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City of Milwaukee Health Department

Quality Management System

Quality Manual

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I. Quality Manual Plan

A. Purpose

The purpose of this plan is to establish and state the general policies governing the Milwaukee Health Department – Keenan Health Center STD Laboratory (KHCL) Quality Management System (QMS). This plan defines how the KHCL will manage operations and activities. This is a top-level plan representing the KHCL's vision for achieving quality assurance and customer satisfaction.

This plan must comply with all departmental or functional quality policies and procedures. All policy and procedure changes will be reviewed to ensure there are no conflicts with the guidance stated in this Quality Manual.

B. Scope

The guidance stated in this manual applies to all operations and activities at the KHCL. The scope of the quality system may be stated as follows:

1. Improved community health status

2. Improved organizational performance

3. Improved service delivery by effective use of resources available within the KHCL and the community

4. Improved employee and customer satisfaction

5. Improved data driven decision-making

6. Increased process standardization

7. Increased KHCL staff participation in performance improvement activities

All Laboratory managers and supervisors are responsible to help define, implement, and maintain the procedures contained in this manual and to ensure all processes comply with these requirements. All employees are responsible to implement these procedures and to strive for continuous improvement in all activities and processes of the KHCL.

The model of a process-based quality management system, shown in Figure 1, illustrates the process linkages presented in clause VII Procedures. Customers play a significant role in defining requirements as inputs. Monitoring customer satisfaction requires evaluation of customer feedback (perception) to determine if the KHCL is meeting customer requirements.

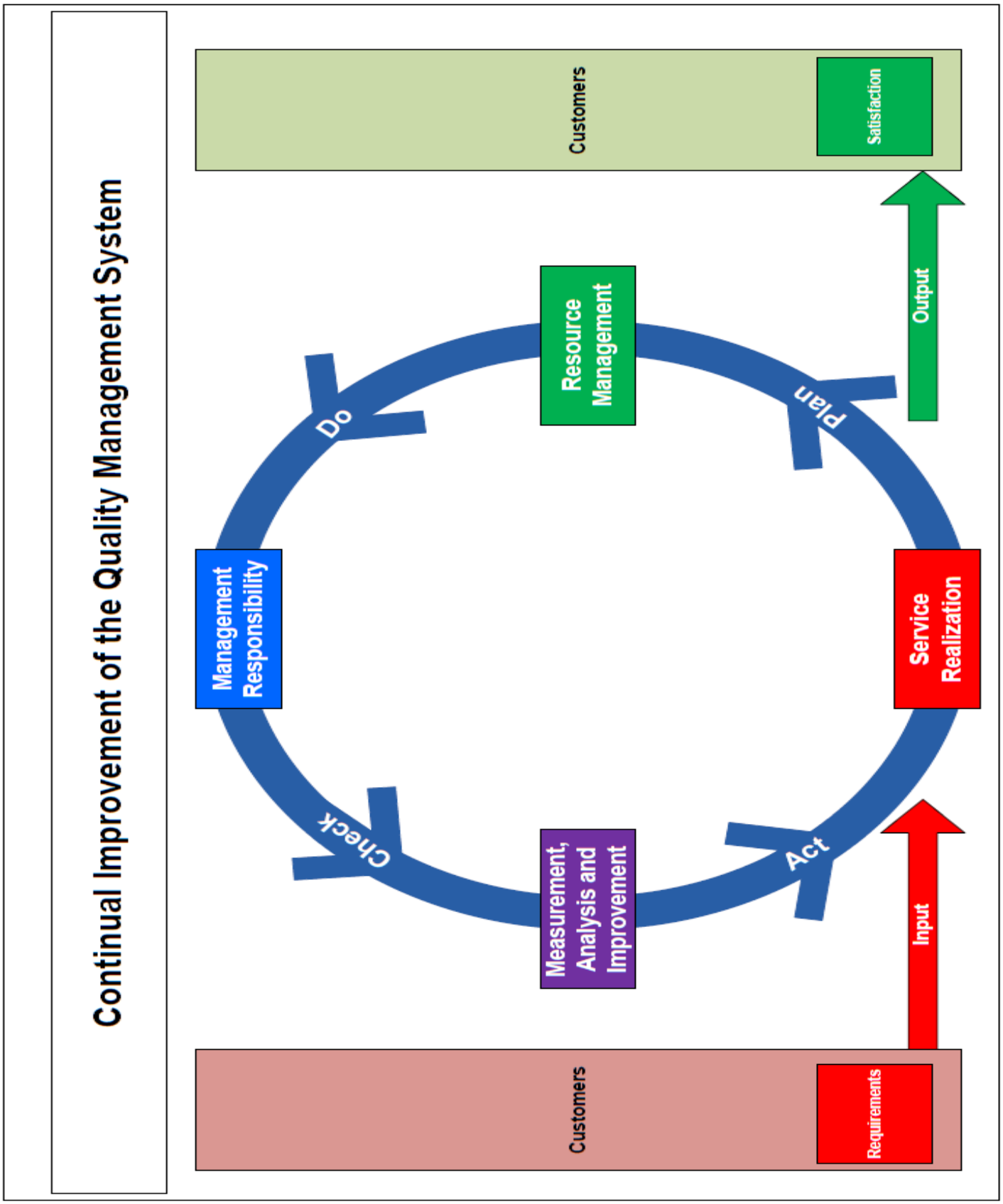

Figure 1: Model of a process-based quality management system

C. Exclusions

None.

II. Authority

Not applicable.

III. Supportive Data

A. Reference

IV. Signature Block with Effective Date

_____ _____

M. Steve Gradus Ph.D. D(ABMM) Date

Public Health Laboratory Director

V. Definitions

A. Policy: A broad, directive statement intended to influence and determine decisions, actions, and other matters. Policies promote organizational results by governing the beliefs and behaviors of individuals and groups throughout the KHCL. Policies help people build knowledge, make decisions, and take action pursuant to the mission of the KHCL. They represent the norms and standards of departmental operation. A general directive from the Office of the Commissioner is an example of a policy.

B. Protocol: A set of minimum standards necessary to implement, manage, and comply with a policy. A protocol identifies outcomes, personnel expected to ensure the outcomes, competencies required of the personnel, areas of responsibility of personnel, and any resources or references related to the topic of the protocol. An example of a protocol would be a Lab testing protocol, or processes that apply to a specific office, program, or unit.

C. Procedure: A standard method for implementing a policy and achieving a specific result. Procedures establish the conditions for performance and the series of steps required to achieve a particular result. An example of a procedure would be the KHCL Procedure AS-001-2008/12, Procedure for Writing, Instituting, and Revising Department Policies, Protocols, and Procedures.

D. Quality Management: Management activities and functions involved in determination of quality policy and its implementation through means such as quality planning and quality assurance including quality control. See also total quality management (TQM).

E. Quality Management System (QMS): A system by which an organization aims to reduce and eventually eliminate non-compliance to specifications, standards, and customer expectations in the most cost effective and efficient manner.

F. Total Quality Management (TQM): A holistic approach to long-term success that views continuous improvement in all aspects of an organization as a process and not as a short-term goal. It aims to radically transform the organization through progressive changes in the attitudes, practices, structures, and systems.

VI. Protocol

Not applicable.

VII. Procedures

A. Quality Management System

1. General Requirements

Through this manual and associated procedures and documents, the KHCL has established, documented, and implemented a Quality Management System. The system is designed to result in continually improving the quality and effectiveness of KHCL operations and increasingly satisfying customers' requirements.

The Quality Management Manager (QMM), in conjunction with all Laboratory managers and supervisors, is responsible for the maintenance of this system. This Quality Manual and associated procedures identifies the processes needed for the KHCL Quality Management System (see Figure 2. General Process Sequence Flowchart).

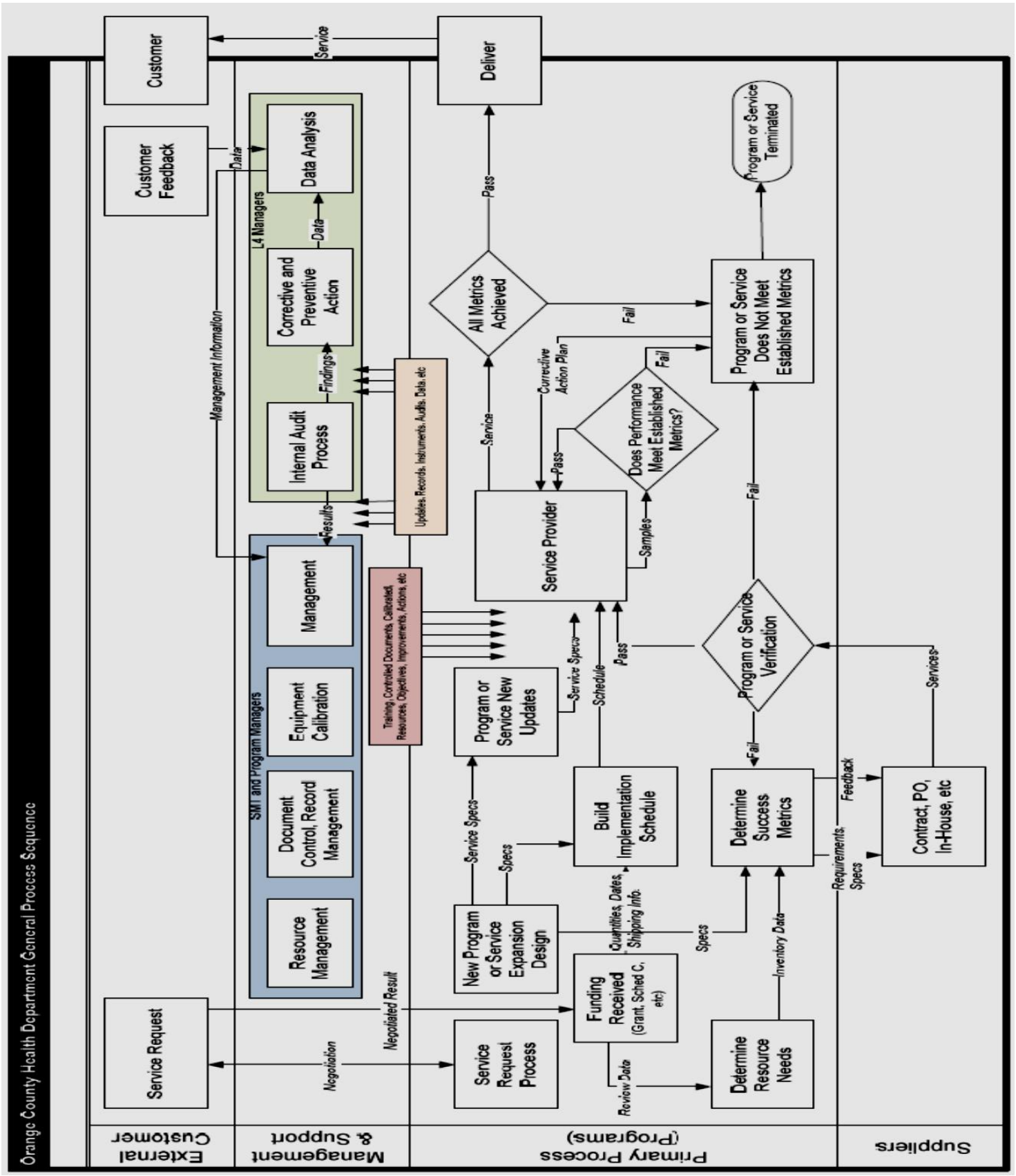

Figure 2: General Process Sequence flow chart

The QMM maintains a document identifying the sequence of these processes and, in conjunction with the appropriate Lab Managers, defines process interactions. Processes for management activities, provision of resources, service delivery, and measurement are included. Procedures shall include the methods needed to ensure the effective operation and control of processes.

