

Washtenaw County Road Commission

ISO 9001-2008

Quality Manual

Providing leadership among county road commissions and other transportation agencies.



This Quality Manual complies with the Requirements of ISO 9001-2008

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QUALITY

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0.0 Introduction

0.1 General

Washtenaw County Road Commission (WCRC) developed and implemented a Quality Management System to establish best business practices, better satisfy the expectations of its customers, and improve the overall management of the organization.

Our Quality Management System meets the requirements of the international standard ISO 9001:2008. This system addresses the design, development, production and servicing of the organization services.

This manual starts with a brief introductory section; the remainder is divided into eight sections that correlate to the Quality Management System sections of ISO 9001:2008. Each section contains specific information pertaining to the procedures that describe the methods used to implement the necessary requirements as well as it delineates authorities, inter-relationships and responsibilities of the personnel responsible for performing within the system.

This manual is used internally to guide our employees through the various requirements of the ISO 9001:2008 standards to ensure customer satisfaction, continuous improvement and provide the necessary instructions that create an empowered work force.

0.2 Distribution

The Quality Manual shall be distributed to the following:

- Managing Director
- Director of Engineering
- Director of Operations
- Director of Finance
- Assistant Director of Engineering
- Human Resource Manager
- Information Technology Manager

Additional copies are distributed to Section Supervisors, Foremen, and employees as directed by Department Directors.

0.3 Organizational Chart

The WCRC Organizational Chart represents the organization in its entirety; a current chart can be accessed in the **Company Shared “W” network drive**.

1.0 Scope

1.1 General

The Quality Manual outlines the policies, procedures and requirements of the Quality Management System. The system is structured to comply with the conditions set forth in the international standard ISO 9001:2008.

1.2 Exclusions

The Quality Management System does not apply to Federal or State statutes, administrative rules or work instructions and departmental directives which define specific departmental tasks.

2.0 Overview of Washtenaw County Road Commission (WCRC)

The WCRC maintains all of the public county roads outside of incorporated cities and villages which are approximately 1650 miles with nearly half of these roads unpaved. Also the WCRC is contracted by the Michigan Department of Transportation to maintain all of the State Trunkline roads in the county. The WCRC is responsible for dust control, gravel road grading, snow removal, pavement resurfacing, storm drainage, tree removal and a variety of other services, including but not limited to road and bridge construction, sign and signal maintenance, pavement marking and guardrail repairs. In addition, the WCRC is responsible for planning, designing and constructing the major improvement projects on the county public roads.

3.0 Terms and Definitions

Audit Team	One or more auditors, and the ISO Management Representative or a member of Executive Management.
Competence	Demonstrated ability to apply knowledge and skills
Containment	Actions taken to assess the extent of and gain control of non conforming product
Continual Improvement	Recurring activity to increase the ability to fulfill requirements
Corrective Action	Action taken to eliminate the cause of a detected nonconformance or other undesirable situation.
Customer Satisfaction	Customer's perception of the degree to which the customer's requirements have been filled.
Design Changes	Changes made to the inputs or plan during design and development activities.
Design Project	Planning of products, services or processes to transform a set of requirements into a product realization process.
Design Validation	Determination of the product's ability to meet user needs.
Design Verification	Determination that the product meets requirements.
Discrepancy Report	A quality management document used to report nonconforming product and the product's disposition.
Engineering Control Notification	Document used to describe the issuance or revision of an item.
FOIA	Freedom of Information Act (Public Act 442 of 1976)

Infrastructure	System of facilities, equipment and services needed for the operation of an organization.
Job Description	A form identifying the qualification requirements for each position within the company.
Management Team	Directors and Program Managers in charge of Human Resources and Information Technology
Nonconformance	Any departure from drawings, specifications, procedures or workmanship standards.
Preventive Action	Action to eliminate the cause of a potential nonconformity or other undesirable potential situation.
Procedure	Document outlining specific work processes and how the requirements of the ISO 9001:2008 standard are being met.
Quality Plan	Documents specifying which procedures and associated resources shall be applied by whom and when to a specific project, product, process or contract.
Quality Records	Documentation of those activities wherein records of said activities must be maintained will be specified in the procedure or work instruction level documents, as applicable.
QMS	Quality Management System
Quality System Review	Action undertaken by management to determine the suitability, adequacy and effectiveness of the subject matter to achieve established objectives.
Records	Completed forms or information generated as a result of the process described in a document and retained as indicated in the Control of Records Procedure.
Training Plan	An employee specific schedule that identifies training needs and a tentative time schedule to complete. At the completion of the action plan the employee will be fully qualified for a position.
Training Record	A form recording the details of a specific training class, job training or group training.
Vault	A shared secured area that contains archived documents. Access is restricted to certain individuals and maintained by the departmental supervisor.
WCRC	Washtenaw County Road Commission
Work Instructions	Step by step directions on how a task should be done.

