## **QUALITY MANUAL**

# Machined Integrations, LLC

ISO9001: 2008

## **Quality Manual**

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## **Machined Integrations, LLC Quality Manual**

# (A) Revision and Approval Log

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1	Original	
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#### **APPROVALS:**

President: Denis Petit

Managing Partner – Accounting & Finance: Jari Bonenfant

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## **Machined Integrations, LLC Quality Manual**

## (B) QUALITY POLICY

Machined Integrations' Quality Policy:

We At Machined Integrations Are Committed To Customer Satisfaction By Meeting or Exceeding Our Customers' Needs, With a Commitment To Continuous Improvement And The Requirements of ISO 9001:2008. We Review the Continued Suitability of This Policy; Promote it Throughout the Organization, Assure Compliance with All Requirements and Continually Maintain the Effectiveness of our QMS.

President: Denis Petit

Managing Partner – Accounting & Finance: Jari Bonenfant

**January 9, 2014** 

## **Machined Integrations, LLC**Quality Manual

## (0) INTRODUCTION

#### 0.1 General

This (QSM) Quality Systems Manual (Quality Manual, Level I) specifies requirements for Machined Integrations to address Customer satisfaction, to meet Customer, statutory and applicable regulatory requirements, applicable to the product and to meet ISO9001: 2008 requirements.

#### 0.2 Process Approach

Machined Integrations determines and manages numerous linked activities (processes/procedures) in Level II and III documentation to enable the transformation of inputs into outputs. The application of a system of processes with the identification and interactions of these processes and their management to produce the desired outcome is a process approach. When used within the QMS, emphasis is on a) understanding and meeting requirements, b) the need to consider processes in terms of added value, c) obtaining results of process performance and effectiveness and d) continual improvement of processes based on objective measurement.

This Manual has adopted the process approach to quality management. Machined Integrations has adopted two linked process approaches to quality management. These approaches, followed throughout the company's processes, include the P-D-C-A (Plan-Do-Check-Act) and D-M-A-I-C (Define-Measure-Analyze-Improve-Control) methodologies.

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## **(1) SCOPE**

#### 1.1 General

This document specifies requirements for a quality management system where Machined Integrations demonstrates its ability to provide consistent product and service that meet Customer and applicable statutory and regulatory requirements, and aims to enhance Customer satisfaction through the effective application of the system, including processes for continual improvement of the system and the assurance of conformity to Customer and applicable statutory and regulatory requirements.

#### 1.2 Application/Exclusions

Machined Integrations excludes 7.3 "Design" from the scope of its business and all operating processes and procedures.

## (2) NORMATIVE REFERENCE

Standards

ISO9001 Fourth Edition 2008-11-15 (ISO 9001:2008(E))

## (3) TERMS AND DEFINITIONS

Throughout the text of this manual, wherever the term "product" occurs, it also means "service".

The term "product" applies to product intended for, or required by, the Customer and b) any intended output resulting from the product realization processes.

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## **4.0 QUALITY MANAGEMENT SYSTEM**

#### 4.1 General Requirements

Machined Integrations has established, documents, implements, maintains and continually improves its quality management system in accordance with the requirements of ISO 9001:2008.

To implement the quality management system, Machined Integrations:

- a) determines the processes needed for the quality management system,
- b) determines the sequence and interaction of these processes,
- c) determines criteria and methods required to ensure the effective operation and control of these processes,
- d) ensures the availability of information necessary to support the operation and monitoring of these processes and
- e) measures, monitors where applicable and analyzes these processes, and implements action necessary to achieve planned results and continual improvement.
- f) implements actions necessary to achieve planned results and continual improvement of these processes.

Machined Integrations manages all processes in accordance with the requirements of ISO 9001:2008.

Where Machined Integrations chooses to outsource any process that affects product conformity to requirements, the company ensures control over these processes.

Note: Processes needed for the quality management system, include processes for management activities, provision of resources, product realization, measurement, analysis and improvement. An "outsourced process" is a process that the company needs for its QMS and which the company chooses to have performed by an external party. Machined Integrations is responsible for control of all Customer, statutory and regulatory requirements in all outsource situations. The type and extent of control are influenced by factors such as, a) the potential impact of outsourcing on

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Machined Integrations' ability to provided conforming product, b) the degree to which the control for the process is shared and c) the capability of achieving the necessary control through the application of 7.4.