The Senior Management Team (SMT) will ensure availability of resources to support the operation and monitoring of processes through regular interaction with Lab Managers. Lab Managers and the QMM will monitor, measure, and analyze processes and implement any corrective actions necessary to achieve intended results and continual improvement of the processes. These results will also be monitored at Quality Council meetings.

Any outsourced processes that may affect service compliance with requirements shall be controlled. The QMM and appropriate Program Manager(s) are responsible for defining the methods to control outsourced processes of procedures.

2. Documentation Requirements

a. General

Lab Managers and supervisors are responsible for identifying any documents needed to ensure the effective planning, operation, and control of processes.

Procedures may vary in detail based on the size of the department or program involved and the type of activity performed. Procedure developers shall consider this as well as the complexity of the processes, interactions, and the competence of the personnel involved. Where competence is used to minimize the content in procedures, records (see

QM section C.2.b Competence, Awareness, and Training) must support the decision.

Documents may be any medium including: software programs, electronic text files, or hardcopy documents for example.

b. Quality Manual

This Quality Manual includes the scope of the KHCL quality management system. Exclusions are documented in QM section I.C. Each section of the manual references appropriate implementing procedures. Interactions between processes are defined in the manual or in the referenced procedures.

c. Document Control

All documents required by the QMS shall be controlled. The Document Control Procedure defines the controls needed to:

(1) Approve documents for accuracy and adequacy prior to issue

(2) Review and update as necessary and re-approve documents

(3) Ensure that changes and the current revision status of documents are identified

(4) Ensure that relevant versions of applicable documents are available at points of use

(5) Ensure that documents remain legible and readily identifiable

(6) Ensure that documents of external origin are identified and their distribution controlled

(7) Prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose

d. Control of Records

Procedures define appropriate records to be maintained in order to provide evidence of conformity to requirements and effective operation of the QMS. Records shall remain legible, readily identifiable, and retrievable. The Quality Records Procedure defines the controls needed for the identification, storage, protection, retrieval, retention time, and disposition of records.

e. Referenced Procedures

QP3000 - DOCUMENT CONTROL (Appendix A)

QP3010 - QUALITY RECORDS (Appendix B)

B, Management Responsibility

1. Management Commitment

The KHCL SMT shows its commitment to the QMS through the development and implementation of this quality manual. Additionally, management commitment is demonstrated through the KHCL Quality Directive, the specific objectives that are set and reviewed during Quality Council meetings, and by providing resources required to meet objectives for continually improving the quality and effectiveness of operations.

The SMT consisting of the Director, Deputy Director, Operations Manager, Lead Staff, and the Program Assistant is chartered with ensuring our services meet customer as well as statutory and regulatory requirements.

2. Customer Focus

The SMT ensures the focus on improving customer satisfaction is maintained by setting and reviewing objectives related to customer satisfaction at SMT meetings.

3. Quality Directive

Laboratory managers and supervisors are responsible for ensuring all employees understand the directive. To ensure our plan remains appropriate, it is reviewed at least annually at the Quality Council meeting.

4. The KHCL Quality Directive:

a. The KHCL designs and produces services that meet or exceed customers' requirements and comply with all statutory and regulatory requirements by adhering to the quality management system and operational methods that recognize customer satisfaction as a primary goal.

b. The KHCL continually strives to improve the effectiveness of the QMS and our commitment to customer satisfaction by monitoring our performance against established objectives and through leadership that promotes employee

involvement. This concept represents our commitment to quality and the increasing need to better serve a growing and more demanding customer base.

5. Planning

a. Quality Objectives

The KHCL Quality Council shall establish quality objectives on an annual basis. These objectives shall be measurable and consistent with the Quality Directive, and reviewed at least annually at Quality Council meetings.

b. Quality Management System Planning

As part of bi-annual strategic planning meetings, KHCL establishes strategic objectives for improvement of our services, processes, and customer satisfaction. These objectives are supported by specific measures that track performance against those objectives. Lab Managers in turn set departmental objectives with specific performance measures and targets that support KHCL objectives. As situations arise that demand changes to the quality management system either to meet objectives or because of changing business conditions, all changes will be reviewed by the Quality Council to ensure integrity of the quality system is maintained.

6. Responsibility, Authority, and Communication

a. Responsibility and Authority

KHCL Responsibilities and authorities are defined in each position description as well as the Management Responsibility procedure. Position descriptions are used during annual performance reviews.

b. Quality Management Manager (QMM)

The QMM, irrespective of other responsibilities, has the responsibility and authority to:

(1) Ensure that processes needed for the quality management system are established, implemented, evaluated, and maintained

(2) Report to the SMT on the performance of the quality management system and any need for improvement

(3) Ensure awareness of customer requirements throughout the organization

(4) Serve as the liaison on matters relating to the quality management system

c. Internal Communication

In line with KHCL's policy of leadership through employee involvement, KHCL's personnel policies have established open communication throughout the organization. The effectiveness of the quality management system is evident through internal audit results, corrective and preventive actions, and departmental performance measures. Other than confidential information, KHCL and departmental performance measures are posted on SharePoint sites throughout the KHCL. Internal audit results, corrective actions and preventive actions are also shared at departmental meetings as appropriate.

d. Referenced Procedures

QP3020 - MANAGEMENT RESPONSIBILITY (Appendix C)

POSITION DESCRIPTION FORM Instructions 304

7. Management Review

a. General

The SMT shall review the KHCL QMS on a semi-annual basis, or more frequently if needed, to ensure continuing suitability, adequacy, and effectiveness. This review shall include assessing opportunities for improvement and the need for changes to the quality management system, quality directive, and quality objectives. The QMM is responsible for maintaining records from management reviews.

b. Review Input

The QMM and Lab Managers provide the following information for

Management Review meetings:

(1) Results of audits

(2) Customer feedback

(3) Process performance and service conformity

(4) Status of preventive and corrective actions

(5) Follow-up actions from previous management reviews

(6) Changes that could affect the quality management system

(7) Recommendations for improvement

c. Review Output

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

(1) Improvement of the QMS and its processes

(2) Improvement of service related to customer requirements

(3) Resource needs

d. Referenced Procedures

QP3020 - MANAGEMENT RESPONSIBILITY (Appendix C)

POSITION DESCRIPTION FORM

C. Resource Management - Provision of Resources

During planning and budgeting processes, and as needed throughout the year, the SMT shall determine and ensure appropriate resources are available to implement and maintain the QMS, continually improve its effectiveness, and enhance customer satisfaction by meeting or exceeding customer requirements.

1 Human Resources

a. General

Personnel shall be competent based on appropriate education, training, skills and experience necessary for the position to which assigned.

b. Competence, Awareness, and Training

The minimum competencies required for each position at the KHCL are defined in each Position Description. Human Resources, Lab Managers, and supervisors are responsible for ensuring position descriptions are accurate.

Personnel who require additional training, or other action, to meet minimum competency requirements will be identified and provided task specific training. General training or education is provided or coordinated by Human Resources. The department or Human Resources will evaluate the effectiveness of training, or other actions taken, as appropriate. The department generates records of mandatory and task-specific training. Human Resources maintains records of all training, education, skills, and experience. Lab Managers are responsible for ensuring their employees are aware of the relevance and importance of their activities and how they contribute to the achievement of quality objectives.

c, Referenced Procedures

POSITION DESCRIPTION FORM

DOH Training Policy

2. Infrastructure

The KHCL provides the infrastructure necessary to achieve compliance with service requirements. During the annual budgeting and strategic planning processes, buildings, workspace, and associated utilities are evaluated and provided. When new personnel are added, Lab Managers coordinate with Human Resources and Information Technology to ensure appropriate equipment, including hardware and software if required, and supporting services such as telephones etc., are available.

3. Work Environment

The SMT, Facilities Manager, and Space Utilization Committee, based on program manager requests, will determine and manage the work environment to ensure the KHCL provides a safe and desirable place to work that is appropriate for achieving compliance with service requirements.

4. Information

Lab Managers treat data as a fundamental resource for conversion to information and the continual development of the KHCL's knowledge base, which is essential for making factual decisions and can stimulate innovation. In order to manage information the KHCL will do the following:

a. Identify its information needs

b. Identify and access internal and external sources of information

c. Convert information to knowledge of use

d. Use the data, information, and knowledge to set and meet its strategies and objectives

e. Ensure appropriate security and confidentiality

f. Evaluate the benefits derived from use of the information in order to improve management of information and knowledge

D. Service Delivery

1. Planning

The KHCL has planned and developed the processes needed to provide customers' services that meet their requirements. Planning of service delivery processes includes determination of requirements and quality objectives for services; development of required processes and process documentation; and establishment of service verification and validation programs. The plan also defines requirements for records necessary to demonstrate process and service conformity.

Process planning includes, as applicable:

a. Definition and evaluation of processes

b. Development of adequate and capable processes

c. Identification of special processes and consideration of associated consequences

d. Establishment and implementation of appropriate process control measures

e. Development of instructions and training for process owners

f. Requirements for records necessary to demonstrate process compliance

2. Customer Related Processes

a. Determination of Service Requirements

Service requirements and quality objectives for service are defined and communicated graphically (process maps) and through specifications, contract documents, internal and external standards, and applicable legal and regulatory requirements.

b. Review of Service Requirements

Before initiating services, either new or existing, to new locations for customers, the KHCL reviews the customer's service requirements to ensure all requirements can be met. This includes reviews of contracts before submission and reviews of contract changes before acceptance. The purpose of these reviews is to determine if the service requirements are adequately defined, differences are resolved, and that the KHCL has the ability to meet the defined requirements for both the service and delivery.

Contract administration processes change orders and/or contract amendments to ensure these items are reviewed by the appropriate departments, that work orders and any other documents are updated, and that affected personnel are made aware of the changes.

The City of Milwaukee Information Technology department manages the KHCL web site. New web pages or changes to content are reviewed by the MHD Public Information Officer and appropriate Lab Managers to ensure commitments expressed in the catalogue and website advertising can be met.

These reviews are defined in the Contractual Services Policies & Procedures. Required records are also defined in this process.

c. Customer Communication

In keeping with a commitment to customer satisfaction, KHCL views effective customer communication as an essential element of customer satisfaction. Appropriate handling of communications can reduce customer dissatisfaction and in many cases turn a dissatisfying scenario into a satisfying experience.