4.0 Quality Management System

4.1 General Requirements

Washtenaw County Road Commission (WCRC) has established, documented and implemented a Quality Management System which is aligned to the ISO 9001:2008 quality management system. The WCRC Quality Management System (QMS) is maintained and continually improved through the use of the Quality Policy, quality objectives, audit results, analysis of data, corrective and preventative action and management review.

4.2 Documentation

4.2.1 General

The QMS is documented within this manual and includes the Quality Manual, Quality Policy, documented procedures, planning and operational documents and documented records providing evidence of conformity of service to specified requirements and demonstrating the effective operation of the QMS.

4.2.2 Quality Manual

This quality manual defines:

- a. The scope of the Quality Management System;
- b. Reference to documented procedures required by this manual;
- c. A description of the interaction between the processes of the QMS.

This manual is issued by the Managing Director of WCRC, maintained as a controlled document and readily available to all WCRC employees.

4.2.3 Control of Documents

Documentation required for the Quality Management System is controlled in accordance with ISO 4.2.3 Control of Documents.

Controlled documents shall be reviewed and approved for adequacy by authorized personnel prior to issuance. Obsolete controlled documents shall be removed from use and replaced by the latest revisions, and clearly marked as being obsolete by the authorized personnel.

Modifications or changes to specifications are reviewed and approved by the authorized personnel of the responsible entity. Departments with locally controlled documents shall maintain records showing the latest revision level for such documents.

4.2.4 Control of Records

Quality records are identified and maintained in accordance with ISO 4.2.4 Control of Records to provide evidence of conformity to the requirements and the effective operation of the QMS. Where required by the ISO 9001:2008 follow up actions will be recorded on the appropriate quality record. Records are to be legible, readily identifiable and retrievable. ISO 4.2.4 Control of Records defines

controls needed for the Identification, Storage, Protection, Retrieval, Retention and Final Disposition.

When specified through a signed FOIA, hard copy quality records may be provided in accordance to the Michigan Freedom of Information Act (FOIA) Public Act 442 of 1976, as amended and consistent with WCRC Policy ADM-03. When specified in contractual agreements with customers, electronic quality records may be provided in accordance with WCRC Enhanced Access to Public Records Policy ADM-04.

5.0 Management Responsibility

5.1 Management Commitment

The Quality Policy defined within this manual has been established by the Washtenaw County Road Commission (WCRC) Management Team. The WCRC Management Team is committed to the development and implementation of the QMS and continuously improving its effectiveness by:

- Emphasizing customer focus as we meet our regulatory requirements;
- Establishing quality objectives and the Quality Policy;
- Ensuring that quality objectives are defined at appropriate levels of the organization;
- Conducting quarterly management reviews;
- Ensuring that appropriate resources are assigned to implement the requirements of the Quality Management System.

5.2 Customer Focus

The WCRC Management Team is committed to establishing and maintaining effective relationships with our constituents and continuously improving customer satisfaction striving to exceed customer expectations. The WCRC Management Team ensures that customer services are of the highest priority and that the actions of our employees reinforce this priority. Our customer service is focused on, but not limited to, our Call Center, involvement of our Capitol Improvement Plan, external and internal newsletters, Project meetings, Town Hall meetings and communication through our organizational web site.

ISO 7.2.3 Customer Communication defines the requirements, as well as guidelines, utilized for communicating with our customers during road project activities. ISO 8.2.1 Customer Satisfaction establishes the methodology used in defining customer requirements and expectations. These methods ensure a strategy and criteria for evaluating customer satisfaction, and strive to continually improve customer satisfaction.