#### 4.2 Documentation Requirements

#### **4.2.1** General

The quality management system documentation includes:

- a) documented quality policy and objectives,
- b) this quality manual,
- c) required documented procedures and records,
- d) documents, including records, determined by the company to be necessary to ensure effective planning, operation and control (4.2.3).

#### 4.2.2 Quality Manual

This quality manual has been established and maintained to include, at a minimum:

- a) the scope of the quality management system, including details of, and justification for, any exclusions,
- b) the documented procedures established for the quality management system and
- c) a description of the interaction between the processes of the quality management system.

This quality manual is a controlled document.

#### 4.2.3 Control of Documents

Documents required for the quality management system are controlled. Records are a special type of document and are controlled according to the requirements given in 4.2.4, below. Documented procedures have been established:

- a) to approve documents for adequacy prior to issue,
- b) to review and update as necessary and re-approve documents,
- c) to ensure that changes and the current revision status of documents are identified.
- d) to ensure that relevant versions of applicable documents are available at points of use,

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- e) to ensure that documents remain legible and readily identifiable,
- f) to ensure that documents of external origin determined by the company to be necessary for the planning and operation of the QMS are identified and their distribution controlled and
- g) to prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose.

The Quality Management System is comprised of four levels:

#### • Level I - Quality Manual (QM)

An overview document which outlines the requirements and how the requirements of ISO 9001:2008 are satisfied.

#### • Level II- Procedures

Identifies the procedures utilized to comply with quality requirements of ISO 9001:2008. The procedures are written to address the everyday business requirements as well as provide for special requirements dictated by the customer or internal forces.

#### • Level III - Work Instructions (WIs)

Detailed "how-to" instructions regarding techniques or unique processes. These are utilized when required and may include the use of flowcharts as instructional documents.

#### • Level IV - Documents or Records

These (records) provide objective evidence that the procedures are utilized and are effective.

#### 4.2.4 Control of Quality Records

Records established to provide evidence of conformity to requirements and to the effective operation of the quality management system are controlled. The company has established a documented procedure to define the controls needed for the identification, storage, protection, retrieval, retention and disposition of records. Records are legible, readily identifiable and retrievable.

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## **5.0 MANAGEMENT RESPONSIBILITY**

#### 5.1 Management Commitment

Top Management provides evidence of commitment to the development and improvement of the quality management system by:

- a) communicating to Machined Integrations the importance of meeting Customer as well as regulatory requirements; (if applicable),
- b) establishing the quality policy and quality objectives,
- c) conducting management reviews and
- d) ensuring the availability of necessary resources.

#### 5.2 Customer Focus

Top Management ensures that Customer needs and expectations are determined per procedures Product Realization 7.0, Customer–Related Processes, converted into requirements and fulfilled with the aim of achieving Customer satisfaction.

#### 5.3 Quality Policy

The President has defined the Company's Quality Policy. This policy:

- a) is appropriate to the purpose of Machined Integrations,
- b) includes a commitment to meeting requirements and to continual improvement,
- c) provides a framework for defining, establishing, documenting and reviewing quality objectives,
- d) is communicated and understood at appropriate levels within the company and
- e) is reviewed for continuing suitability.

## 5.4 Planning

## 5.4.1 Quality Objectives

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The Partnership ensures that quality objectives, including those needed to meet requirements for service, are established within Machined Integrations. The quality objectives are measurable and consistent with the quality policy and include the commitment to continual improvement as well as those needed to meet requirements for service.

#### 5.4.2 Quality Management System Planning

Top Management ensures that the resources needed to achieve the quality objectives are identified and planned. The quality plan is documented and kept according to procedures 5.0 Management Responsibility and 7.0 Product Realization. The Management Representative ensures that change is conducted in a controlled manner and that the integrity of the quality management system is maintained during this change.

### 5.5 Responsibility, Authority and Communication

### 5.5.1 Responsibility and Authority

Top Management ensures that responsibilities and authorities are defined and communicated within the organization.

