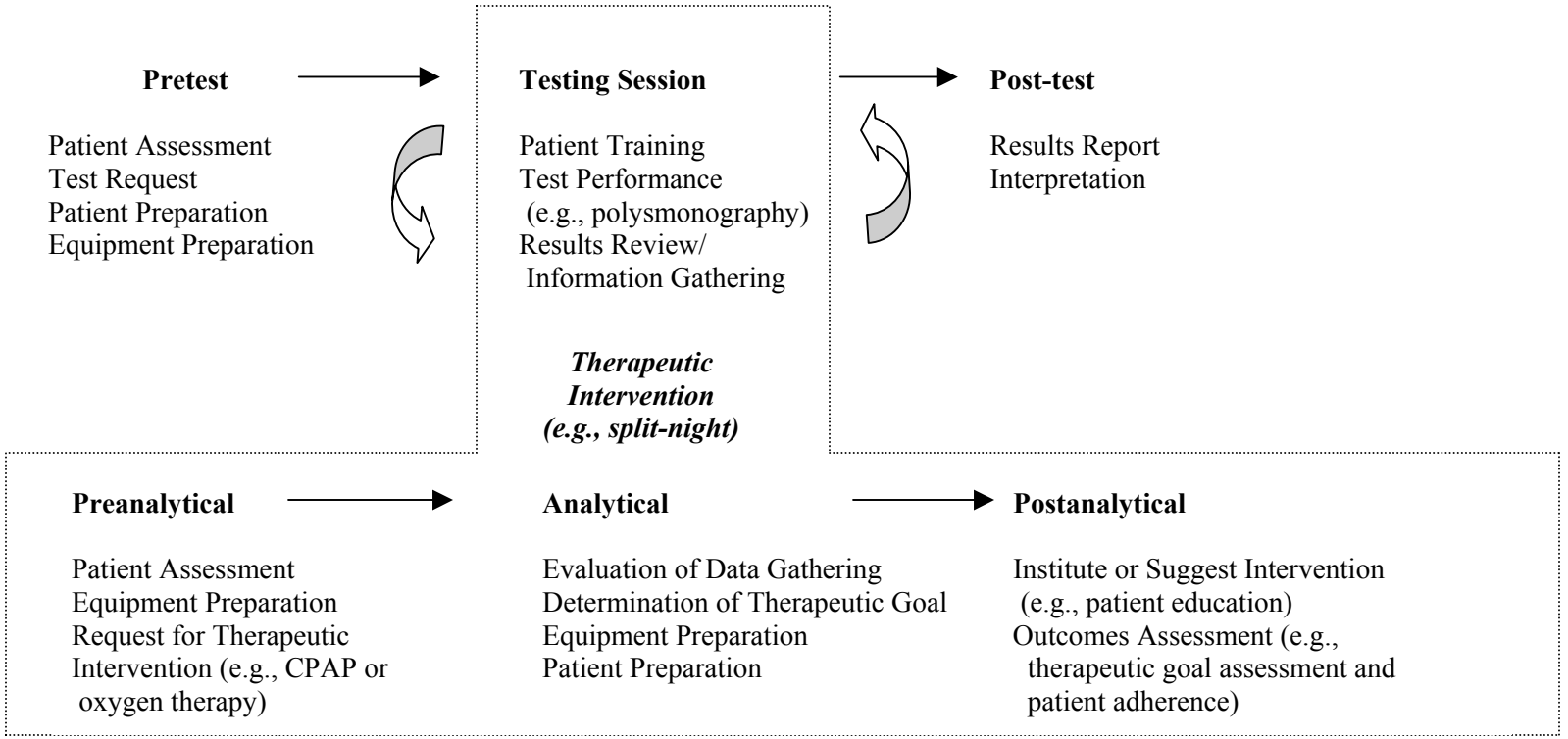


Figure 3. Structure for an Integrated Respiratory Service Path of Workflow. Adapted from NCCLS document HS1—*A Quality System Model for Health Care*

5.4 Application of Path of Workflow Across the Continuum of Care

An individual may enter the continuum of care at any point. 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, pulmonary rehabilitation, SNF, subacute care);
- Wellness and prevention (e.g., community care, occupational/environmental services, pulmonary rehabilitation, smoking cessation programs); and
- Primary care (e.g., diagnostic services, educational services, therapeutic services).

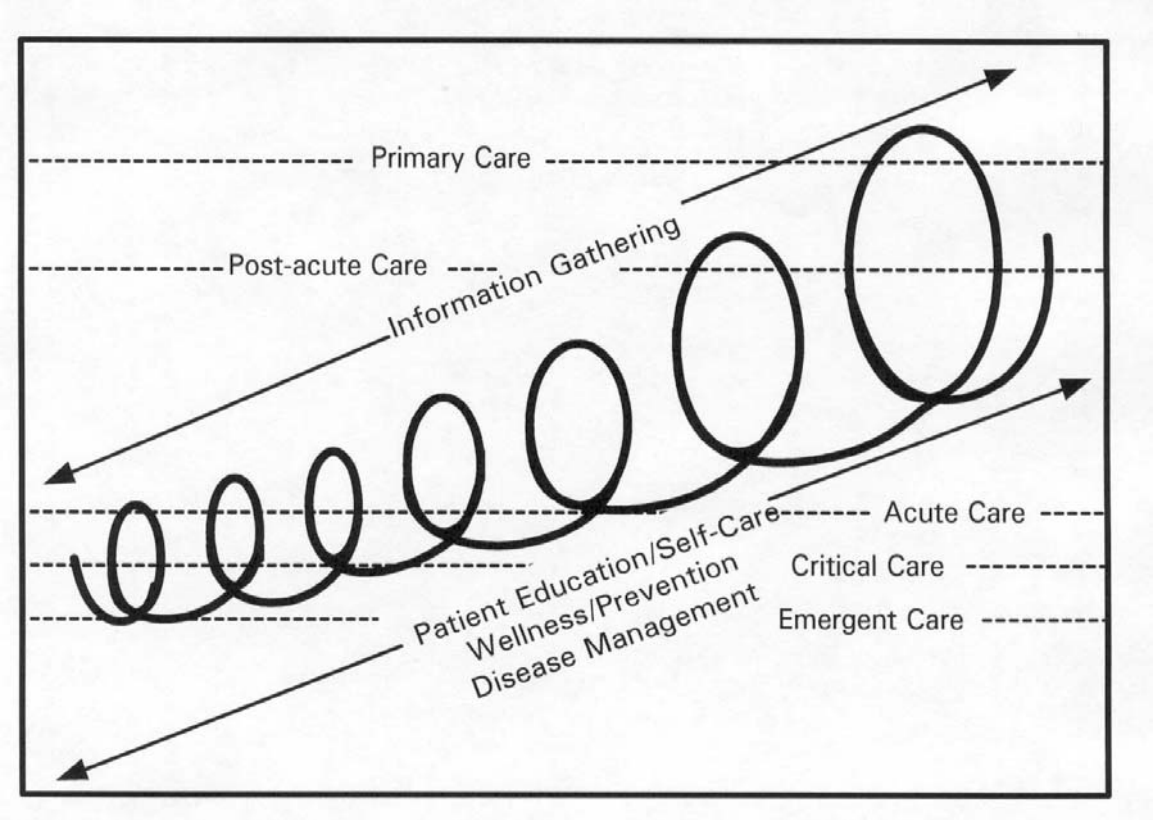


Figure 4. The Continuum of Care

The spiral depicted in Figure 4 represents the frequency of assessment and intervention by the respiratory therapist 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 the respiratory therapist.