Communication systems, their purpose and responsibilities are summarized in the following table:

Communication System	Purpose	Responsibility
Call Center	<ul style="list-style-type: none"> - Record service requests - Inquiries & Questions 	<ul style="list-style-type: none"> - Managing Director
Capital Improvement Plan	<ul style="list-style-type: none"> - Provide 5 year plan of major projects 	<ul style="list-style-type: none"> - Director of Engineering
External Newsletter	Update on WCRC major: <ul style="list-style-type: none"> - Activities - Events - Projects - Community Interests 	<ul style="list-style-type: none"> - Managing Director
Project Planning Meetings	<ul style="list-style-type: none"> - Input on project requirements - Identify special requirements - Identify potential concerns - Provide project proposals - Provide project schedules 	<ul style="list-style-type: none"> - Director of Engineering - Director of Operations
Township Meetings	<ul style="list-style-type: none"> - Provide information - Gather input on services - Provide project proposals - Provide project schedules 	<ul style="list-style-type: none"> - Managing Director
WCRC Web Site	<ul style="list-style-type: none"> - FAQs - Permit information - Road Work & Project Status - Services - General public outreach - WCRC News/Updates <ul style="list-style-type: none"> - Media advisories - Press Releases - Notices 	<ul style="list-style-type: none"> - Web Master - Project Engineers - Project Managers

5.3 Quality Policy

The WCRC has long been recognized for its leadership among county road commissions and other transportation agencies in the State of Michigan for proficiently planning, funding, and performing the highest quality services to assure that the county road system is a reasonably safe and convenient system for the traveling public in Washtenaw County.

Whereas, the Board and staff of the WCRC are committed to continuing our ongoing efforts to:

- Enhance the safety, condition, and mobility of our road system;
- Integrate quality management principles and openness into our business processes and decision-making practices;
- Further establish ourselves as leaders amidst every aspect of the Michigan transportation industry;
- Provide unsurpassed customer service by satisfying the needs and expectations of our customers in the most timely and efficient manner possible;
- Establish effective and efficient policies, procedures, and quality standards, and ensure compliance of them, for the benefit our customers and to prolong the service life of the county road system;
- Identify alternative revenue sources, implement continual cost-saving measures, and demonstrate conscientious and ethical fiscal responsibility in the use of public funds;
- Pursue continual technological advancement so as to provide state-of-the-art services;
- Comply with all applicable state and federal regulatory requirements; and
- Uphold our principles, policies, practices, and responsibilities as public servants in the highest moral and ethical manner possible, being ever conscious that in representing this public agency, we must honor public trust.

5.4 Planning

The WCRC Management Team shall establish quality and customer satisfaction objectives which encompass the processes and procedures outlined in the QMS and ISO 5.4 Planning. Each Department Director and / or Section Supervisor shall subsequently set business-specific quality and customer satisfaction objectives consistent with the overall plan. The Managing Director shall regularly review the Departmental / Section objectives and progress against the organizational objectives.

5.4.1 Quality Objectives

Quality objectives are established and reviewed annually in order to support the efforts of the organization in achieving our Quality Policy (ISO 5.3). Objectives shall be established in a measurable format and documented for each department. Directors and Supervisors shall assure that quality plans are consistent with the Quality Policy (ISO 5.3) and that they include the commitment to continual improvement as defined in ISO 5.1 Management Commitment.

5.4.2 Quality Management System Planning

Our QMS has been planned and implemented to meet the quality objectives and the requirements of ISO 4.1 General Requirements of the ISO 9001:2008 standard. The WCRC Management Team shall ensure that all changes are conducted in a controlled manner and that the integrity of the Quality Management System and its objectives are maintained during change processes.

5.5 Responsibility, Authority, and Communication

WCRC Directors shall establish quality and customer satisfaction objectives which encompass the processes and procedures outlined in the QMS. Each Department and / or Section Supervisor shall subsequently set business-specific quality and customer satisfaction objectives consistent with the overall plan. The Managing Director shall regularly review the Departmental / Section objectives and progress against the general organization's objectives.

5.5.1 Responsibility and Authority

Each WCRC Department Director is ultimately responsible for the business of their respective Department. Department Directors may delegate responsibility and authority for managing the various businesses and functions in each section to the Section Supervisor. The Department Directors and Supervisors are responsible for establishing and reviewing the strategies and objectives of their department and/or section as well as ensuring that each employee understands their responsibility as it pertains to our quality system.