The Business Office is responsible for establishing communication methods to ensure enquiries, contracts, including amendments, and customer feedback, including customer complaints, are handled expeditiously and professionally. Refer to the Contractual Services Policies & Procedures and Customer Complaint procedures.

The Public Information Officer has primary responsibility for developing service information and literature and is the primary customer contact for service information.

d. Referenced Procedures

Contractual Services Policies & Procedures

QP3070 - CUSTOMER COMPLAINTS (Appendix D)

3. Service Design and Development

Design and Development is a set of processes that transforms requirements into specified characteristics or specifications for a new or unique service or process. The following activities shall be performed to ensure that customer requirements are met:

a. Planning

Lab Managers shall plan and control the design and development of a new service or extensive modification to an existing service. A Project Manager will be assigned and be responsible for developing a Design Plan that defines the

design and development stages. The Design Plan will be updated as changes occur and the design evolves. The Project Manager is also responsible for task assignments, managing the schedule, developing the project plan, and communicating with the design team or appropriate department. During the planning phase the following shall be determined:

· Project Charter and Statement of Work

· Communication Plan

· The design and development stages

· The review, verification and validation that are appropriate to each design and development stage, and

· The responsibilities and authorities for design and development

Planning output shall be updated as the design and development progresses.

b. Input

Inputs relating to service requirements shall be determined and records maintained. These inputs shall include:

· Functional and performance requirements

· Applicable statutory and regulatory requirements

· Information derived from previous similar designs, if applicable

· Other requirements essential for design and development

These inputs shall be reviewed for adequacy. Requirements shall be complete and explicit.

c. Output

Output shall be provided in a form that enables verification against the input and shall be approved prior to release. This may be in the form of technical specifications, documents, drawings, test results, etc.

The outputs shall:

· Meet the input requirements

· Provide appropriate information for purchasing

· Identify or reference acceptance criteria

· Specify the characteristics of the service that are essential for its safe and proper use

d. Review

At the appropriate stages defined in the Design and Development Plan, systematic reviews of design and development shall be performed:

· Evaluate the ability of design and development results to meet requirements

· Identify any problems and propose corrective actions

Participants in such reviews shall include representatives of functions concerned with the design and development stages being reviewed.

Records of review results and any corrective actions shall be maintained.

e. Verification

Verification shall be performed in accordance with planned arrangements to ensure that the outputs have met the input requirements. One or more of the following methods may be acceptable for verification:

· Comparing a new design with a similar proven design

· By tests or demonstrations

Records of verification results and any corrective actions shall be maintained.

f. Validation

Validation shall be performed in accordance with planned arrangements to ensure that the resulting service is capable of meeting the intended use or requirements for the specified application. Whenever practicable, validation shall be completed prior to delivery or implementation of the service. Records of the results of validation and any corrective actions shall be maintained. Validation can be performed in the following manner:

· Full validation: Whenever the service is standardized

· Partial validation: Pilot testing using focus group to represent the target audience

· Partial validation: Simulation by physical or computer modeling

· Partial validation: Structured review against user needs

g. Changes

Changes shall be identified and records maintained. The changes shall be reviewed, verified, and validated, as appropriate, and approved before implementation. The review of changes shall include evaluation of the effect of the change on constituent service already delivered. Records of the results of the review of changes and any corrective actions shall be maintained.

h. Referenced Procedures:

QP3300 - DESIGN AND DEVELOPMENT (Appendix L)

QP3310 - DESIGN CHANGE (Appendix M)

QP3320 – SERVICE DEVELOPMENT AND QUALITY PLANNING (Appendix N)

4. Purchasing

a. Purchasing Process

The purchasing process is essential to the KHCL's ability to provide customers with services that meet their requirements. The KHCL ensures that purchased product conforms to specified purchase requirements. KHCL accomplishes this by controlling our supplier base and inspecting purchased products as required. Obviously, the type and extent of control applied to the supplier and the purchased product shall be dependent upon the effect of the purchased product on subsequent service delivery.

It is the responsibility of Lab Managers to evaluate and select suppliers based on their ability to supply product in accordance with specified requirements. Criteria for selection, evaluation, and reevaluation are defined in the Purchasing Policy and Procedures. Records of the results of evaluations and any necessary actions arising from the evaluation are maintained.

b. Purchasing Information

The KHCL uses purchase orders (PO's) to describe the product to be purchased, including where appropriate:

(1) Requirements for approval of product, procedures, processes, and equipment

(2) Requirements for qualification of personnel

(3) Quality management system requirements

The Purchasing Department (City Hall) is responsible for ensuring the adequacy of specified purchase requirements before transmitting the request to the supplier.

c. Verification of purchased product

Purchased items and materials are verified for correctness by the receiving department or location. If additional inspection is required, it is noted on the purchase order and the item is sent to the requesting department or location for inspection. Should the KHCL or any of their customers decide to perform verification at the supplier's premises, the verification arrangements and method of product release shall be stated in the purchasing information.

d. Referenced Procedures

Purchasing Policy and Procedures

5. Service Provision

a. Control of Service Provision

The KHCL plans and carries out service activities under controlled conditions. Controlled conditions shall include, as applicable:

(1) The availability of information that describes the characteristics of the service

(2) The availability of work instructions, as necessary

(3) The use of suitable equipment when necessary

(4) The availability and use of monitoring and measuring devices

(5) The implementation of monitoring and measurement

(6) The implementation of release, delivery, and post-delivery activities

Inspection Procedures and Service Procedures define the KHCL plan for service. These procedures provide detailed planning of all phases including the methods, equipment, and test criteria to be used. This detailed planning will be documented for each service in the form of work instructions, drawings, or specifications.

b. Validation of Processes for Service Provision

Employees, with assistance from Lab Managers, are responsible for ensuring validation of all service provision processes, where the resulting output cannot be verified by subsequent monitoring or measurement. This includes any processes where deficiencies become apparent only after the service has been delivered. Validation shall demonstrate the ability of these processes to achieve planned results.

Validation documentation for these processes will include, as applicable:

(1) Defined criteria for review and approval of the processes

(2) Approval of equipment and qualification of personnel

(a) Use of specific methods and procedures

(b) Requirements for records

(c) Revalidation

(d) Identification and Traceability

All personnel are responsible for identifying the service, by suitable means, throughout the process from request of service through the final service outcome. Service identification will be provided by using a unique service identification name or number.

Personnel performing monitoring and measuring activities are responsible for clearly identifying the service status with respect to monitoring and measurement requirements. To ensure only items that have passed required tests and/or inspections proceed to the next operation or process, all products or artifacts (such as data, reports, and other deliverables), will be appropriately labeled, tagged, stamped, or accompanied by routers or check-out sheets to properly indicate their inspection status. The inspection status shall clearly indicate pass or fail as appropriate.

For services where component traceability is a requirement, the Encounter form or Work Order will be used to record the unique identification of the traceable components used in the final service.

c. Preservation of Service

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All personnel shall handle materials, components, and products in a manner that preserves the compliance of service during internal processing and delivery to the intended destination. This preservation shall include identification, handling, storage and protection. Preservation shall also apply to the constituent parts of a service and includes items such as special storage requirements and statutory or regulatory requirements for retention of other records. Details of appropriate preservation controls are included in Receiving and Inspection section of the Purchasing Policy and Procedures.

d. Referenced Procedures

Purchasing Policy and Procedures

6. Control of Monitoring and Measuring Devices

Lab Managers define and implement effective and efficient measuring and monitoring processes, including methods and devices for verification and validation of services and processes, to ensure the satisfaction of customers and other interested parties. These processes include surveys, kaizens, and other measurement and monitoring activities.

Personnel performing monitoring and measurement activities shall determine the monitoring and measuring devices needed to provide evidence of compliance with service to determined requirements. The QMM will provide assistance in selecting the appropriate device as required.

a. Calibration Activities

The Laboratory Operations Manager is responsible for calibration activities at each department. Responsibilities include establishing and maintaining monitoring and measurement processes in a manner consistent with requirements, taking into account the tolerances required for the measurement and the accuracy and precision of the instrument. Where necessary to ensure valid results, measuring equipment shall be included in the calibration program. The calibration program ensures measuring equipment is:

(1) Calibrated or verified at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards; where no such standards exist, the basis used for calibration or verification shall be recorded;

(2) Adjusted or re-adjusted as necessary

(3) Identified to enable the calibration status to be determined

(4) Safeguarded from adjustments that would invalidate the measurement result

(5) Protected from damage and deterioration during handling, maintenance and storage

In addition, the QMM shall assess and record the validity of the previous measuring results when the equipment does not comply with requirements. The organization shall take appropriate action on the equipment and any product affected. Records of the results of calibration and verification shall be maintained.

When used in the monitoring and measurement of specified requirements, the ability of computer software to satisfy the intended application shall be confirmed. This shall be undertaken before initial use and reconfirmed as necessary. Records of this confirmation shall be maintained with calibrations records.

b. Referenced Procedures

Purchasing Policy and Procedures (Supplier Evaluation)

E. Measurement, Analysis, and Improvement

1. General

As part of our QMS and our commitment to continuous improvement, KHCL has planned and implemented the monitoring, measurement, analysis, and improvement processes needed to demonstrate compliance with the service, to ensure compliance with the quality management system, and to continually improve the effectiveness of the QMS. This includes determination of applicable methods, including statistical techniques, and the extent of their use, with the intention of converting data to information and presenting it in a suitable format for decision-making.

2. Monitoring and Measurement

a. Customer Satisfaction

The KHCL monitors information relating to customer perceptions to determine if we have met customer requirements. The methods for obtaining and using this information are defined in the Customer Satisfaction procedure, (Appendix E).

b. Internal Audit

The KHCL conducts internal audits at planned intervals to determine whether the QMS complies with the planned arrangements for service delivery, QMS requirements, and to determine if the QMS is effectively implemented and maintained.

The Internal Audit Procedure details the audit program including requirements that the audit program be planned, taking into consideration the status and importance of the processes and areas to be audited, as well as the results of previous audits. The audit criteria, scope, frequency, and methods shall be defined. Selection of auditors and conduct of audits shall ensure objectivity and impartiality of the audit process. Auditors shall not audit their own work.

The QMM is responsible for the Internal Audit Program. The responsibilities and requirements for planning and conducting audits, and for reporting results and maintaining records are further detailed in the Internal Quality Audit Procedure, (Appendix F).

Lab Managers shall ensure that actions are taken without undue delay to eliminate non-compliant items and their causes. Follow-up activities shall include verification of the actions taken and reporting of verification results as indicated in the Corrective Action Procedure, (Appendix J).

c. Process Monitoring and Measurement

Lab Managers and the QMM are responsible for monitoring the effectiveness of the processes under their control. These methods shall demonstrate the ability of the processes to achieve planned results.

Correction and corrective action shall be taken, as appropriate, to ensure conformity of the service when planned results are not achieved. Information from process monitoring shall also be considered for continual improvement efforts.

Each process may require different measures depending on its nature.