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 diagnostics and therapeutics apply across the continuum of care.

6 Application of Quality System Essentials (QSEs) to Respiratory Care Services

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 respiratory services.

6.1 QSE: Documents and Records

6.1.1 Document Control

Document control is a means to ensure that only the latest version of approved documents are being used by the staff. The respiratory service and/or laboratory should appoint someone with the vested responsibility for overseeing the document control system. Document control includes:

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

6.1.1.1 Document Identification (numbering/coding)

Each 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 respiratory services and/or pulmonary laboratory 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

Example #2: This is an example of a document identification number for a test procedure used in the pulmonary function laboratory's testing operations.

PF525S.01
Where PF = Pulmonary Function
525 = procedure document number 525
S = Spirometry
.01 = first version

Example #3: This is an example of a document identification number for a form used in the respiratory service department's operations.

RC625A.02
Where RS = respiratory services
625 = procedure document number 625
A = form A for this procedure
.02 = second version

6.1.1.2 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, the use of colored paper or stamps are other examples of version identification.

6.1.1.3 Revision Control

In a quality system, a formal means of revision 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. Deficiencies regarding documents are among the most common cited by regulatory and accreditation agencies. The following example (see Figure 5) of a document change request form commonly used in quality systems may assist to request changes to approved documents. Services 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.

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

Document number/version Facility Name/Location Page 1 of 1
Effective Date

Figure 5. Sample Document Change Request Form

6.1.1.4 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 hardcopy 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.

6.1.1.5 Master Index Example

The master index illustrated in Figure 6 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. Software applications for personal computers, such as spreadsheets and databases, are also useful for maintaining the master index.

Master Index

Document Control Number and Version	Document Name	Effective Date	Location(s)
PF625S.02	Spirometry	1/15/90	PF lab/RC dept.
PF625S.03	Spirometry	2/1/95	PF lab/RC dept./Outreach clinic/asthma center

Figure 6. Sample Master Document Index

6.1.1.6 Distribution

The document master file and index should indicate each location where active copies of a document are placed. Document locations may be added or deleted as needed by the pulmonary laboratory/respiratory service. The same process is applicable to electronic document formats.

6.1.1.7 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. Duration of retention may be defined by regulations or accreditation requirements for laboratories, and the organization's business requirements.

6.1.2 Records Management

6.1.2.1 Records Review

Reviews of records should be performed according to regulations and accreditation requirements for the respiratory service's and or the laboratory's own policies and procedures. Policies and procedures are usually reviewed on an annual basis. All reviews should be documented with the review date and the reviewer's name/initials.

6.1.2.2 Archiving

Records must be stored in a manner to prevent loss or damage and to promote easy retrieval. The duration of retention may be defined by regulations or accreditation requirements for laboratories and the organization's business requirements.

6.2 QSE: Organization

To accomplish the objective of improving operations and services to its customers, the healthcare organization's executive management, the respiratory services management and/or pulmonary diagnostics laboratory management, and respective medical directors must actively support establishing and maintaining the quality system. Visible participation of medical and administrative management in setting 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 for any respiratory service or pulmonary laboratory service.[21,22]

It is advisable to select a team composed of representatives of each section of respiratory services (therapeutics, rehabilitation, home care, sleep) and a staff member knowledgeable in quality process to oversee the implementation of the quality system phases. For example, in pulmonary diagnostics, a team composed of pulmonary laboratory staff and a staff member knowledgeable in quality process may oversee the implementation of the quality system phases. 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.

6.2.1 Staff Involvement

It is necessary to include all respiratory and diagnostic staff members in the implementation of the quality system. At a minimum, all employees should receive training on the quality system and their responsibilities in the training, occurrence management, and data collection/indicator monitoring processes. All staff should participate in flowcharting their respective work processes, identifying where SOPs are needed, and recommending changes for improvement. Staff involvement in organization-wide quality improvement teams is encouraged.

6.3 QSE: Personnel

6.3.1 Job Qualifications and Descriptions

The responsibility for specifying job qualifications and descriptions should reside within each respiratory service and should meet recommended minimum job qualifications.[21-32]

6.3.2 Development and Documentation of Training and Competence Assessment Programs

Respiratory services and pulmonary laboratories should provide orientation, training, and competence assessment to ensure good laboratory practice.[21]

6.3.2.1 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);
- respiratory or pulmonary laboratory orientation, general respiratory service requirements, and competency assessment;
- safety training;
- computer training;
- job-specific tasks; and
- the organization's, respiratory and/or laboratory's quality system, the employee's role, and the use of continuous improvement tools and techniques.

Table 1 provides a more detailed listing of the components of a training program for the pulmonary laboratory service.

Table 1. Components of a Training Program for the Arterial Blood Gas (ABG) and Pulmonary Function (PF) Laboratory Service

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 • Blood-borne pathogens • Hazard communication—laboratory specific • Tuberculosis
Quality knowledge	Code of ethics Organization's and department's quality system Organization's problem solving approach Department's quality assurance program Laboratory's quality control program Employee's expected roles in each of the above
Job-related knowledge	Listing of SOPs that everyone in the department must follow • Computer access • Record keeping • Occurrence reporting, etc. Listing of SOPs that persons with that job must follow • Test procedures • Quality control procedures • Troubleshooting procedures, etc.

There should be a written description of the respiratory and/or laboratory's process for training when:

- new employees are hired;
- new procedures have been implemented;
- procedures are changed;
- periodic reverification of competency is required; and when
- retraining and remediation is necessary.

The training guide should also include a plan for assessing age-specific skills.

6.3.2.2 Training Guides

Training guides are useful in conveying important background information to employees and include the rationale for particular actions in a procedure. Training guides provide instructions for both trainers and trainees and help assure that each trainee receives the same basic information every time. Table 2 displays sample contents for a training guide.

Table 2. Sample Contents for Training Guides

Training Guide Content	Function
Current SOP	Serves as outline for each procedure in the training guide.
Annotated SOP	SOP with training notes inserted for use by the trainer during demonstrations and practice.
Required reading	Used by employee to define the required reading to achieve didactic knowledge to achieve competency.
Cognitive orientation guidelines	Used by employee and trainer to define the required knowledge to achieve competency.
Learning objectives	Used by employee and trainer to define the scope of training.
Direct observation checklist	Used by employee for self-evaluation after practicing the SOP. Used by the trainer to assess whether training has been successful. Used for periodic ongoing competence assessment to assure skills have been retained. Used after remedial training 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
Training checklist	Used to assure completeness of training and outcome.
Training documentation records	Tracks training and competence over time.