### 5.5.2 Management Representative

The Partnership has appointed the Managing Partner – Operations, a member of the company's management, as the Representative who, irrespective of other responsibilities, has the responsibility and authority for:

- a) ensuring that processes of the quality management system are established, implemented and maintained,
- b) reporting to top management on the performance of the quality management system, including needs for improvement and
- c) promoting awareness of Customer requirements throughout Machined Integrations.

#### 5.5.3 Internal Communication

Machined Integrations has created appropriate communication processes to ensure communication among its various levels and functions regarding the processes of the quality management system and their effectiveness.

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#### 5.6 Management Review

#### **5.6.1 General**

The Machined Integrations' management team reviews the quality management system at least once per year to ensure its continuing suitability, adequacy and effectiveness. This review evaluates any need for changes to Machined Integrations' Quality Management System while assessing opportunity for improvement, including our quality policy and quality objectives.

#### 5.6.2 Review Input

Input to management review includes current performance and improvement opportunities related to the following:

- a) audits results,
- b) feedback from internal and external Customers,
- c) process performance and service conformance,
- d) status of preventive and corrective actions,
- e) follow-up actions from earlier management reviews,
- f) changes that could affect the quality management system and
- g) recommendations for improvement

## 5.6.3 Review Output

The outputs from the management review include actions or decisions related to the:

- a) improvement of the quality management system and its processes,
- b) improvement of service related to Customer requirements and
- c) resource needs.

Results of management reviews are recorded and maintained.

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## **6.0 RESOURCE MANAGEMENT**

#### 6.1 Provision of Resources

The Machined Integrations Partnership working with staff, reviews resource needs to a) implement and maintain the quality system and continually improve its effectiveness and b) enhance Customer satisfaction by meeting Customer requirements.

#### 6.2 Human Resources

#### 6.2.1 General

Personnel performing work affecting conformity to product requirements are competent on the basis of appropriate education, training skills and experience.

#### 6.2.2 Competence, training and awareness

Machined Integrations management:

- a) determines the necessary competence of personnel performing work affecting conformity to product requirements,
- b) where applicable, provides training or takes other action to achieve the necessary competence,
- c) evaluates the effectiveness of actions taken,
- d) ensures that its employees are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives and
- e) maintains appropriate records of education, experience, training and qualifications.

#### 6.3 Infrastructure

Machined Integrations determines, provides and maintains the infrastructure needed to achieve conformity to product requirements, including:

a) workspace buildings and applicable utilities,

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- b) process equipment (hardware and software) and
- c) supporting services (such as transport, communication or information systems).

#### 6.4 Work Environment

Machined Integrations has determined and manages a work environment needed to achieve conformity to product requirements.

Overall safety is paramount at Machined Integrations. The company constantly and consistently takes all safety measures and precautions as part of the scope of its business. The company maintains a published Safety Manual, has an active and robust Safety Committee and meets or exceeds all local, state and federal safety and health regulatory requirements.

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## 7.0 PRODUCT REALIZATION

#### 7.1 Planning of Product Realization

Machined Integrations has planned and developed the necessary processes for product realization. Planning for this product realization is consistent with the requirements of other processes of the quality management system. In planning the processes for realization of product, Machined Integrations has determined the following, as appropriate:

- a) quality objectives for the product, project or contract,
- b) the need to establish processes and documents, and to provide resources specific to the product,
- c) verification, validation, monitoring, measurement, inspection and testing where applicable, specific to the product and the criteria for acceptability and
- d) the records that are necessary to provide confidence of conformity of the processes and resulting product.

The output of this planning is in a form suitable for the company's method of operation.

#### 7.2 Customer-Related Processes

#### 7.2.1 Determination of Requirements Related to the Product

Machined Integrations determines Customer requirements including:

- a) requirements specified by the Customer, including the requirements for delivery and post-delivery activities,
- b) requirements not specified by the Customer but necessary for intended or specified use,
- c) regulatory and statutory requirements applicable to product, and
- d) any additional requirements considered necessary by the company.

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Note: Post-delivery activities include, for example, actions under warranty provisions, contractual obligations such as maintenance services and supplementary services as recycling or final disposal.

#### 7.2.2 Review of Product Requirements

Machined Integrations reviews the requirements related to product. This review is conducted prior to the commitment to supply a product to the Customer (e.g. submission of a purchase order, acceptance of a contract or order, acceptance of contract changes) and ensures that:

- a) product requirements are defined,
- b) contract and order requirements differing from those previously expressed are resolved, and
- c) the company has the ability to meet defined requirements.