Examples of potential measures include: process capability, cycle times, efficiency and effectiveness measures, utilization of technologies, waste reduction, and cost allocation and reduction.

d. Service Monitoring and Measurement

KHCL's quality planning defines points at which the characteristics of services are monitored and measured to verify that service requirements have been met (see section VII.D.1).

Inspection records show evidence of conformity with the acceptance criteria. Records shall indicate the person(s) authorizing delivery of service.

Delivery of services shall not proceed until the activities defined in the quality plan have been satisfactorily completed. Any exceptions must be approved by the SMT, and where applicable, by the customer.

e. Referenced Procedures

Purchasing Policy and Procedures

QP3230 - CUSTOMER SATISFACTION (Appendix E)

QP3240 - INTERNAL QUALITY AUDITS (Appendix F)

QP3250 - MONITORING & MEASUREMENT OF PROCESSES (Appendix G)

QP3270 - DATA ANALYSIS AND CONTINUAL IMPROVEMENT (Appendix I)

QP3280 - CORRECTIVE ACTION (Appendix E)

3. Control of Non-Compliant Service

All service that does not comply with requirements shall be identified and controlled to prevent its unintended use or delivery. The Control of Non- Compliant Service Procedure (Appendix H) defines controls and related responsibilities and authorities for dealing with non-compliant service.

a. Non-Compliant Service Actions

The KHCL deals with non-compliant service in one or more of the following ways:

(1) Taking action to eliminate the detected nonconformity

(2) Authorizing its use, delivery, or acceptance under concession by a relevant authority and, where applicable, by the customer

(3) Taking action to preclude its original intended use or application

b. Records of the nature of non-compliant items and any subsequent actions taken, including concessions obtained, shall be maintained according to the Quality Records Procedure (Appendix B).

When non-compliant service is corrected, it shall be subject to reverification to demonstrate compliance with the requirements. When non-compliant service is detected after delivery has started, KHCL shall take action appropriate to the effects, or potential effects, of the non-compliance.

c. Referenced Procedures

QP3260 - CONTROL OF NON-COMPLIANT SERVICE (Appendix H)

QP3010 - QUALITY RECORDS (Appendix B)

4. Analysis of Data

a. Quality Management System Evaluation

The QMM and Lab Managers are responsible for determining, collecting, and analyzing appropriate data to demonstrate the suitability and effectiveness of the QMS and to evaluate where continual improvement of the effectiveness of the QMS can be made. This shall include data generated as a result of monitoring and measurement and from other relevant sources. The analysis of data shall provide information relating to:

(1) Customer satisfaction

(2) Compliance with service requirements

(3) Characteristics and trends of processes and services including opportunities for preventive action, and suppliers

l. Referenced Procedures

QP3010 - QUALITY RECORDS (Appendix B)

QP3070 - CUSTOMER COMPLAINTS (Appendix D)

QP3230 - CUSTOMER SATISFACTION (Appendix E)

QP3260 - CONTROL OF NON-COMPLIANT SERVICE (Appendix H)

QP3270 - DATA ANALYSIS AND CONTINUAL IMPROVEMENT (Appendix I)

5. Improvement

a. Continual Improvement

The KHCL shall continually improve QMS effectiveness using the quality manual, quality objectives, audit results, analysis of data, corrective and preventive actions, and management review programs.

b. Corrective Action

The QMM is responsible for managing the Corrective Action Program. As defined in the Corrective Action Procedures (Appendix J), all personnel are responsible for taking action to eliminate the cause of non-compliant items in order to prevent recurrence. Corrective actions shall be appropriate to the effects of the non-compliant items encountered.

The Corrective Action Procedure defines requirements for:

(1) Reviewing non-compliant items (including customer complaints)

(2) Determining the causes of non-compliance

(3) Evaluating the need for action to ensure that noncompliant items do not recur

(4) Determining and implementing action needed

(5) Records of the results of action taken

(6) Reviewing corrective action taken

c. Preventive Action

The QMM is responsible for managing the Preventive Action Program.

Preventive action is greatly preferred to Corrective action and is substantially less costly. As defined in the Preventive Action Procedures (Appendix K), all personnel are responsible for taking action to eliminate the causes of potential non-compliant items in order to prevent their occurrence. Preventive actions shall be appropriate to the effects of the potential problems.

The Preventive Action Procedure defines requirements for:

(1) Determining potential non-compliant items and their causes

(2) Evaluating the need for action to prevent occurrence of non-compliant items

(3) Determining and implementing action needed

(4) Records of results of action taken

(5) Reviewing preventive action taken

d. Continual Improvement of KHCL

In order to ensure the future of the KHCL and the satisfaction of its customers, the SMT creates a culture which involves people actively seeking opportunities for improvement of performance in processes, activities, and services. To involve people, the SMT creates an environment where authority is delegated and people are empowered to accept responsibility for identifying opportunities where the KHCL can improve performance. The SMT achieves this with activities such as: setting of objectives for people and projects, benchmarking, and best practices.

r. Referenced Procedures

QP3270 - DATA ANALYSIS AND CONTINUAL IMPROVEMENT (Appendix I)

QP3280 - CORRECTIVE ACTION (Appendix J)

QP3290 - PREVENTIVE ACTION (Appendix K)

VIII. Distribution List

Electronically, using Everyone mailing list, and posted to KHCL web page.

IX. History Notes

Original procedure effective June 1, 2014

Revision Date Summary of Revision

See Document Details via SharePoint

X. Appendices

A. QP3000 - Document Control

B. QP3010 - Quality Records

C. QP3020 - Management Responsibility

D. QP3070 - Customer Complaints

E. QP3230 - Customer Satisfaction

F. QP3240 - Internal Quality Audits

G. QP3250 - Monitoring & Measurement of Processes

H. QP3260 - Control of Non-Compliant Service

I. QP3270 - Data Analysis and Continual Improvement

J. QP3280 - Corrective Action

K. QP3290 - Preventive Action

L. QP3300 – Design and Development

M. QP3310 – Design Change

N. QP3320 – Service Development Quality and Planning

Appendix A - QP3000 – DOCUMENT CONTROL

Purpose: To define the methods and responsibilities for controlling procedures, procedure revision, and distribution.

Scope: Applies to all KHCL Procedures.

Responsibilities:

Lab Managers and Supervisors are responsible for ensuring that relevant and legible versions of documents are available at points of use. The Planning and Project Manager is responsible for reviewing all procedures and instructions at least annually to ensure documents remain current.

Definitions:

Procedure: A document that provides information or direction for performance of work involving one or more KHCL programs.

Document: Information and its supporting medium. The medium can be paper, magnetic, electronic, optical computer disc, photograph, or sample.

Procedure:

1.0 PROCEDURE DISTRIBUTION

1.1 The Planning and Project Manager is responsible for the distribution of KHCL procedures. Distribution will be accomplished by posting the procedures to the Policies

SharePoint site.

The SharePoint site will contain the following information:

· Document Number

· Document Title

· Effective Date

· Program

Distribution of updated procedures will be accomplished by moving the previous version to the RESCINDED POLICIES AND PROCEDURES folder and posting the revised procedure to the KHCL CURRENT POLICIES AND PROCEDURES folder.

2.0 PROCEDURE REVISION

2.1 To ensure that procedures remain current, the Planning and Project Manager is responsible for reminding Lab Managers to review and update their procedures on an annual basis.

2.2 New procedures, or revisions to existing procedures, may be submitted at any time.

2.3 Submission of new procedures or procedure revision will be in accordance with the current procedure (KHCL Procedure for Writing, Instituting, and Revising Department Policies, Protocols, and Procedures).

Effectiveness Criteria:

Average time to release document changes.

References:

KHCL Procedure for Writing, Instituting, and Revising Department Policies, Protocols, and Procedures.

Quality Manual:

· QM VII.A.2.c - Control of Documents

Records:

Signed master copies of KHCL procedures.

Appendix B – QP3010 – QUALITY RECORDS

Purpose: To define the process of properly maintaining quality records so that evidence of adherence to requirements and the effective operation of the Quality Management System can be demonstrated. This procedure explains how documentation for records affecting the quality process at the KHCL is accomplished.

Scope: This procedure applies to all records generated, handwritten, hardcopy and electronic, that serves to record KHCL activities related to quality. This procedure covers from the time a new quality record is received or created to the time of its disposition.

Responsibilities:

Lab Managers are responsible to ensure that quality records relative to each section of this QMS remain readily identifiable, legible, and retrievable. All personnel are responsible for ensuring records they generate are legible, readily identifiable and retrievable.

Procedure:

1.0 IDENTIFICATION OF QUALITY RECORDS

1.1 The KHCL requires documentation for every aspect of a service delivery. Records maintained by each department, to provide objective evidence of adherence, implementation, and effective operation of the QMS, are defined in each procedure and/or work instruction.

1.2 QP3010-1 QUALITY RECORDS provides a complete list of Quality Records.

2.0 RECORD GENERATION

2.1 All personnel are responsible for ensuring records they generate are legible, readily identifiable, and retrievable.

2.2 Quality records which can be faxed within an acceptable time frame are also considered readily retrievable.

2.3 Quality records should be protected from unauthorized change.

2.4 Changes or corrections to records should be recorded, dated and initialed by the person

making the change.

3.0 RECORD MAINTENANCE AND CONTROL

3.1 Each program manager is responsible for assuring records are maintained in a suitable environment that prevents damage, deterioration, and loss of the records.

3.2 The storage and protection of the record are defined by whether it is hard copy or electronic, and where the document is stored. It is the responsibility of each program manager to create methods for storage to prevent loss of records as appropriate for the particular record.

3.3 Active quality records must be readily retrievable. Active records are those that have not yet met their minimum retention times. Inactive quality records may be archived.

Archived records are retrievable, but not necessarily readily retrievable.

3.4 Records should have security access.

3.5 Quality records are destroyed after their minimum retention time is attained.

Effectiveness Criteria:

N/A

References:

Quality Manual

· QM VII.A.2.d - Control of Records

Records:

QP3010-1 QUALITY RECORDS

QP3010-1 QUALITY RECORDS

Record	File Location	Authority	Minimum Retention	Disposition
Internal Audit Records	Program Files	Program Managers Quality Management	3 years	Destroy
Process Audits	Quality Management	Quality Management	3 years	Destroy
Inspection Records	Quality Management	Quality Management	7 years	Destroy
Service Records	Quality Management	Quality Management	7 years	Destroy
Non-compliance Reports	Quality Management	Quality Management	3 years	Destroy
Corrective Actions	Program Files	Program Managers	5 years	Destroy
Preventive Actions	Program Files	Program Managers	5 years	Destroy
Document Masters	Document Control	Quality Management	5 years	Destroy
Customer Complaints	Quality Management	Quality Management	3 years	Destroy
Process Validation Records	Quality Management	Quality Management	Life of Process	Destroy
Customer Satisfaction Surveys	Customer Service	Customer Service	5 years	Destroy

Appendix C – QP3020 – MANAGEMENT RESPONSIBILITY

Purpose: To ensure that management is responsible for establishing, documenting and implementing a quality management system that conforms to specified customer requirements and reviewing the quality system to ensure continued suitability and effectiveness.