Guidance on the preparation of training guides can be found in the most recent version of NCCLS document GP21— *Training Verification for Laboratory Personnel*.

6.3.2.3 Competence Assessment

Individuals providing respiratory services should have their competence assessed initially and periodically thereafter to determine if they have maintained and continue to demonstrate the skills for which they were trained. Competence assessment should include the need for retraining and remediation. Competence assessment applies to all employees, and competency expectations should be well defined. The remediation process should be documented and quantified.[33-35]

6.3.2.4 Documentation of Training and Competence Assessment

All training and competence assessments must be documented. When assessments fail to meet expectations, retraining must be initiated and documented.

The respiratory and laboratory service should develop a system to document and track employee training and competence assessment. Documentation systems can be manual[34,36] or computerized.[37,38]

Guidance for development of a manual documentation system for training and competence assessment can be found in the most current edition of NCCLS document GP21—*Training Verification for Laboratory Personnel*.

6.4 QSE: Equipment

6.4.1 Equipment Management Plan for Pulmonary Diagnostics

There should be a pulmonary laboratory equipment management plan so that all instruments and equipment are properly selected, installed, calibrated, and function verified.

6.4.1.1 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 matrix.[39,40]
(3) Evaluation of selected equipment; equipment should meet or exceed minimum equipment performance standards.
(4) Determination of acceptable limits of accuracy and precision.
(5) Consideration of database management options.
(6) Consideration of quality control standards and ease of calibration routines.
(7) Consideration of the computer standards for the healthcare system.
(8) Identification of well-defined warranty and service agreements.
(9) Performance of an on-site evaluation of the equipment.[40]
(10) Comparison of test results between the old equipment and the new equipment.

6.4.1.2 Equipment Installation

There should be a plan for installing all new pieces of equipment and instrumentation to verify proper functioning prior to reporting test results. The plan should include verifying the adequacy of the facilities such as electricity, ventilation, temperature, and other environmental conditions. Verification activities should be documented and the installation process should include:

- the development of an installation manual;
- equipment validation performed by the manufacturer;
- equipment validation performed by the pulmonary laboratory staff;
- biomedical safety checks performed by an internal or external biomedical department (may be included in the preventive maintenance provided by the manufacturer); and
- validation of selected reference values by the laboratory under medical supervision (i.e., medical director).

The laboratory should determine the requirements for calibration, quality control, maintenance, and adjustments. 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. The laboratory should have written SOPs for all calibration, maintenance, quality control, and performance monitoring activities.[22-29]

6.4.2 Equipment Management Plan for Respiratory Therapeutics

There should be an equipment management plan so that all instruments and equipment are properly selected, installed, calibrated, and function verified. The equipment management plan should include:

6.4.2.1 Equipment Selection

(1) Develop a list of acceptable vendors based on the defined equipment needs and required specifications.
(2) Develop a product-evaluation matrix.[39,40]
(3) Evaluate selected equipment; equipment should meet or exceed minimum equipment performance standards, or other performance standards.[41]
(4) Determine acceptable limits of accuracy and precision.
(5) Consider database management options.
(6) Consider quality control standards and ease of calibration routines.
(7) Consider the computer standards for the healthcare system.
(8) Identify well-defined warranty and service agreements.
(9) Perform an on-site evaluation of the equipment.[40]
(10) Compare performance between the old equipment and the new equipment.
(11) Consider ability to update equipment software.

6.4.2.2 Equipment Installation

There should be a plan for installing all new pieces of equipment and instrumentation to verify proper functioning prior to use. The plan should include verifying the adequacy of the facilities such as electricity, ventilation, temperature, and other the environmental conditions. Verification activities should be documented and the installation process should include:

- the development of an installation plan and documentation (e.g., original documents) by an independent source or by staff;
- equipment validation performed by the manufacturer as appropriate;
- biomedical safety checks performed by an internal or external biomedical department;
- equipment validation performed by staff; and
- validation of methodology (e.g., nitric oxide, heliox) under medical supervision (i.e., medical director).

Each respiratory service should determine the requirements for calibration, quality control, maintenance, and adjustments based on the organization's operational requirements and the manufacturer's requirements. 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 postrepair recalibration or revalidation. Each respiratory service should have written SOPs for all calibration, maintenance, quality control, and performance monitoring activities.[21,32,41]

A comprehensive equipment management plan for all services should include a master list of all equipment and instruments with respective identifying information, calibration and maintenance schedules, and persons designated to review the plan and respective records at defined intervals.[21]

6.5 QSE: Purchasing and Inventory

Efficient and cost-effective respiratory, pulmonary and arterial blood gas laboratory operations need the uninterrupted availability of supplies and services. Each service should set expectations, and build and maintain good relationships with providers of materials and services. Services should have a process to receive and evaluate incoming critical materials (e.g., methacholine, ABG controls, disposable vinyl supplies) to assure that necessary requirements have been fulfilled.[42]

6.5.1 Purchasing

The respiratory and/or laboratory should identify critical supplies and services and define the necessary characteristics or functional requirements for each. All products, including substitutions, must meet the pre-established requirements. These expectations should be communicated to the respective vendors, who are then evaluated for the ability to meet the service's requirements. Vendor approval may be granted based on criteria such as licensure or approval of test methods or instruments; external certification of the vendor's quality system (e.g., ISO 9000 series registration/certification); a review of past history with the vendor; or any other facility-determined criteria.

Contracts to obtain critical supplies, materials, and other services should be reviewed to ensure that each party's expectations are defined. Any amendments or other changes should also be reviewed and approved by both parties.

6.5.2 Inventory

The respiratory service and/or laboratory must have a process to receive incoming materials and supplies, inspect them prior to acceptance, test them prior to use where required, and maintain an adequate inventory.

Guidance for a laboratory inventory control system can be found in the current edition of NCCLS document GP6— *Inventory Control Systems for Laboratory Supplies*.

6.6 QSE: Process Control

It is only through understanding and controlling the respiratory or pulmonary laboratory's many processes that it can become both more effective in meeting requirements and more efficient in the use of its costly human and other resources.

6.6.1 Developing Flowcharts for Respiratory and Laboratory 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 SOPs 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.

Figures 7, 8, and 9 illustrate a process in the pulmonary laboratory's path of workflow for spirometry test result selection and reporting. This process, presented in three formats (Figure 7-Manual; Figure 8-Table; Figure 9-Electronic), describes the responsibilities, actions, and documents needed for selection and reporting of spirometry test results. This process lists SOPs for specific tasks that must be properly performed for the process to be successfully accomplished.