An organizational chart has been established to illustrate the interrelation of personnel in the organization. Job descriptions define the responsibilities and authorities of each of the positions on the Organizational Chart. These documents shall be made available throughout the organization to help employees understand their responsibilities and authorities.

5.5.2 Management Representative

The Managing Director shall appoint a member of the WCRC Management Team as the management representative who has the responsibility and authority for:

- a. Ensuring that processes of the Quality Management System are established, implemented and maintained in accordance to the requirements of this Quality System Manual;
- b. Reporting to the Managing Director on the performance of the Quality Management System, including needs for improvement;
- c. Promoting customer requirements throughout the organization; and
- d. Acting as the liaison with external parties such as customers or auditors on matters relating to the Quality Management System.

5.5.3 Internal Communication

Processes are established for communication within the organization. Methods of communicating the effectiveness of the QMS include department and management meetings, circulation of Board minutes, reports, memos, newsletters, emails, and notices on walls/notice boards. Each manager is responsible for ensuring that quality information provided at Board, Director, Supervisor, Engineering, Operations, Administration and Safety meetings are communicated to each of their employees.

5.6 Management Review

Our Quality Management System is reviewed regularly by the Managing Director and the WCRC Management Team to assess the suitability and effectiveness of the quality management system. The reviews shall include the assessment of opportunities for improvement and any potential need for change to the Quality Management System. Records of the review meetings and the actions taken are kept by the Quality Manager or designee in accordance with the requirements specified in the Records Retention procedure.

6.0 Resource Management

6.1 Provision of Resources

Each Department Director is responsible for identifying resource requirements, providing adequate resources, and assigning trained personnel for the management and implementation of activities as defined in this Quality System Manual. The Managing Director and Human Resources Manager shall continuously review resource needs to assure that resources are available to meet these quality objectives and business objectives in accordance with ISO 6.1 Provision of Resources.

6.2 Human Resources

6.2.1 General

Human Resources procedures assure that personnel performing work affecting the quality of product or services shall be competent on the basis of appropriate education, training, skills and experience.

6.2.2 Competency, Awareness, and Training

It is the responsibility of each Director / Supervisor to ensure that the necessary and appropriate training and development is determined so that each of their direct reports, including temporary workers, has the skills to perform activities affecting quality. Qualifications are reviewed upon hire, when an employee changes positions, or the requirements of a position change. Human Resources shall maintain records of each employee's qualifications. If any differences between the employee's qualifications and the requirements for the job are found, training or other action is taken to provide the employee with the necessary competency for the job. Training and evaluation are conducted in accordance with ISO 6.2.2 Competency, Awareness, and Training.

6.3 Infrastructure

To meet quality objectives and product requirements Washtenaw County Road Commission (WCRC) has determined the infrastructure needed as documented in ISO 6.3 Infrastructure. Department Directors shall identify, provide, and maintain infrastructure to achieve conformity of product requirements, utilizing asset management principles and documenting plans as follows:

- a. Buildings, workspace and associated utility maintenance plans;
- b. Preventative maintenance plans;
- c. Capital Improvement Plans;
- d. Long Term Plan

6.4 Work Environment

The WCRC Management Team determines and manages the work environment to ensure product conformity. Requirements are determined during quality planning and documented in ISO 6.4 Work Environment. The work environment is managed for continuing suitability. Data from the QMS is evaluated to determine if the work environment is sufficient for achieving product conformance, or if preventative or corrective action related to the work environment is required.

7.0 Product Realization

7.1 Planning of Project Realization

Quality planning is required before new projects are implemented. The quality planning process depicted in ISO 7.1 Planning of Project Realization applies to projects of a larger scale (\$ - ___, or above ?). The Project Engineer along with the Project and Development Engineering Section plan and develop the processes needed for project realization.

During this planning, management or assigned personnel identify:

- The quality objectives and requirements for the project
- Processes, documentation and resources specific to the product
- Verification, validation, monitoring, inspection and test activities
- Criteria for product acceptance

Project schedules are maintained by the Project Engineer to record and track product development and to advise the Management Team.

7.2 Customer-Related Processes

7.2.1 Determining Requirements

The Washtenaw County Road Commission (WCRC) shall ensure that customer concerns related to the WCRC and project activities are documented and acted upon as well as ensuring that statutory and regulatory requirements related to projects are followed in accordance to guidelines.