Scope: This procedure applies to the Senior Management Team (SMT), Quality

Management Manager, and all Laboratory managers and supervisors involved with the KHCL's QMS.

Responsibilities:

The SMT holds primary responsibility for implementation of this procedure and ultimately the entire QMS. Laboratory managers and supervisors, as part of the Management Team are responsible for supporting the SMT and QMM in implementing this procedure.

The QMM has responsibility and authority that includes ensuring processes needed for the QMS are established, implemented and maintained; reporting to the SMT and the Quality Council on the performance of the QMS and any need for improvement; and ensuring the promotion of awareness of customer requirements throughout the organization.

Human Resources (HR) has the responsibility to establish and maintain Job Descriptions to define responsibilities and authorities throughout KHCL. HR also maintains the KHCL Organization Chart.

Definitions:

Quality Council: Selected Laboratory managers and supervisors, and the Quality Management Manager.

Procedure:

1.0 CUSTOMER FOCUS

It is our policy to understand and satisfy the current and future needs of our present and potential customers and to provide services that meet those needs while enhancing customer satisfaction.

2.0 PLANNING

2.1 On an annual basis, the SMT conducts strategic planning meetings with the Quality Council (see Annual Strategic Planning Process for details).

2.2 Strategic goals and objectives, as well as quality objectives, are set at the strategic planning meetings. Planning provides the framework for developing objectives to meet current and future needs of the KHCL and our customers. Objectives are measurable, defined at the planning session, consistent with the quality policy, and they include a commitment to continual improvement. The integrity of the QMS is maintained when changes are made to the system. The Quality Council is responsible and has the authority for planning activities.

3.0 RESPONSIBILITIES, AUTHORITIES, AND COMMUNICATION

3.1 It is management policy to ensure that responsibilities and authorities are defined and communicated within the organization. Management ensures the use of internal communication to convey the effectiveness of the QMS. The Quality Council is responsible for communication activities.

3.2 Supervisors develop and Human Resources maintains Job Descriptions for all positions at KHCL. (See POSITION DESCRIPTION FORM)

4.0 MANAGEMENT REVIEW

4.1 It is management policy to ensure that formal management review meetings are conducted, at planned intervals, with documented agenda and minutes as records.

4.2 During these meetings, management reviews the entire QMS for continuing suitability, adequacy and effectiveness.

4.3 Management reviews critical indicators, that represent the organization's performance in achieving quality objectives, and assesses opportunities for improvement and the need for change to the QMS, including the quality policy and objectives.

4.4 Management review minimally includes:

· internal quality system audit results

· customer feedback

· process performance and service conformity

· status of preventive and corrective actions

· follow-up actions from previous management reviews

· changes that could affect the quality management system

· recommendations for improvement

4.5 The Quality Management Manager is responsible for ensuring minutes of the meeting

are taken and for maintaining the minutes as a Quality Record (see Quality Procedure:

QP3010 - QUALITY RECORDS (Appendix B).

4.6 The output from a management review includes decisions and actions related to:

· Improvement of the effectiveness of the QMS and processes

· Service improvement related to customer requirements

· Resource needs

4.7 The Quality Council is responsible and has the authority for management review activities.

Effectiveness Criteria:

NA

References:

Quality Procedures:

QP3010 - QUALITY RECORDS (Appendix B)

POSITION DESCRIPTION FORM

Records:

Management Review Minutes

Appendix D – QP3070 - CUSTOMER COMPLAINTS

Purpose: This procedure defines the process for receiving, reviewing, documenting, and taking action on all forms of customer complaints. A customer complaint is defined as any written or verbal communication from the customer expressing dissatisfaction with the service provided by the KHCL in which further investigation and possible corrective action is required.

Scope: This procedure applies to personnel who receive customer calls or complaints regarding services the KHCL provides.

Responsibilities:

Customer Service Representative has the responsibility to review each customer complaint according to this procedure and ensure that the appropriate action is taken on the complaint.

All employees have the responsibility to understand and follow this procedure if a customer has an issue with KHCL services.

Lab Managers are responsible to ensure that all employees are properly trained in this procedure.

All programs are responsible for assisting Customer Service to resolve customer complaints.

Procedure:

1.0 PROCESS

1.1 Any employee of the KHCL can receive a customer complaint and therefore needs to understand this procedure for acting on these complaints.

1.2 Complaints will be defined as any communication from the customer expressing dissatisfaction regarding the services offered by the KHCL.

1.3 Complaints can be received by telephone, fax, electronic mail, written letters, internet, or verbal messages.

1.4 The person receiving the complaint will document this complaint in an email and send it to mhdlab@milwaukee.gov ensuring that all the applicable information has been gathered. The name and email address of the person issuing the complaint is entered on the email.

2.0 RECEIVING A CUSTOMER COMPLAINT

2.1 A customer service representative will enter the information about the complaint into a database with the appropriate information including date, customer name, service description and brief description of the problem or reason for the contact. Further, the database should document whether the contact was resolved (i.e. by telephone) or if a customer service contact has been completed.

2.2 Proper investigation and/or corrective action of all complaints/problems should be taken as appropriate and documented on the Complaint Master Database.

2.3 While customer complaints are in process, the database record should be kept open until final disposition is reached.

2.4 Upon completion/resolution of the complaint/problem, copies will be emailed to the following individuals:

· Program manager

· Quality management manager

3.0 PROBLEM DIAGNOSIS

3.1 When receiving a call by telephone or when calling a customer in regards to a written complaint, discuss with the customer what the problem is, what the service is, etc.

3.2 If the problem/question can be rectified by telephone, make sure that the problem is corrected and that everything is resolved properly before hanging up with the customer.

4.0 ANALYSIS:

4.1 To facilitate failure detection or detect trends of service non-compliance, customer service will perform the following:

· Create monthly reports from the Complaint Master database.

· Review of Complaint Files.

4.2 The Customer Service representative will review the customer service database for any recurring problems/complaints. If any trends are detected, the Customer Service representative will review the problems with the Quality Management Manager. Based upon this review, appropriate investigation and corrective action will be determined

(QP3280 - CORRECTIVE ACTION (Appendix J)).

Effectiveness Criteria

Customer satisfaction

Timely complaint resolution

References:

Quality Manual:

· QM VII.D.2.c - Customer Communication

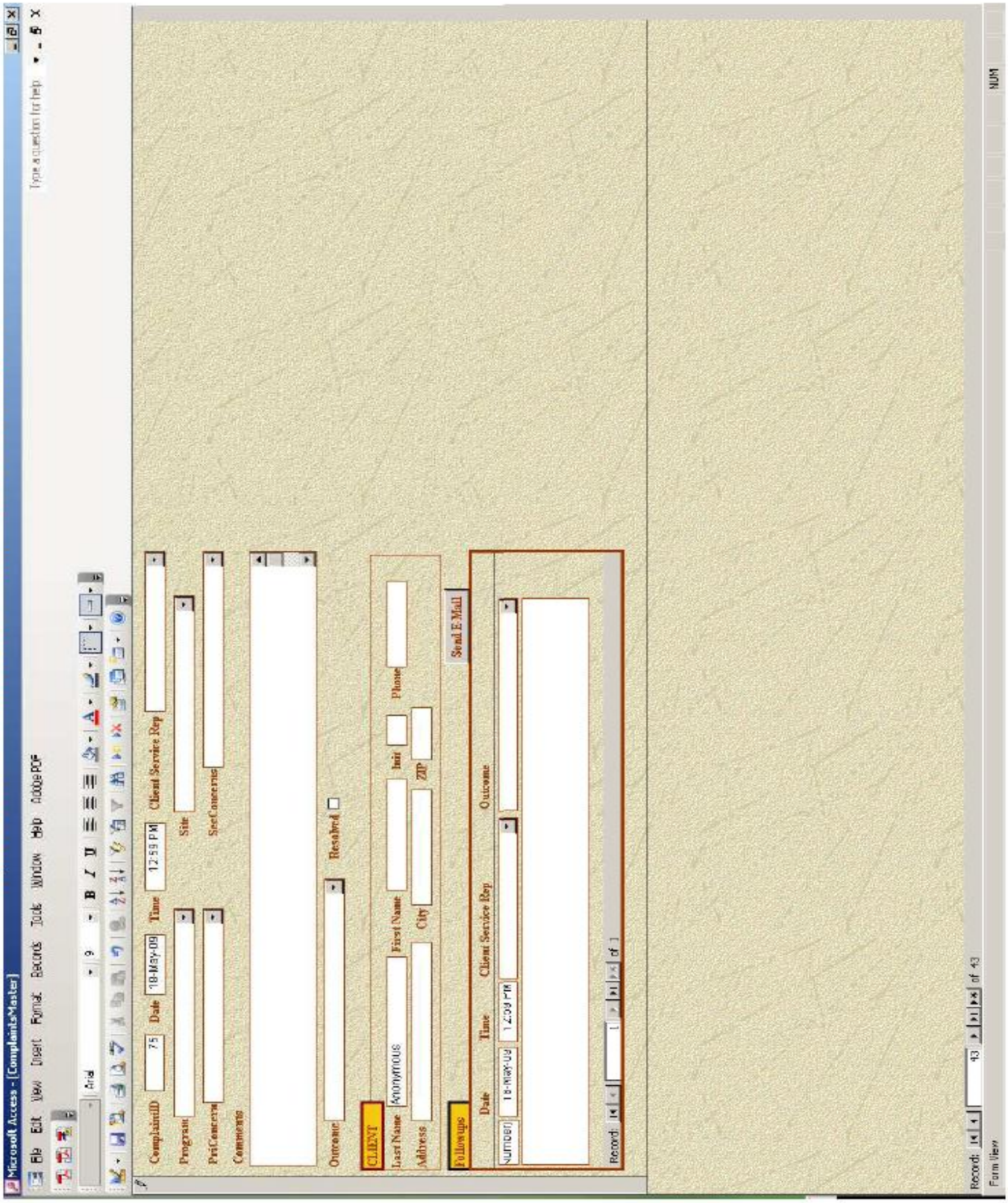
Quality Procedure:

· QP3280 - CORRECTIVE ACTION (Appendix J)

Records:

QP3070-1 COMPLAINTS MASTER DATABASE

Customer Complaints



QP3070-1 COMPLAINTS MASTER DATABASE

Appendix E – QP3230 - CUSTOMER SATISFACTION

Purpose: This procedure describes the steps for obtaining information regarding our customers' perception as to whether the KHCL has met their requirements with our services.

Scope: This procedure applies to each program that provides services to our customers.

Responsibilities:

The program representative will be responsible for interfacing with the customer to determine whether the KHCL meets or exceeds the customer's requirements. The SMT is responsible for ensuring KHCL meets or exceeds customer requirements.

Procedure:

1.0 GENERAL

Each program gathers customer satisfaction surveys after the delivery of the service. These surveys are used to determine customer satisfaction with our processes and the delivery of our services. Information gathered will be used to make improvements in our operations, quality control, etc.

2.0 CUSTOMER SURVEY

2.1 On a monthly basis, the Data Analysis section prints a report from the computer system of survey data completed over the past 13 months.