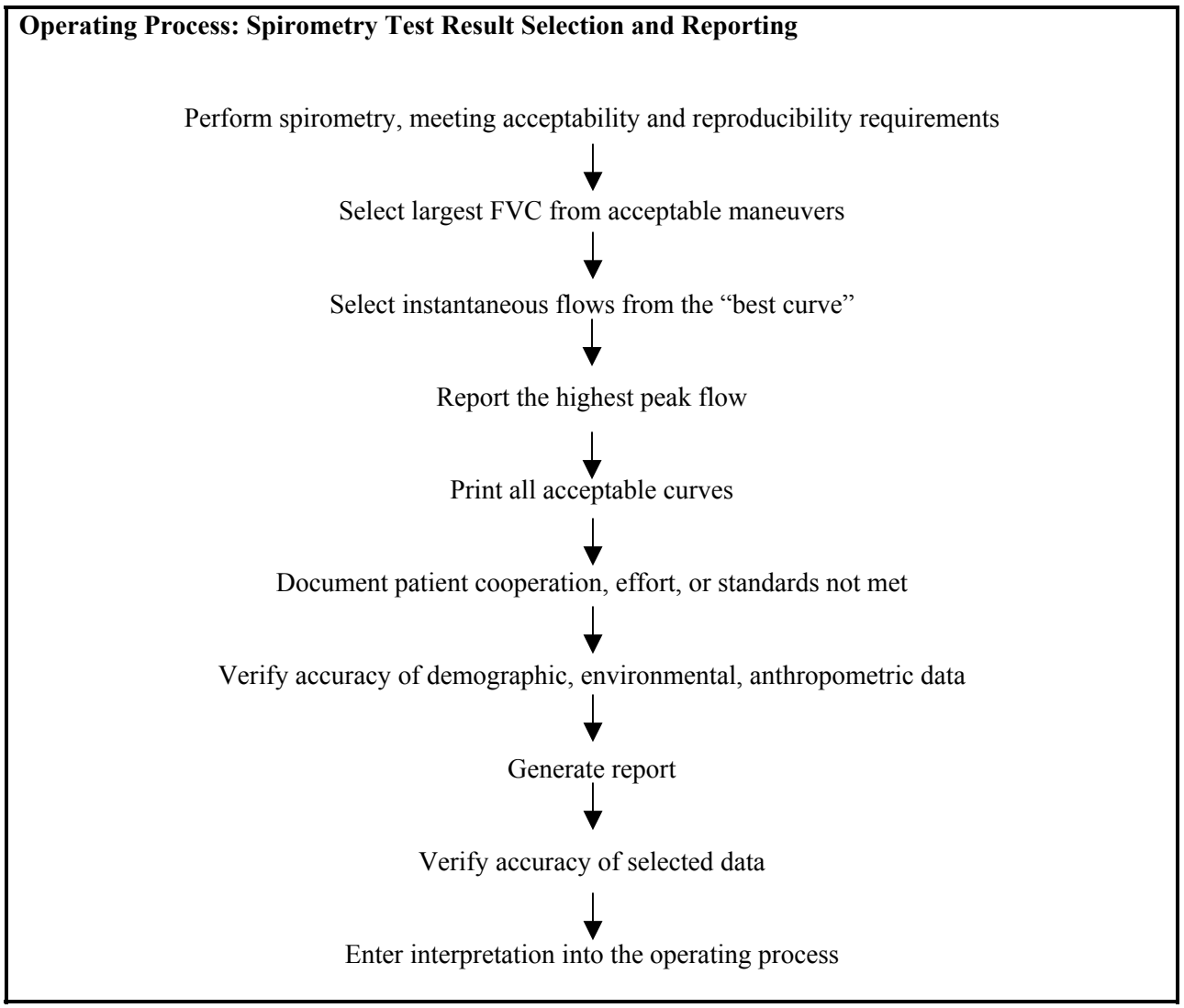


Figure 7. Sample Process Description in PF Laboratory Operations: Spirometry Test Result Selection and Reporting— Manual Flowchart Format

Operating Process: Spirometry Test Result Selection and Reporting

Purpose To describe the process for spirometry test result selection and reporting.

Process This process is supported by the steps and documents in the table that follows:

What Happens	Who's Responsible	Results: Documents
1. Performs spirometry meeting ATS acceptability and reproducibility criteria.[24]	Therapist/Technologist	SOPs for: • Spirometry performance
2. Selects largest FVC from acceptable maneuvers. 3. Selects largest FEV1 from acceptable maneuvers. 4. Selects instantaneous flows from the "best curve." 5. Selects highest peak flow.	Therapist/Technologist	SOPs for: • Data selection • Selection of best curve
6. Prints all acceptable curves.	Therapist/Technologist	SOPs for: Data to print and maintenance of hard copies
7. Documents patient cooperation, effort, and standards not met. 8. Verifies accuracy of demographics, environmental, and anthropometric data. 9. Verifies accuracy of selected data.	Therapist/Technologist	SOP for: • Report comments • Data entry criteria
10. Generates report.	Therapist/ Technologist Support staff	SOP for: • Report generation and entry into interpretation process

Expected Results: Accurate and reliable test results.

Figure 8. Sample Process Description in Pulmonary Function (PF) Laboratory Operations: Spirometry Test Result Selection and Reporting— Table Format

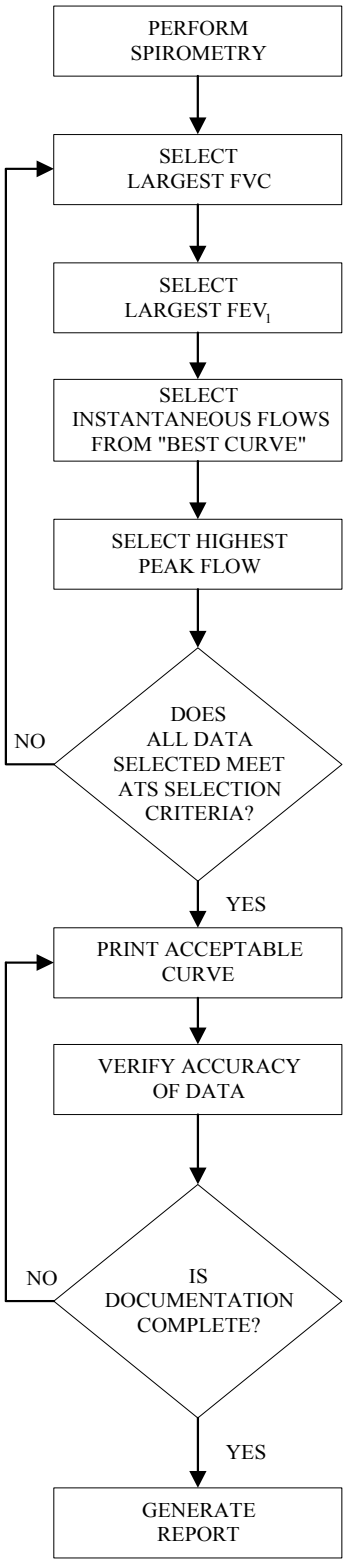


Figure 9. Sample Process Description in Pulmonary Function (PF) Laboratory Operations: Spirometry Test Result Selection and Reporting— Electronic Flowchart Format

Figures 10, 11, and 12 illustrate a process in the path of workflow for sputum induction. This process, presented in three formats: Figure 10 (Manual); Figure 11 (Table) and Figure 12 (Electronic) describes the responsibilities, actions, and documents needed for completion of a sputum induction protocol. This process lists SOPs for specific tasks that must be properly performed for the process to be successfully accomplished.