7.2.2 Review of Requirements

Requirements related to customer-related processes are reviewed for clarity and verification that the WCRC expectations are met to the defined requirement. If any changes are required, relevant personnel shall receive appropriate communication; documents are maintained and amended showing results of the review in accordance with ISO 4.2.4 Control of Records.

7.2.3 Customer Communication

The WCRC determines and implements effective processes for communicating with customers in relation to product and services, contracts, inquiries and customer feedback. Organizational communication systems include Board of Road Commissioners meeting, Annual Township meetings, Public Information meetings, Project Planning meetings, Capitol Improvement Plan (CIP) report, external newsletter (Roads in Review), e-mail communication, and the WCRC Web Site.

7.3 Design Control (Project Plans)

7.3.1 Design and Development Planning

The WCRC adheres to the Design Development and Planning Procedures that have been established by the Federal Highway Administration and the Michigan Department of Transportation.

7.3.2 Design and Development Inputs

Design input requirements relating to project design include applicable statutory and regulatory requirements as well as inputs as defined in ISO 7.3 Design Control.

7.3.3 Design and Development Outputs

Design and development is submitted to the Michigan Department of Transportation (MDOT) and appropriate local agencies as defined in ISO 7.3 Design Control.

7.3.4 Design and Development Review

Design reviews are incorporated into the schedule documented in the MDOT Local Agency Program Project Planning Guide.

7.3.5 Design and Development Verification and Validation

Verification and validation are performed by MDOT following guidelines as stipulated in ISO 7.3 Design Control.

7.3.6 Control of Design and Development Changes

The Design and Development procedure includes identifying, recording, verifying, validating and approving design changes. The review of design and development changes includes an evaluation of the effect of the changes and delivered product. Records are maintained to show the results of the review and any necessary actions identified during the review.

7.4 Purchasing

7.4.1 Purchasing Process

ISO 7.4 Purchasing is followed to ensure that purchased product conforms to the specified purchase requirements. The procedure outlines the extent of control required for suppliers. Suppliers and/or vendors are evaluated and selected based on their ability to supply product in accordance with requirements as outlined in ISO 7.4.1 Purchasing Process.

7.4.2 Purchasing Information

Purchasing information includes responsibility, central purchasing processes and internal controls for orders exceeding \$500. Additional controls are discussed for purchases exceeding \$10,000. Specifications are outlined in ISO 7.4.2 Purchasing Information.

7.4.3 Contracts and Leases

Contract and Lease information describes the steps required for professional services, legal counsel and leasing of property. Specifications are outlined in ISO 7.4.3 Contracts and Leases.

7.4.4 Environmental Preferable Purchasing

In recognition of the impact to our environment by our purchasing decisions, ISO 7.4.4 Environmental Preferable Purchasing addresses procedures which support minimizing adverse environmental impacts. All employees involved in purchasing decisions shall evaluate environmentally preferable products and encourage the purchase whenever favorable.

7.5 Production and Service Provision

7.5.1 Control of Production and Service Processes

The WCRC plans and carries out projects and services as stipulated by federal, state and local standards and requirements.

7.5.2 Validation of Processes

The WCRC will validate any production and service processes where the resulting output cannot be verified by subsequent measurement or monitoring. Validation shall demonstrate the ability of these processes to achieve planned results. Standards are created and issued by the Federal Highway Administration, MDOT, and Road Commission Design and Construction Standards. These standards shall be continually updated and improved using input of new data.

7.5.3 Identification, Traceability and Status

The WCRC identifies the product throughout product realization according to the Identification and Traceability. Product is identified with respect to monitoring and measurement requirements. The WCRC controls and records the unique identification of the product wherever traceability is a requirement.

7.5.4 Preservation of Product and Public Property

Care will be exercised at any time that public property is under the control of the WCRC. Public property will be identified and verified and standard procedures and practices shall be followed for the protection of all known public property and materials in accordance with ISO 7.5.4 Preservation of Product and Public Property. Care will be taken to ensure that products are preserved and are not damaged through inappropriate handling.

7.6 Control of Measuring Devices

The Engineering Section Supervisor for the affected function, under the direction of the Director of Engineering, is responsible for ensuring that all measurement devices used in road projects and maintenance are safeguarded from adjustments that would invalidate the measurement result and are properly maintained and calibrated as necessary to meet measurement precision and accuracy requirements.