2.2 If any corrective action needs to be taken or customer concerns addressed, the appropriate program is responsible for contacting the customer and resolving the situation. If applicable, this will include following the standard operating procedures for Customer Contact/Complaint Handling.

2.3 The survey will then be routed to all Laboratory managers and supervisors for their review and to determine if any improvements in their operational or design areas are needed.

Effectiveness Criteria:

Return rate of surveys

References:

Quality Manual:

· QM VII.E.2.a - Customer satisfaction

Records:

QP3230-1 CUSTOMER SATISFACTION REPORTS

QP3230-1 CUSTOMER SATISFACTION REPORT

Person Calling:_____ Date:_____

Customer Name:_____ Telephone:_____

Contacted: ❒ Yes, Spoke with:_____

❒ No, Left message with:_____

Telephone Conversation

Opening Message:

"Hi, I'm _____

and we saw you _____

last ____/____/_____ and I'm following up to see if everything was handled correctly and if there is anything that we can do for you._____

Initial Customer Feelings

❒ Very Happy
❒ Satisfied
❒ Unhappy
❒ Very Unhappy

Comments:_____

"Would you help us by answering the following questions about your service?

"Were you treated courteously?" ❒ Yes ❒ No

"Was the _____ ready when promised?" ❒ Yes ❒ No

"Was the location at ____ _____clean?" ❒ Yes ❒ No

"Is there anything we can do to improve our service?"_____

"Thank you for taking the time to answer our questions." < Say goodbye and hang-up >

STOP - Customer Service Personnel Comments ONLY -

Do you feel the customer's feelings towards ORCHD improved by the end of your conversation?

Approximate time spent talking with customer:_____

Additional Comments or Follow-up action:_____

Copy To:

Appendix F – QP3240 - INTERNAL QUALITY AUDITS

Purpose: To provide for a system and instructions to assign responsibilities for conducting internal quality audits.

Scope: All operations affecting the KHCL Quality Management System (QMS).

Responsibilities:

The Quality Management Manager (QMM) is responsible for the Internal Audit program.

Internal Auditors are responsible for conducting complete, detailed, and objective Internal Audits and reporting their findings.

All personnel are responsible for cooperating with Internal Auditors in the course of the audit process and taking appropriate corrective action for any deficiencies found during the course of the audits.

Procedure:

1.0 PLAN ANNUAL SCHEDULE OF AUDITS

1.1 The QMM is responsible for planning and scheduling internal quality audits. Each activity/location is audited at least once a year. Activity/location is a single activity of the QMS implemented in a single location. In addition to the annually scheduled audits, certain activities/locations are selected for more frequent auditing, depending on their status, importance, and past compliance history.

1.2 Prior to the audit, an audit plan will be prepared. The audit plan is a matrix with the vertical side listing all activities of the quality system and the horizontal side listing plan dates and locations (areas, functions, programs etc) where the QMS is implemented.

1.3 The internal auditing plan schedules dates and assigns audit teams for all auditable activities/locations. Several units may be clustered into one audit.

1.4 The internal audit plan is synchronized with management reviews of the QMS, so that results of an auditing cycle are available for the management review meeting.

Steps Target:

Annual Audit Schedule will be prepared within the first month of each year. Each location unit will be audited at least once a year.

2.0 IDENTIFY AUDIT TEAM

2.1 Personnel assigned to carry out internal audits are independent of those having direct responsibility for the audited activity.

2.2 All internal auditors are trained and training records are maintained.

Steps Target:

All internal auditors will be trained before they are assigned to carry out audits.

3.0 PREPARE FOR AUDIT

3.1 Auditors prepare for an audit by fully familiarizing themselves with the QMS and relevant operational procedures, reviewing non-compliance reports and corrective action files and preparing questions and checklists. Steps Target: Audit Checklists will be prepared prior to an audit.

4.0 CONDUCT AND REPORT THE AUDIT

4.1 The manager responsible for the area scheduled for audit is contacted at least one week in advance with the proposed audit date. The manager responds with a confirmation or proposes an alternative date.

4.2 While conducting the audit, auditors seek objective evidence demonstrating whether the audited activities comply with the requirements of the documented QMS. When noncompliance is noted, it is brought to the attention of, and discussed with the responsible manager. Before the end of an audit each noted non-compliant item is documented using the audit non-compliance report form. Auditors fill out only the first part of the form, describing the noted non-compliant item. The form is then handed over to the responsible manager who uses its second part to propose a corrective action.

5.0 CORRECTIVE ACTION AND FOLLOW-UP

5.1 Once a non-compliant item is identified and documented, further processing of the noncompliance report follows the same procedure as applies to corrective action requests. Upon receiving the report, the responsible manager investigates the cause of the problem noted as a non-compliant item, proposes a corrective action to be taken, and indicates the date by which the corrective action will be fully implemented. The auditor/management representative reviews and approves the proposed action.

5.2 On or after the due date for implementation of corrective action, the auditor follows up with an inquiry or an audit to determine if the corrective action has been implemented and if it is effective. When there is objective evidence that the corrective action is effective, the non-compliance report is closed out. If more work is needed to fully implement the action, a new follow-up date is agreed upon.

Step Target:

Proposed corrective action will be documented within 1 week.

6.0 DOCUMENTATION AND RECORD

6.1 Internal audits, implementation of resulting corrective actions, and follow-up audits are documented using the audit non-compliance report form.

6.2 Part 1 of the form contains a description of the non-compliant condition. Part 2 contains the proposal for a corrective action and Part 3 is reserved for the follow-up audit and close-out of the report.

6.3 Pending non-compliance reports are kept by the auditor who initially issued the report.

6.4 At the end of an auditing cycle, all non-compliance reports established during the cycle are compiled and analyzed, and are presented at the Quality Council.

Effectiveness Criteria:

Compliance with Quality Manual requirements.

References:

Quality Manual

· QP3280 - CORRECTIVE ACTION (Appendix J)

Records:

QP3240-1 QUALITY ASSURANCE AUDIT CHECKLIST

QP3280-1 CORRECTIVE ACTION PLAN

Audit Reports, log and objective evidence

QP1240-1 QUALITY ASSURANCE AUDIT CHECKLIST

Audit Objectives: _____ **Audit No.:** _____

Audit Scope: _____ **Date:** _____

Standard (Requirements)/Applicable Documents: _____

_____

Item No.	Activity To Be Checked	Compliance (Y/N)	Remarks

Sign Auditor: *Sign Auditee:*

Auditor Name: *Auditee Name:*

Date: *Date:*

Distribution ☐ *QMM*

☐

_____

_____

Others : _____

Appendix G – QP3250 - MONITORING AND MEASUREMENT OF PROCESSES

Purpose: This procedure describes the process for the scheduled Monitoring & Measurement of key characteristics of KHCL activities, and provides guidance for preparing monthly reports which will be reviewed during monthly Quality Council meetings. Data collected via this procedure will be a component of the Management Review function of this QMS, to ensure Continuous Improvement, adequacy and effectiveness of the QMS.

Scope: This procedure applies to all quality management system processes, including processes used for service delivery.

Responsibilities:

The Quality Management Manager is responsible for collecting, analyzing, and publishing measurement data.

All Laboratory managers and supervisors are responsible for producing and using process monitoring and measuring data to continuously improve the KHCL QMS and customer satisfaction.

Procedure:

1.0 CRITERIA

1.1 Determine what parameters are to be measured and recorded along with Lab Managers from each program.

1.2 The process for Monitoring & Measurement associated with those programs and activities will include specific details on:

· What parameter to monitor and measure.

· How such measurement is to occur (including frequency).

· Record keeping.

· Reporting of measurements, including deviations from normal operations.

· Reference to appropriate calibration of equipment, as necessary.

1.3 Ensure appropriate resources (financial, human, and technological) are available to monitor and measure the selected parameters.

1.4 Ensure training is provided on monitoring and measurement methods.

1.5 Collect the Monitoring & Measurement data from the identified activities and services to prepare a report. This report could include initial data to establish baseline conditions for future comparison, and would be structured at a minimum to:

· Provide status of programs designed to fulfill KHCL Objectives & Targets.

· Provide status of performance indicators as related to targeted timeframes,

· Provide compliance status.

1.6 programs receiving the outputs of the processes should be included when determining the effectiveness criteria and measurements to be used.

1.7 Lab Managers are responsible for defining measurements, where possible, for measuring process effectiveness.

2.0 PERFORMANCE TRACKING

2.1 Program data collected to reflect service performance is to be maintained in a manner that allows the evaluation of progress toward KHCL Objectives & Targets.

2.2 Lab Managers submit monthly reports on process monitoring and measuring data to the Quality Management Manager for data analysis (see QP3270 - DATA ANALYSIS AND CONTINUAL IMPROVEMENT).

2.3 The QMM publishes monthly reports analyzing the data supplied by Lab Managers.

3.0 IMPROVEMENT

3.1 When process monitoring shows that planned results are not achieved, corrective action shall be taken to ensure compliance with service (see QP3280 - CORRECTIVE ACTION (Appendix J)).

3.2 Information resulting from process monitoring and measuring activities shall be used in continual improvement efforts, including Preventive Action (see QP3290 – PREVENTIVE ACTION (Appendix K)).

Effectiveness Criteria:

Progress in meeting objectives.

References:

Quality Manual section:

· QM VII.E.2.c - Monitoring and Measurement of Processes

Quality Procedures:

· QP3020 - MANAGEMENT RESPONSIBILITY (Appendix C)

· QP3270 - DATA ANALYSIS AND CONTINUAL IMPROVEMENT (Appendix I)

· QP3280 - CORRECTIVE ACTION (Appendix J)

· QP3290 - PREVENTIVE ACTION (Appendix K)

Records:

Process monitoring reports

Appendix H – QP3260 - CONTROL OF NON-COMPLIANT SERVICE

Purpose: This procedure outlines the handling of non-compliant service. Any noncompliant service items or processes are to be identified and documented to prevent their inadvertent use. Non-compliance reports are an invaluable tool in tracking performance and trends that give indication where and when cost effective improvements should be implemented.

Scope: This procedure applies to all non-compliant items or steps found during delivery of the service.

Responsibilities:

The Quality Management Manager and Program Manager are responsible for determining the resolution of non-compliant services or processes. All personnel are responsible for identifying non-compliant or suspected noncompliant service items or processes and notifying management of the noncompliant item.

Definitions: Non-Compliant Service: Any item, step, or process that does not meet established specifications.

Procedure:

1.0 IDENTIFICATION AND DOCUMENTATION

1.1 Each program is responsible for identifying non-compliant service in the course of their activities. In addition, all other personnel, regardless of their other responsibilities, are encouraged to watch for and identify non-compliant services.

1.2 Wherever non-compliance is identified, it is documented as a NCR report.

1.3 After the nature of the identified non-compliant item is documented, the service noncompliance report is further processed with regard to non-compliance review, disposition, and correction.

1.4 The rejected step or process shall be clearly identified to prevent it from being accidentally used as acceptable service.