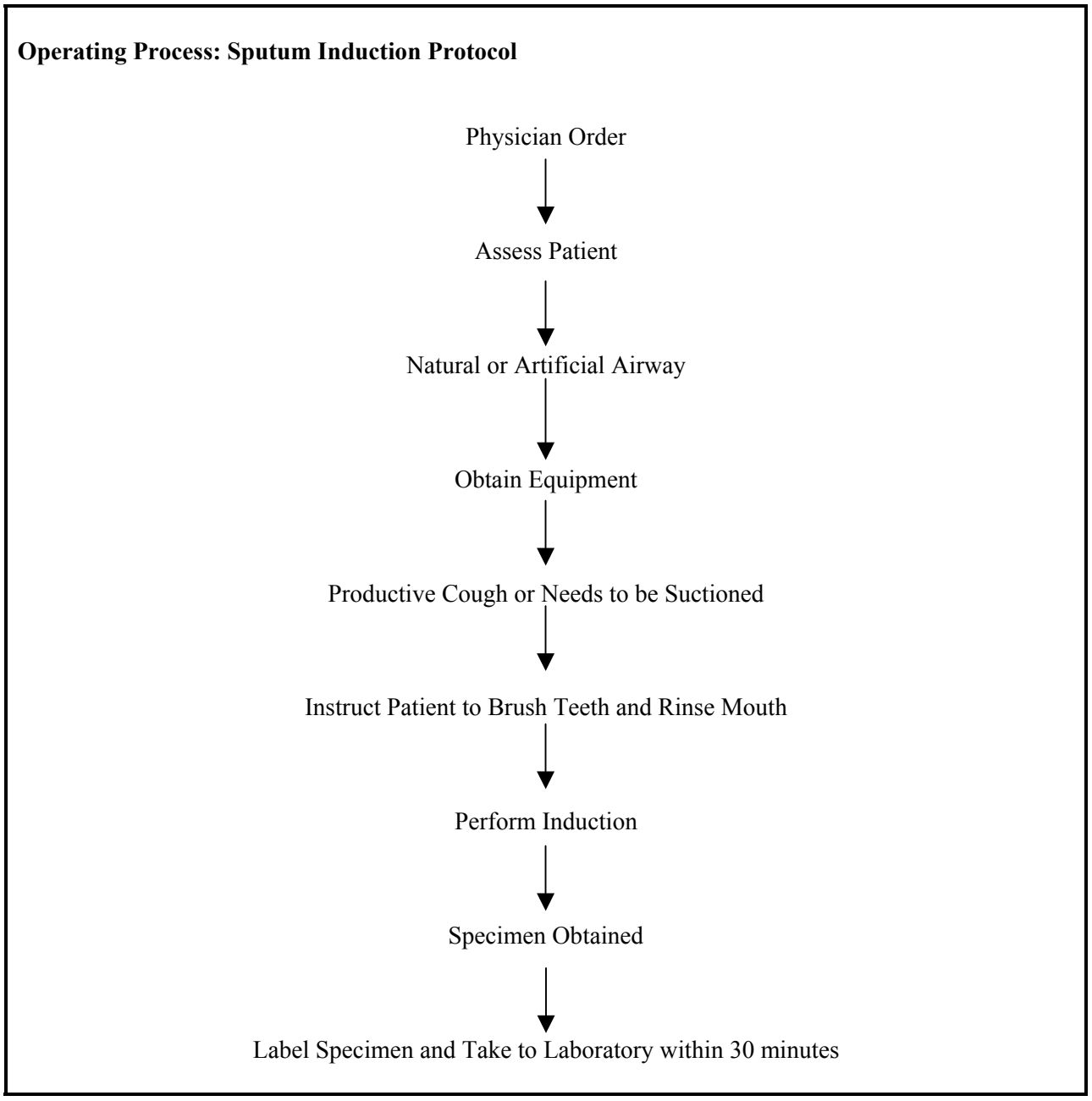


Figure 10. Sample Process Description for Respiratory Therapeutics: Sputum Induction Protocol—Manual Flowchart Format

Operating Process: Sputum Induction Protocol

Purpose To describe the process for obtaining and selecting the method to perform a sputum induction.

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

What Happens	Who's Responsible	Results: Documents
1. Physician writes order for sputum induction.	Physician	SOPs for: • Physician order sheet.
2. Assesses patient. 3. Determines whether patient has natural or artificial airway. 4. Chooses equipment appropriate for patient condition.	Therapist	SOPs for: • Patient assessment. • Sputum induction. • Equipment stock and location.
5. Determine whether patient has productive cough or needs to be suctioned. 6. Have patient brush teeth and rinse mouth.	Therapist	SOPs for: • Suctioning. • Patient hygiene.
7. Perform induction. 8. Obtain specimen in sterile container.	Therapist	SOPs for: • OSHA standards. • Infection control standards. • Use of personal protective equipment.
9. Label specimen and take to laboratory within 30 minutes of specimen acquisition.	Therapist/Transporter	SOPs for: • Transport of specimen. • Documentation policy.

Expected Results: Quality sputum specimen that provides diagnostic information.

Figure 11. Sample Process Description for Respiratory Therapeutics: Sputum Induction Protocol—Table Format