8.0 Measurement, Analysis and Improvement

8.1 General

The Washtenaw County Road Commission (WCRC) shall define and implement the monitoring, measurement, analysis, and improvement processes needed in order to achieve continual improvement of the distribution process and the Quality Management System. The results of these measurements are used to demonstrate conformance of the process or product to specified requirements. When deviations occur or improvements are indicated, the measurements lead to corrective or preventive actions on the product, the process, or the Quality Management System.

8.2 Monitoring and Measurement

8.2.1 Customer Satisfaction

The WCRC monitors information relating to customer perception as to whether the organization has fulfilled customer requirements. The method for obtaining and using this information is identified in ISO 8.2.1 Customer Satisfaction and ISO 5.1 Management Commitment.

8.2.2 Internal Audits

Periodic audits are performed in the respective departments and sections to monitor and verify compliance with the procedures and methods that establish and define the Quality Management System. Among other things, the auditor(s) verify compliance to department specifications, the quality procedures, and the records that support the implementation of the Quality System. The audits cover the applicable elements of the ISO 9000 series of standards and, where applicable, federal and state standards, contractual requirements, and the WCRC internal requirements.

The WCRC develops the audit plans, taking into consideration the status and importance of the activities and areas to be audited as well as the results of previous audits. The audit plan is revised after each audit and updated if needed.

Internal auditors are trained in proper audit procedures and are independent of the activity they audit. Results of the internal audits are documented, and copies of the audit reports are provided to the supervisor of the department and /or section audited. Department Directors are responsible for deciding on appropriate corrective action in a timely manner or documenting/explaining why no action is required. Copies of audit reports and reports of corrective action taken to correct deficiencies are maintained by the Managing Director.

8.2.3 Monitoring and Measurement of Processes

The WCRC applies suitable methods for monitoring and measurement of the Quality Management System processes. These methods demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, corrective action is taken, as appropriate, to ensure conformity of the process. The process for identifying and carrying out the required monitoring and measuring of processes is documented in ISO 8.2.3 Monitoring and Measurement of Processes and ISO 5.1 Management Commitment.

8.2.4 Monitoring and Measurement of Product

The WCRC monitors and measures the characteristics of projects to verify that project requirements are fulfilled. This is carried out at appropriate stages of the project life in accordance to the process identified in ISO 8.2.4 Monitoring and Measurement of Projects. Evidence of conformity with the acceptance criteria is maintained with records indicating the Project Manager assigned to the project.

8.3 Control of Nonconforming Product

The WCRC ensures that any project, including maintenance and construction, as well as materials and components which do not conform to specifications, requirements, and standards is identified and controlled prior to continuance of further project work. The specific activities and responsibilities are defined in ISO 8.3 Control of Nonconforming Product.

8.4 Analysis of Data

The WCRC determines, collects and analyses appropriate data to determine the suitability and effectiveness of the Quality Management System (QMS) and to evaluate where continual improvement of the QMS can be made. The process for determining, collecting and analyzing this data is defined in ISO 5.1 Management Commitment. Appropriate data includes data generated as a result of monitoring and measurement and from other relevant sources. The analysis of data provides information relating to:

- Customer Satisfaction
- Project Management
- Financial Performance
- Efficiency
- Safety – Internal and External

8.5 Improvement

8.5.1 Continual Improvement

The WCRC continually improves the effectiveness of the Quality Management System through the use of the Quality Policy, quality objectives, audit results, analysis of data, corrective and preventative actions and management review. The initiation and determination of the urgency of a corrective or preventive action is the responsibility of each department and/or section. Any changes in procedures or specifications resulting from corrective or preventive actions are documented per ISO 4.2.3 Document Control.

8.5.2 Corrective and Preventative Action

The WCRC takes corrective action to avoid and eliminate the cause of nonconformities in order to prevent recurrence. Corrective action is to be appropriate to the impact of the nonconformities encountered. The responsibility for corrective action lies in the department where the work is being performed. Records are maintained to show adequacy of corrective action after implementation.

The WCRC identifies preventive action to avoid and eliminate the causes of potential nonconformities to prevent occurrence. Preventive actions taken are appropriate to the impact of the potential problems. Potential problems are identified from many sources of information, including design reviews, quality audits, quality records, and customer inputs. Records are maintained to show the action(s) taken to address potential problems.