2.0 NON-COMPLIANCE REPORT

2.1 The person identifying the non-compliant item also completes the top section of the

QP3260-1 NON-COMPLIANCE REPORT. The following items must be completed:

· Date

· Service name or description

· Problem description

· Location of service

· Printed name of person identifying the service item, step or process

2.2 Forward the Non-Compliance Report to Quality Management.

3.0 DISPOSITION

3.1 Non-compliant service may be:

· Reworked to meet the specified requirements of customers and program objectives.

· If the service would in any way affect quality and issues related to policy matters or if there is a possibility for an accept-as-is decision, the evaluation and disposition and corrective action will be made with consultation and/or directives of the program manager.

3.2 The managers determining the disposition sign the QP3260-1 NON-COMPLIANCE REPORT in the appropriate area.

3.3 Revised services or processes must be re-evaluated in accordance with procedures to verify that they comply with the same requirements as originally specified.

4.0 CORRECTIVE ACTION

4.1 The Quality Management Manager while performing the disposition determines if corrective action is required to prevent recurrence of the non-compliant service. If corrective action is required, then QP3280-1 CORRECTIVE ACTION PLAN (CAP) must be completed and the CAP number is indicated in the appropriate block of the QP3260-1 NON-COMPLIANCE REPORT. If no corrective action is required, indicate N/A.

4.2 Each program is responsible to review, categorize, quantify, and analyze noncompliance reports to detect trends and identify the possible need for corrective and preventive actions. These activities are regulated by Corrective and Preventive Action procedures.

Effectiveness Criteria:

Prevention of non-compliant services reaching customers.

Adequate records for improvement data analysis.

References:

Quality Manual section:

· QM VII.E.3 - CONTROL OF NON-COMPLIANT SERVICE

Quality Procedures:

· QP3070 - CUSTOMER COMPLAINTS (Appendix D)

· QP3280 - CORRECTIVE ACTION (Appendix J)

Records:

QP3260-1 NON-COMPLIANCE REPORT

Non-Compliant Repair Instruction

Variance or Deviation Request

QP3260-1 NON-COMPLIANCE REPORT

Attach additional sheets if necessary

Service Name		**NCR #:**
Service Description		
NR#	**Location**	
Non-Compliant Item		
Originator:		**Date:**
Disposition		
❒ ❒ ❒		
Detail Instructions:		
Dispositioned By:		**Date:**
Action Taken:		
By		**Date:**
Corrective Action		
Corrective Action Required?		CAP #
Authorized By:		**Date:**

Appendix I – QP3270 - DATA ANALYSIS AND CONTINUAL IMPROVEMENT

Purpose: This procedure communicates the process that engages the KHCL in the identification, collection, and analysis of appropriate data to demonstrate the effectiveness of the quality management system, and implementation of strategic and operational initiatives necessary to achieve the KHCL's core mission, and to evaluate where continual improvement can be made.

Scope: This procedure applies to all programs included in the QMS.

Responsibilities:

The Quality Management Manager is responsible for collecting, analyzing and publishing measurement data.

All Laboratory managers and supervisors are responsible for producing and using process monitoring and measuring data to continuously improve KHCL's QMS.

Procedure:

1.0 DATA COLLECTION

1.1 All programs collect data and send it to the Quality Management Manager for analysis

(see QP3250 - MONITORING AND MEASUREMENT OF PROCESSES (Appendix G)).

1.2 The data analysis shall be based in the following criteria:

· Customer Satisfaction

· Service quality data regarding conformity to customer requirements

· Process monitoring and measurement data

2.0 DATA ANALYSIS

2.1 The Quality Management Manager analyzes the data using statistical techniques where appropriate.

2.2 The Quality Management Manager reports the information generated from the data analysis in a format that quickly shows the important information for management decisions. This is usually a graphic format with areas of interest or concern highlighted in some fashion.

2.3 The information reported includes:

· Trends and issues related to customer satisfaction

· Service conformity to customer requirements

· Characteristics and trends of processes and services including opportunities for preventive action and continual improvement

3.0 CONTINUAL IMPROVEMENT

3.1 The results of data analysis are reviewed by the Quality Council during management review meetings (see QP3020 - MANAGEMENT RESPONSIBILITY (Appendix C)).

3.2 The Quality Council considers the results of data analysis, the quality policy, quality objectives, internal audit results, and corrective and preventive actions to determine opportunities to continually improve the effectiveness of the QMS.

3.3 When specific opportunities are identified, the Quality Council initiates a Quality Improvement Team to investigate, analyze, and report findings and recommendations for improvement (see QP3280 - CORRECTIVE ACTION (Appendix J) and QP3290 - PREVENTIVE ACTION (Appendix K)).

3.4 The Quality Council reviews the reports and presentations by the Quality Improvement Teams and approves or declines the recommended actions based on cost, projected return on investment, and other factors determined by the SMT.

3.5 If approved, management provides the resources required to implement the recommended actions. A new charter is put in place with the original Quality Improvement Team and members from the functional area being improved. 3.6 The effectiveness of these actions is monitored by the Quality Council in quarterly meetings with the Quality Improvement Teams and in future management reviews.

Effectiveness Criteria:

Cost reductions

Process improvement

References:

Quality Manual sections:

· QM VII.B - MANAGEMENT RESPONSIBILITY

· QM 8.4 - ANALYSIS OF DATA

· QM 8.5 - IMPROVEMENT

Quality Procedure sections:

· QP3020 - MANAGEMENT RESPONSIBILITY (Appendix C)

· QP3250 - MONITORING AND MEASUREMENT OF PROCESSES (Appendix G)

· QP3270 - DATA ANALYSIS AND CONTINUAL IMPROVEMENT (Appendix I)

· QP3280 - CORRECTIVE ACTION (Appendix J)

· QP3290 - PREVENTIVE ACTION (Appendix K)

Records:

Data Analysis Reports

Meeting Minutes and Reports

Appendix J – QP3280 - CORRECTIVE ACTION

Purpose: Establish the minimum requirements for corrective action.

Scope: This procedure applies to all causes of non-compliant items relating to service discovered during service delivery or during internal quality audits.

Responsibility and applicability:

Quality Management Manager is responsible for reporting on corrective and preventative actions taken during Internal Audits and Management Review

Meetings.

All KHCL personnel are responsible for identifying non-compliant conditions and initiating a Corrective Action Plan.

Procedure:

1.0 INITIATING A CORRECTIVE ACTION

1.1 When documented quality management process goals are not achieved, corrective action shall be taken, as appropriate, to ensure conformity of the service or process.

1.2 Each program shall maintain a documented procedure for corrective action. The corrective action procedure shall include:

· Evaluating non-compliant items that have occurred and identifying their root causes,

· Evaluating appropriate action to contain, resolve, and prevent recurrence of noncompliant items,

· Executing action determined to be needed,

· Documenting results of analysis of root causes, actions taken, and confirming the effectiveness of the corrective action.

1.3 The following are examples of cases for which corrective action is commonly initiated:

· Customer complaints or disruptions,

· Audit non-compliant findings,

· Supplier quality issues,

· Service or support deficiencies,

· Internal quality problems or alerts,

· Negative trends, and

· Safety issues.

2.0 RECORD

2.1 All records pertaining to corrective actions that are completed shall be maintained in the relevant file.

Effectiveness Criteria:

Timeliness of corrective actions.

Prevention of recurrence.

References:

Quality Manual section:

· QM VII.E.5.b - CORRECTIVE ACTION

Records:

Corrective Action Plan

Appendix K – QP3290 - PREVENTIVE ACTION

Purpose: Establish the minimum requirements for preventive action.

Scope: All KHCL personnel are responsible to detect, analyze, and eliminate potential causes of non-compliant items and customer complaints.

Responsibilities:

Program Manager and the Quality Management Manager are responsible for using information generated during data analysis to initiate Preventive Actions as appropriate to the nature of the potential non-compliant item identified.

Definitions: Quality Improvement Team: A Quality Improvement Team is a cross-functional team chartered with the task of identifying the cause or causes of the potential non-compliant items and identifying the actions to be implemented to eliminate the potential non-compliant items.

Procedure:

1.0 INITIATING A PREVENTIVE ACTION

1.1 Each program shall maintain a documented procedure for preventive action. The

preventive action procedure shall:

· Identify potential non-compliant items and their root causes,

· Evaluate appropriate action to prevent potential non-compliant items,

· Execute action determined to be needed,

· Document results of analysis of potential root causes, actions taken, and confirming the implementation of the preventive action.

1.2 Analysis of information is one of the techniques that shall be used to identify preventive actions.

1.3 The following are examples of activities that may lead to preventive action/improvement activities:

· Risk assessments,

· Change control effects,

· Opportunities for improvement (e.g. noted in audit reports),

· Lessons learned, and

· Trend analysis for improving leading indices such as for market and technology trends, customer orders, supplied materials, yield enhancement, outlier programs, and equipment maintenance programs.

2.0 RECORD

2.1 All records pertaining to preventive actions that are completed shall be maintained in the relevant file.

Effectiveness Criteria:

Reduced rate of non-compliant items.

Reduced customer complaints.

References:

Quality Procedures:

· QP3020 - MANAGEMENT RESPONSIBILITY (Appendix C)

· QP3270 - DATA ANALYSIS AND CONTINUAL IMPROVEMENT (Appendix I)

· QP3280 - CORRECTIVE ACTION (Appendix J)

Records:

Corrective Action forms

Preventive Action forms

QIT meeting minutes

Appendix L - QP3300 – DESIGN AND DEVELOPMENT

Purpose: To define the steps for planning, designing, developing, and reviewing new services or extensive modification to an existing service to meet customer requirements.

Scope: This procedure applies to all new services and all significant changes to existing services.

Responsibilities:

All personnel in the KHCL are encouraged to be involved in process improvement.

Definitions:

Failure Mode and Effects Analysis - Failure Mode and Effects Analysis (FMEA) is

an evaluation technique for testing the design of services in which failures are assumed to occur. “Failure modes” means the ways, or modes, in which something might fail. Failures are any errors or defects, especially ones that affect the customer, and can be potential or actual. “Effects analysis” refers to studying the consequences of those failures.

Procedure:

1.0 NEW SERVICE OR MODIFICATION TO EXISTING SERVICE INITIATION

All personnel in the KHCL are encouraged to be involved in service and process improvement. Lab Managers shall determine and initiate viable service development projects.

2.0 PLANNING AND DEVELOPMENT

2.1 Documentation shall be created describing the new service or modification to an existing service that detail the reasons for the request and proposed recommendations.

2.2 The Legal Office shall ensure that all new services or modification to existing services comply with local and state laws.

2.3 The Grants Administrator shall search for the possibility of external funds, if they are available, for the type of service or modification to service that is being proposed.

2.4 Lab Managers shall ensure that steps are taken to identify and mitigate potential risk to the users of the services or processes. Cost analyses and risk assessments shall be performed before moving forward with the project.

2.5 A Project Manager shall be assigned to oversee the planning and development of the new service or modification of existing service. The Project Manager shall form a specification and design team that will include representation from the program.

2.6 The function of this team shall be to translate customer needs from the initial Design

Input document into a technical design input document ensuring requirements are complete and explicit.