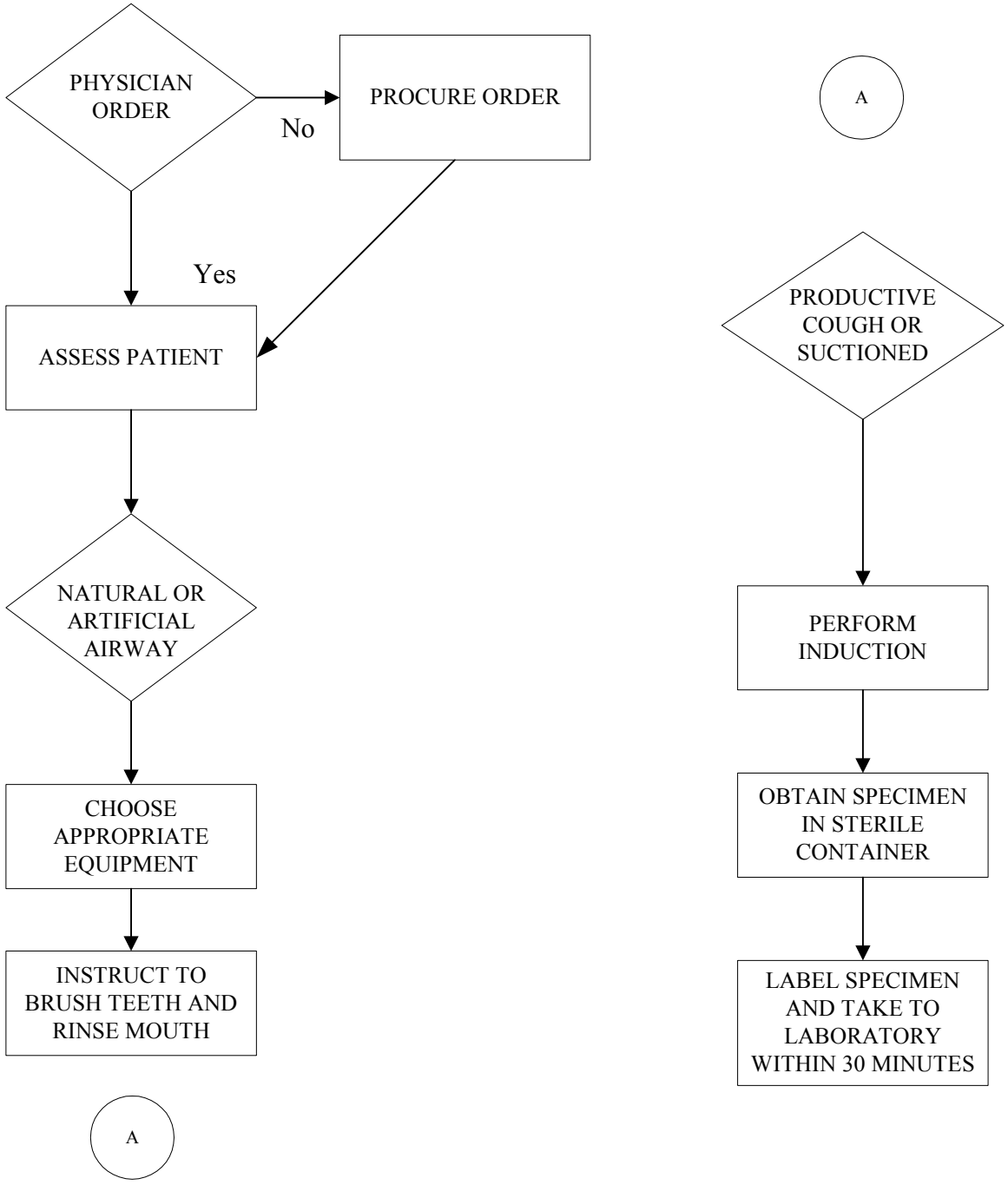


Figure 12. Sample Process Description for Respiratory Therapeutics: Sputum Induction Protocol—Electronic Flowchart Format

6.6.2 Process Validation

Validation consists of a plan for personnel to challenge and document the results of new or modified processes or procedures to assure personnel that the processes or procedures work as expected in clinical application before actual implementation.[42,43] Whenever a change is necessary, the new process or procedure should be validated to assure that the results will continue to meet clinical needs and expectations, and those of its customers. When developing the operating SOPs to be used in the process, those for calibration, maintenance, and QC must also be included. A sample validation protocol is outlined below.

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. SOPs to be used
    2. Personnel to perform
    3. Equipment needed
    4. Material to be used
B. Test samples required
C. Testing conditions to be used
D. Data to be collected
E. Acceptance criteria
F. Protocol
    1. Prepared by
    2. Reviewed by
    3. Approved by

V. 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

6.6.3 Identifying and Writing Standard Operating Procedures (SOPs)

There should be written SOPs for critical steps in the quality system essentials.[21] There should also be SOPs for critical steps in the respiratory therapeutics or laboratory's processes in each operating system throughout the entire path of workflow. As mentioned previously, the respiratory services and pulmonary laboratory staff should collaborate with other healthcare providers that impact the path of workflow.

Example: For tests performed for an office practice the laboratory may wish to consider providing patient instruction and order forms.

Example: Scheduling delivery of therapy within the context of the patient's daily care plan.

Guidance for which procedures to develop for the QSE is given in the "Procedure" column of the tables in Section 7.2 of NCCLS document HS1—*A Quality System Model for Health Care*. The current edition of NCCLS document GP2—*Clinical Laboratory Technical Procedure Manuals* provides a template for technical procedure formatting.

SOPs should be easy to read, use, and follow, as shown in the example in Figure 13.

Identifying the Patient for Specimen Collection Effective Date: mm/dd/yy
Document # / version #

Identifying the Patient for Specimen Collection

Purpose

This procedure provides instructions for correctly identifying patients for specimen collection.

Policy

- A patient's name and a second identifier (e.g., medical record number or date of birth) are required.
- Exceptions are not allowed.

Supplies

Patient identification band (see example in Appendix 1)

Procedure A: Inpatients

Follow the steps in the table below to properly identify inpatients.

Step	Action	
1	Ask the patient to state his or her last name when able.	
2	Verify that the patient is wearing an identification band.	
3	Follow the directions in the table below for identifying the patient.	
	If:	**Then:**
	there is no ID band anywhere in the room,	• do not proceed, and • notify the patient's nurse. Note: During disasters or codes, refer to the emergency identification procedure.
	the ID band is attached to the bed,	• do not proceed • ask the patient's nurse to identify the patient, and • ask the nurse to document the verification on the collection list, labels, or requisition.
	the ID band is present but not attached to the patient,	• do not proceed, and • notify the patient's nurse.
4	Match the ID band to the requisition, collection list, or labels.	
5	*Proceed with specimen collection only when patient identification is verified.*	

Continued on next page

Figure 13. Sample Preanalytic Procedure

Identifying the Patient for Specimen Collection (continued)

Procedure B: Outpatients

Follow the steps in the table below to properly identify outpatients.

Step	Action	
1	Ask the patient to • spell his or her first and last names, and • give his/her date of birth.	
2	Verify the spelling and date of birth against the • label, and • requisition.	
3	*Proceed with specimen collection <u>only</u> when patient identification is verified. If identification cannot be verified, proceed to step 4.*	
4	Follow the directions in the table when steps 1 and 2 cannot be followed.	
	If:	**Then:**
	the patient is unable to provide information for whatever reason,	• get the information from a family member or caregiver, if present, or • if not present, notify the person in charge.
	the identifiers do not match,	• contact the registration desk, and • resolve the discrepancies before proceeding.
	the ID band is present but not attached to the patient,	• do not proceed, and • notify the patient's nurse.
5	*Proceed with specimen collection <u>only</u> when patient identification is verified.*	

Related Procedures

Procedure ID. XXX: Emergency Identification Procedure

Appendixes

Appendix 1: Example of Patient Identification Band

End

Figure 13. Sample Preanalytic Procedure (continued)

6.6.4 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 respiratory and laboratory processes include:

- a quality control program that reflects the internal needs of each respiratory service and meets minimum regulatory requirements (see Section 6.6.4.1);
- proficiency testing (applicable in arterial blood gas labs) programs that offer an external peer-based assessment of process output (see Section 6.6.4.2);
- programs that offer an external peer-based assessment of process output, i.e., may need to be developed by best practice review, user groups, or benchmarking;
- occurrence logs which itemize and characterize problems with process or product output (see Section 6.8.);
- statistical techniques which help laboratory personnel to understand process performance and analyze trends (see Section 6.6.4.3); and
- quality indicators that include thresholds which cause respiratory and laboratory staff to review the process (see Section 6.9).

6.6.4.1 Quality Control (QC)

Quality control is a vital part of assuring the quality of the laboratory's test methods. In the respiratory and/or laboratory's written policy for QSE: Process Control, it should state that the QC program considers government regulations, accreditation requirements, manufacturer's recommendations, and laboratory needs.[21]

6.6.4.2 Proficiency Testing for Arterial Blood Gas Laboratories (External Quality Assessment)

In the laboratory's written policy for QSE: Process Control, it should state that the laboratory participates in a program of external quality assessment such as proficiency testing (PT). There should be a written description of the PT process that minimally includes:

- enrollment in appropriate programs;
- rotation of testing personnel and equipment;
- the laboratory's procedure for handling PT specimens;
- 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.*

6.6.4.3 Use of Statistical Tools

Statistical tools have been described and used for controlling processes. These include:

- run charts;
- Pareto chart;
- histogram;
- control chart; and
- process capability.

These tools extend the use of statistics beyond the traditional Levey-Jennings charts commonly used for results of QC control tests.[44]

6.7 QSE: Information Management

The organization's commitment to quality in the flow of information between service units within the organization, as well as communication with external entities, should be defined unequivocally. Please refer to NCCLS document HS1—*A Quality System Model for Health Care* for more detailed information on developing this QSE.

6.8 QSE: Occurrence Management

The policy for QSE: Occurrence Management should state that the respiratory service and/or laboratory will capture information about occurrences that could have or have had adverse implications for patients, employees, or visitors.

6.8.1 Uniform Document for Capturing Information

The respiratory service and/or laboratory should develop an internal system 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 respiratory service and/or laboratory's ability to meet its customers' expectations; all occasions of verbal or written customer complaints; communications failures within the respiratory service and/or laboratory and to outside customers; and problems with technical operations. An occurrence report form should minimally include space for tracking number, date/time of occurrence, description, and resolution. An example of an occurrence report form is provided in Figure 14 below.

Occurrence Report Form

OR#:		
Department employees: Complete this section only and return to supervisor.		
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					
ABG Laboratory		Home care		Rehabilitation	
ABG/PF Laboratory computer system		Hospital computer system		Safety	
Administration		Other		Sleep diagnostics	
Adult acute care		Outreach program		Specimen analysis	
Cardiac diagnostics		Pediatric acute care		Subacute care	
Dept. computer system		Point-of-care testing		Transport	
General therapy		Pulmonary diagnostics			

OCCURRENCE CLASSIFICATION					
Accident		Mislabel		QC documentation	
Communication		Other		Report error	
Equipment malfunction		Personal deviation from SOP		A B C	
External department		Planned deviation from SOP			

QUALITY SYSTEM ESSENTIAL					
Assessment		Information Management		Process Control	
Documents and Records		Occurrence Management		Process Improvement	
Equipment		Organization		Purchasing/Inventory	
Facilities and Safety		Personnel		Service and Satisfaction	

Continued on next page

Figure 14. Sample Occurrence Report Form

OPERATING SYSTEM-PULMONARY LABORATORY			
PRETEST	Patient assessment		Request
	Equipment preparation		Patient preparation
TESTING	Patient training		Testing
	Patient assessment for further testing		Results review and selection
POST-TESTING	Reporting		Interpretation

SOP(s) 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 SOP**: approved by supervisor or medical director. - **personal deviation from SOP**: unapproved deviation from SOP. - **complaint**: dissatisfaction with any elements of the service. - **QC documentation**: failure to appropriately document QC or any comments associated with QC. - **accident**: nonpreventable occurrences. - **mislabel**: any type of specimen 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 laboratory. 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 SOP. - **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 SOP(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

Document number/version Facility Name/Location Page 2 of 2
Effective Date

Figure 14. Sample Occurrence Report Form (continued)

6.8.2 Immediate Action and Investigation

The employee who discovers the problem should take the necessary steps 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. A sample occurrence log is illustrated in Figure 15 below. Electronic spreadsheets and databases can also be used, as well as hard copy to record and analyze data.

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

Document number/version Facility Name/Location Page 1 of 1
Effective Date

Figure 15. Sample Occurrence Log

6.8.3 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 6.10 for a discussion on the continuous improvement process.

6.9 QSE: Assessment

The policy for "QSE: Internal Assessment" should state that the respiratory and/or pulmonary laboratory will develop and monitor indicators for paths of workflow and periodically conduct internal assessments of its quality system and operations. Quality indicators are those observations, statistics, or data that typify the performance of a process. There is no one set of indicators that has been required, recommended, or suggested for pulmonary or other respiratory service functions. On the contrary, each respiratory service has been encouraged to identify its own high-risk, high-cost, and problematic issues. Blood gas laboratories may also voluntarily participate in a subscription service of quality assurance studies that benchmarks their performance to that of their peers.

6.9.1 Mapping Current Quality Indicators to the Pulmonary Laboratory's Path of Workflow

Pulmonary laboratories 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 A. The results of such mapping will show the laboratory which areas in the path of workflow they are not currently monitoring. To assure that all the laboratory's 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.

Published indicators[45,46] that are applicable to arterial blood gas laboratories have been grouped by operating system and QSE. The list is provided in Appendix B.

6.9.2 Mapping Current Quality Indicators to the Respiratory Services' Path of Workflow

Each respiratory service is encouraged to map its 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 C. The results of such mapping will show the service which areas in the path of workflow it is not currently monitoring. To assure that all of the service's 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.[46]

6.9.2.1 Internal Auditing

A quality system audit reviews the facility's quality system. It assesses whether or not the respiratory service and/or laboratory has a quality system in place, and evaluates the service's compliance with its internal policy statements as well as any applicable regulations and requirements.

6.9.2.2 The Quality Audit[47,48]

The auditor assesses the intent, implementation, and effectiveness of the facility's quality system by reviewing the documented quality system and conducting personal observations. The purpose is to verify that a quality system exists, is being followed, and is effective in maximizing the quality of testing and services to the customer.

To evaluate 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 testing and services rendered from the stated processes and procedures meet the stated intent, any applicable regulations or requirements, and the customers' needs.

6.9.2.3 Auditors

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

6.9.2.4 The Audit Report

At the conclusion of the audit, the auditor issues a report to management that describes any discrepancies between the laboratory's 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 testing and services to its customers.

6.9.3 Periodic Reporting

Respiratory services and pulmonary laboratories should periodically report their findings from quality indicators and audits to the organizational body responsible for monitoring/maintaining the service's quality function and management.

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

6.10 QSE: Process Improvement

The policy for "QSE: Process Improvement" should state that respiratory services and the pulmonary laboratory uses a problem resolution process and quality improvement tools to resolve problems and improve the quality of its test results and services to its customers. (Please refer to the most current version of HS1—*A Quality System Model for Health Care* for more detailed information on the development of this QSE.) Respiratory services and the pulmonary laboratory should apply the problem resolution process to all quality improvement efforts undertaken.

6.10.1 Periodic Reporting

The respiratory service should, at predefined intervals, report its quality improvement activities, progress, and findings to the organization's quality management committee.