2.7 The Project Manager and the design team shall prepare a plan to execute the project.

This plan shall include:

· Project Charter

· Communication Plan

· Schedule and resource plan

· Quality Plan

2.8 The project schedule shall have each activity identify with a description of the activity, the time frame for accomplishment, and responsible individual for the task.

2.9 Upon approval of the development plan, each team will be given adequate authority to take actions for accomplishment of their phase without repeated approval processes.

3.0 INPUTS AND OUTPUTS

3.1 The program manager shall identify process inputs that affect the design and development of services and facilitate effective and efficient process in order to satisfy the needs and expectations of customers, and those of other interested parties. These external needs and expectations plus those internal needs of KHCL should be considered for the design and development process.

a. External inputs such as

· Customer and marketplace needs and expectations

· Needs and expectations of other interested parties

· Supplier’s contributions

· User input

· Changes in relevant statutory and regulatory requirements

· International and national standards

· Healthcare codes of practice

b. Internal inputs such as

· Policies and objectives

· Needs and expectations of employees in the organization

· Technological developments

· Competence requirements for employees performing the work

· Feedback information from past experience

· Records and data on existing processes and services

· Outputs from other processes

c. Inputs that identify characteristics of processes or services that are crucial to proper functioning, such as

· Operation, installation and application

· Storage, handling and delivery

· Physical parameters and the environment

· Requirements for disposal of waste

3.2 Outputs should include information to enable verification and validation to planned requirements, such as:

· Data demonstration the comparison of process inputs to process outputs

· Service specifications, including acceptance criteria

· Process specifications

· Material needs

· Testing specifications

· Training requirements

· User and consumer information

· Purchase requirements

· Reports

· IT requirements and support

3.3 Lab Managers shall prepare a documented service requirement based on the inputs and outputs above. The service requirement helps translate customer requirements and expectations into a preliminary set of specifications as the basis for subsequent design work and analysis. This becomes the initial Design Input and Output document.

3.3 Outputs should be reviewed against inputs to provide objective evidence that outputs have effectively and efficiently met the requirements for the process and service.

3.4 Upon completion of the service requirements the Quality Council, in conjunction with the program manager, will evaluate the service idea for individual viability and compare to any other service ideas the KHCL is contemplating at the time. This process serves to selectively qualify ideas in order to allocate financial and personnel resources and prioritize projects.

3.5 The Quality Council will then initiate development of the service idea.

3.6 During development of prototypes, the design team will continually review customer requirements. The quality aspects of the design should be clear and adequately define characteristics important to quality, such as acceptance and rejection criteria. Both fitness for purpose and safeguards against misuse should be considered.

3.7 Changes made to the specifications during the development process, that are accepted as design changes, will be documented and evaluated to assure that they accomplish the intended result and do not compromise effectiveness or safety.

4.0 REVIEW AND VERIFICATION

4.1 At the completion of each phase of design development, a formal, documented, systematic and critical review of the design results should be performed.

4.2 Reviews should be objective, unbiased examinations by appropriately trained personnel, which include individuals other than those responsible for the design.

4.3 A design review checklist should be constructed based on the specifications document.

4.4 Review results should be well documented in report form and signed by designated individuals as complete and accurate. All changes made as a result of review findings should be documented.

5.0 VALIDATION

5.1 The design and development plan should include activities to define methods for testing and measurement and the acceptance criteria applied to evaluate the service design during the development phase.

5.2 The results of all tests and evaluations should be documented.

5.3 Changes made to the design after the validation shall follow the Design Change Procedure.

Effectiveness Criteria:

Customer requirements met

Design requirements met.

Project schedule and budget met.

References:

Quality Manual:

QM VII.D.3 - Design and Development

Quality Procedures:

QP3310 - DESIGN CHANGE (Appendix M)

QP3010 - QUALITY RECORDS (Appendix B)

Records:

Design Input Documents

Design Review records (meeting minutes)

Design Verification records

Design Validation records

Appendix M - QP3310 – DESIGN CHANGE

Purpose: To outline the steps and responsibilities to request changes to services or processes and the implementation of those changes to assure an orderly, controlled, and effective change to all aspects of the service or process and all related documentation.

Scope: This procedure applies to all processes and services in KHCL related to the quality management system.

Responsibilities:

All personnel are encouraged to be involved in service and process improvement.

Procedure:

1.0 GENERAL

1.1 This Change Procedure is to be followed when any change or modification to the activities or deliverables that have been identified on the requirements document or project plan or Statement of Work.

1.2 The Change Procedure consists of three activities:

· Change Request Initiation

· Change Request Review

· Change Request Approval

1.3 Change Requests may be of either of the two following types:

· Design changes - Any changes that modify the Project Work effort Scope, as outlined in the Statement of Work.

· Non-compliance changes - Changes that result from a lack of resources planned for a specific Project Work effort segment, or a delay caused by failure of an individual or group to meet a responsibility outlined in the Statement of Work.

1.4 For minor service/process changes and/or changes in documentation only, the change process may be skipped and the change implemented by the section of this procedure.

2.0 CHANGE REQUEST INITIATION

2.1 Change Requests can be initiated by a program manager.

2.2 All Change Requests must be made in writing. This document requesting the change shall be produced and approved by the program manager. This document should have as much detail as necessary to adequately describe the reason for the request and proposed recommendations. Additional documentation can be attached to provide increased clarity or further information.

2.3 The Program Manager and the KHCL's Quality Council will be responsible for evaluating the viability of the request

2.4 As part of the initiation of a Change Request, each Change Request must:

· Identify the name of the individual requesting the change request

· Identify the name of the individual submitting the change request

· Clearly describe the requested change

· Identify the estimated dollar cost to implement the change request

· Identify the estimated revised completion date

2.5 On a detailed summary (to be attached to the Change Request):

· Identify all of the resources (including system and people) required to implement the change

· Identify the estimated time required to implement the change

3.0 CHANGE REQUEST REVIEW

3.1 All Change Requests will first be provided to the Manager of the Project for:

· Initial review of the nature and substance of the change request

· Review of estimates of work plan schedule and cost impacts

3.2 The Project Manager will assign a sequential number to each Change Request received, for purposes of tracking change activity on the project. Change request sequence numbers will be numeric, and for each project, will begin with the number “1”.

4.0 CHANGE REQUEST APPROVAL

4.1 A meeting will be set to review, evaluate and determine the proposed plan for implementation or resolution of the change. The following functional areas will be evaluated for the impact of the change.

· Quality Management - Quality Management shall be evaluated to determine the effect of all changes on test requirements and on overall quality of our services plus compliance with customer, KHCL, and regulatory agency requirements.

· Program Manager – Program manager is responsible for making certain that the change is feasible and complies with appropriate KHCL and customer specifications and with accepted standards. Every major change must be verified and validated as appropriate and the results documented before it becomes a change order.

· Budget - Budget shall be evaluated to make certain that all financial aspects have been considered.

4.2 All change requests will be subject to Change Approval Criteria included with the Statement of Work. Change Approval Criteria specify the categories into which changes will be classified, and the approval hierarchy for change requests.

4.3 All approvals will be given by a written signature of the approving individual on the

Change Request document.

4.4 Change Approval Criteria will apply to all requests for changes to the project. All requests for changes must be submitted in writing, using a Change Request document.

4.5 Disagreements that cannot be resolved will be forwarded to the project management team for resolution. Two (2) days will be provided for resolution response

Effectiveness Criteria:

Accuracy of documentation

Promptness of change

References:

Quality Procedures:

· QP3000 - DOCUMENT CONTROL (Appendix A)

· QP3010 - QUALITY RECORDS (Appendix B)

· QP3300 - DESIGN AND DEVELOPMENT (Appendix L)

Records:

Document requesting change with associated design change verification and validation records.

Appendix N - QP3320 - SERVICE DEVELOPMENT QUALITY AND PLANNING

Purpose: This procedure pertains to all business processes that affect deliverable service quality and to all services and processes developed and managed by the KHCL. KHCL's programs and procedures will be developed and continually maintained and redefined for assuring that appropriate service development activities are correctly performed.

Scope: This procedure applies to all programs and individuals involved with the development and release of a new or modified service program prior to full-scale service delivery.

Definitions: Quality is the totality of features and characteristics that bears upon the ability of a service or process to satisfy fitness-for-intended-use, including (but not limited to) safety, regulatory compliance and performance.

Quality Management System is the organizational structure, responsibilities, procedures, processes, and resources for implementing quality management.

Quality Objectives are the goals established to, as a minimum, support KHCL quality policy.

Service and/or Process Quality Plan is a document that establishes the quality objectives and requirements for services and/or processes and designates areas where elements of the quality management system are applied.

Responsibilities:

Design and development is responsible for developing, implementing, maintaining and assuring compliance with the KHCL's QMS and documentation as identified in this procedure.

Quality Management ensures that all service specifications have been met as required.

Program Manager is accountable for establishing and assuring compliance with Service and/or Process Quality Plans in association with the Design and Development Guidelines.

All employees have responsibility for supporting the KHCL's Quality Procedure, complying with the requirements of the KHCL's QMS and striving to attain the quality objectives set forth in KHCL's strategic plan.

Procedure:

1.0 DESIGN COMPLETION

1.1 After the Design and Development Validation phase is complete, the new service or modification to existing service is ready to be transitioned to development.

1.2 Any changes, modifications or corrections made to the service or existing documentation must adhere to proper document change and design change procedures. See Quality

Procedures: QP3310 - DESIGN CHANGE and QP3000 - DOCUMENT CONTROL.

2.0 DESIGN TRANSFER AND DOCUMENTATION

2.1 Quality Management gives consideration to the orderly transfer of the service development into service release during design validation phase.

2.2 Program manager should consider all significant aspects of the service and its ultimate use. The quality objectives and requirements for the service are clearly defined in service and/or processes specifications.

3.0 SERVICE DEPLOYMENT PLAN

3.1 Service processes should be planned, developed, validated and documented to assure they will routinely achieve the intrinsic level of quality designed into the new or modified service.

3.2 Process validation and testing will demonstrate the ability of the process to achieve the planned results.

3.3 Lessons learned associated with previous service designs or changes should be analyzed to eliminate or reduce similar problems in new or modified services.

3.4 Acceptable ranges or limits must be established for each attribute based on the specification requirements.

3.5 Process Failure Mode and Effects Analysis (FMEA) should be used to identify potential process problems that could result in service nonconformities (see procedure QP3290 -

PREVENTIVE ACTION (Appendix K)).

3.6 The service planning process should also include development of programs to train personnel as required to produce the new or modified service.

3.7 Any discrepancies in the finished service versus the specification and other elements of the design and development, or quality objectives must be resolved before the service is released to customers.

Effectiveness Criteria:

Smoothness of transition

Overall process yield

Compliance with Project Schedule

References:

Quality Procedures:

· QP3000 - DOCUMENT CONTROL (Appendix A)

· QP3300 - DESIGN AND DEVELOPMENT (Appendix L)

· QP3310 - DESIGN CHANGE (Appendix M)

· QP3290 - PREVENTIVE ACTION (Appendix K)

Records:

Process Validation records