6.11 QSE: Service and Satisfaction

One aspect by which a respiratory service's effectiveness can be measured is customer service and satisfaction. Respiratory service providers should identify their customers, determine customers' respective needs, structure their processes and procedures to meet these needs to the customers' satisfaction, and actively seek customer feedback to determine if the needs are being met.

Respiratory services customers include both internal and external groups. External to the site of the delivery of respiratory therapeutics are customers such as patients, physicians, outreach clients,

accrediting/regulatory agencies, and other healthcare providers. Internal customers include physicians, respiratory therapists, nurses, and other caregivers in the organization, who impact or are impacted by the delivery of respiratory therapeutics. Respiratory service providers should develop mechanisms 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, the service should undertake corrective actions.

Consultation with customers is also the responsibility of respiratory service providers. Pulmonologists are commonly queried to provide advice on therapeutic interventions, whereas respiratory service providers are often contacted by patients and caregivers about the status and outcome of therapeutic interventions. Each service should have a process for providing and monitoring consultation services and procedures for contacting those who provide consultations.

Guidance for the development and measurement of customer satisfaction tools may be provided by marketing, public relations, or quality management departments.[49]

6.12 QSE: Facilities and Safety

Each healthcare service should provide and maintain a work environment that provides safety for all, in compliance with standards and requirements. Please refer to the most current version of NCCLS document HS1—*A Quality System Model for Health Care* for more detailed information on the development of this QSE.

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Appendix A. Examples of Pulmonary Function (PF) Laboratory Quality Indicators by Operating System

Determining rate of/source of/and reasons for:

Patient Assessment
- unstated reasons for test orders.
- inappropriate reasons for test orders.

Test Request Process
- requests missing required or critical information.
- missing patient instructions.
- incorrect scheduling.

Patient Preparation
- inaccuracies in entry of patient demographics.
- lack of adherence to pretest instructions.

Equipment Preparation
- lack of calibration data.
- incorrect reference values.

Patient Training
- ineffective or lack of test performance instructions.

Laboratory Information System
- security violations.
- unscheduled downtimes.
- inability to retrieve archived patient results and information.

Testing and Review
- lack of trial acceptability.
- lack of reproducibility.
- inadequate number of trials.

Laboratory Interpretation
- disparities in
  - PF results obtained by two separate methods.
  - calculated and measured parameters.

Results Reporting
- times alert values were not reported or documented.
- completeness/correctness of reports.
- delayed reports.
- corrected reports due to reporting errors.
- disparities between preliminary and final reports.

Post-test Data Management
- retained data unable to be retrieved.

Clinical Interpretation and Application
- inappropriate action taken after report of results.
- inappropriate test performed per protocols.

Appendix B. Published Laboratory Quality Indicators (Applicable to the Arterial Blood Gas Laboratory) Grouped by Laboratory Operating System and QSE

Patient Assessment
- Practice guideline implementation.
- Duplicate test ordering.

Test Request
- Ordering accuracy.
- Accuracy of order transmission.
- Verbal order evaluation.

Specimen Collection/Labeling
- Wristband evaluation.

Specimen Transport
- Transit time.
- Stat transit time.

Specimen Receiving/Processing
- Adequacy of fine-needle aspiration.
- General specimen acceptability.
- Chemistry specimen acceptability.
- Sputum specimen adequacy.

Testing and Review
- Proficiency testing.
- Quality control.
- Testing turnaround time.
- Turnaround time outliers.

Laboratory Interpretation
- Fine-needle cytohistological correlation.
- Results reporting.
- Report adequacy (autopsy, breast carcinoma, lung carcinoma, surgical pathology).
- Correct physician sent report.
- Charting of results.
- Critical diagnosis reporting.
- Reporting error.

Clinical Interpretation and Application
- Critical test results.
- Nosocomial infection rate.

QSE: Personnel
- Competence evaluation.
- Employee retention**.**

QSE: Process Control
- Safety.
- Comparative cost of in-house vs. reference laboratory testing.

QSE: Occurrence Management
- Incidents.

QSE: Internal Assessment
- On-site inspections/assessments.
- Self-inspections/assessments.

QSE: Service and Satisfaction
- Quality of telephone responsiveness.
- Reference laboratory service quality.
- Customer satisfaction.
- Complaint.

References for Appendix B

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Appendix C. Examples of Respiratory Services Quality Indicators for Operating Systems

Determining rate of/source of/and reasons for:

Assessment
- Inappropriate reason for therapy.
- Inappropriate mode of therapy.
- Outcomes appropriate for patient.

Information Gathering
- Necessary laboratory data available.
- All healthcare providers consulted.
- Consensus on need for therapy.
- Patient goals meet AARC CPG indicators for therapy.

Patient Preparation
- Ineffective or lack of understanding of therapy.
- Inability to follow commands or perform therapy.

Equipment Preparation
- Lack of adequate equipment.
- Infection control rates.
- Equipment safety verification testing.

Request for Therapy
- Verification of therapist skills.
- Adequate staffing.
- Request missing required or critical information.
- Verbal orders verified according to medical staff bylaws.
- Orders transcribed correctly into electronic system.

Determine Therapeutic Goal
- Goals for therapy meet AARC CPGs compared to care path processes.

Equipment Preparation
- SOP for equipment followed.
- Yearly competency for therapist.
- Ineffective or lack of patient to follow instructions.

Patient Preparation
- SOP for verification of patient.
- Ineffective or lack of patient to comply with instructions.

Outcomes Assessment
- Ineffective or lack of patient to follow instructions.
- Assess patient/therapy outcomes to AARC CPGs.
- Therapy not adjusted to meet needs of patient.

Chart
- Policy and Procedure for charges.
- Charting is legible.
- Delayed charting.

Outcomes with Healthcare Team
- Compare outcomes of therapy to care path guidelines.
- Delayed conferencing/notification of healthcare team.

Summary of Comments and Working Group Responses

NCCLS consensus procedures include an appeals process that is described in detail in Section 9 of the Administrative Procedures. For further information contact the Executive Offices or visit our website at www.nccls.org.

HS4-P: *A Quality System Model for Respiratory Services; Proposed Guideline*

General

1. One concern is the overall time that must be dedicated to the implementation of this type of program. When each department or service is dedicating the resources required to implement a program of this nature, these resources must be taken from patient care, so that in the short term, patient care resources may be reduced.

- **The working group agrees that dedication of time is required to implement a quality model. However, the working group believes that with consistent direction and "buy-in" of the organization's management, resources will not be taken from patient care, rather implementation of this model will enhance patient care. As accrediting and regulatory bodies move toward a quality system philosophy, the model will provide the added benefit of simplifying the process.**

Related NCCLS Publications*

GP2-A4 **Clinical Laboratory Technical Procedure Manuals; Approved Guideline — Fourth Edition (2002).** This document provides guidance on development, review, approval, management, and use of policy, process, and procedure documents in the laboratory testing community.

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; Proposed 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 (NRSCL).

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

NOTES

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