The results of the review and subsequent follow-up actions are recorded and maintained.

When the Customer provides no documented statement of requirement, The Customer requirements shall be confirmed by the company prior to acceptance.

Where product requirements are changed, Machined Integrations ensures that relevant documentation is amended and that relevant personnel are made aware of the changed requirements.

#### 7.2.3 Customer Communication

Machined Integrations determines and implements effective arrangements for communicating with Customers relating to:

- a) product information,
- b) inquiries, contracts or order handling, including amendments and
- c) Customer feedback, including Customer complaints.

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#### 7.3 Design and/or Development

Machined Integrations is a non-design company. M.I. is a "contract-manufacturer", whose objective is to service Customers by providing quality products that meet their specific requirements.

#### 7.4 Purchasing

#### 7.4.1 Purchasing Process

Machined Integrations ensures that purchased product conforms to specified purchase requirements. The type and extent of control applied to the supplier and the purchased product is dependent upon the effect of the purchased product on the subsequent product realization or the final product. Machined Integrations evaluates and selects its suppliers based on their ability to supply product in accordance with company requirements. Criteria for selection, evaluation and reevaluation are established.

All results of evaluations and follow-up actions are recorded

## 7.4.2 Purchasing Information

Purchasing information describes the product to be purchased, including where appropriate:

- a) requirements for approval of product, procedures, processes and equipment (i.e. First Article Approval, Verifying Supplier internal In–Process Inspection Methods (i.e. AQL), Final Product Approvals, etc.)
- b) requirements for the qualification of personnel and
- c) quality/validation requirements (i.e. Certificates of Conformance or Analysis, RoHS conformance, REACH, Country of Origin, etc. as applicable)

The company ensures the adequacy of specified purchase requirements prior to their communication to the supplier.

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#### 7.4.3 Verification of Purchased Product

If necessary, Machined Integrations shall establish and implement inspection, assessment or other activities necessary for verification of purchased product.

Where Machined Integrations or its Customer proposes to perform verification activities at the supplier's premises, the company states the intended verification arrangements and method of product release in the purchasing information.

#### 7.5 Production and Service Provision

#### 7.5.1 Control of Production and Service Provision

Machined Integrations controls service provisions through:

- a) the availability of information that specifies the characteristics of the product,
- b) where necessary, the availability of work instructions,
- c) the use and maintenance of suitable equipment,
- d) the availability and use of measuring and monitoring equipment, where applicable,
- e) the implementation of monitoring and measurement, and
- f) the implementation of product release, delivery and applicable postdelivery activities.

#### 7.5.2 Validation of Processes for Production and Service Provision

Machined Integrations validates any processes for production and service provision where the resulting output cannot be verified by subsequent measurement or monitoring and, as a consequence, deficiencies may become apparent only after the product is in use.

Validation demonstrates the ability of the processes to achieve planned results.

Machined Integrations has established arrangements for validation that include the following, as applicable:

a) defined criteria for review and approval of the process,

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- b) qualification of equipment and personnel,
- c) use of defined methodologies and procedures,
- d) requirements for records and
- e) re-validation.

#### 7.5.3 Identification & Traceability

Machined Integrations identifies, where appropriate, the product, by suitable means throughout product realization. Status is identified with respect to measurement and monitoring requirements throughout product realization. Machined Integrations controls and records the unique identification of the product, where traceability is a requirement and maintains records.

#### 7.5.4 Customer Property

Care is exercised while Customer property, when applicable, is under control or being used by Machined Integrations. Machined Integrations will identify, verify, protect and safeguard Customer property provided for use or incorporated into the product. Occurrence of any Customer property that is lost, damaged or otherwise found to be unsuitable for use is recorded and reported to the Customer immediately. Machined Integrations reports this to the Customer and maintains records. An immediate corrective Action Report is issued internally to determine root cause, corrective action and the need for preventive action in such situations.

#### 7.5.5 Preservation of Product

Machined Integrations preserves product during internal processing and delivery to the intended destination, in order to maintain conformity to requirements, if/when applicable. As applicable, preservation includes identification, handling, packaging, storage and protection and applies to the constituent parts of a product.

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#### 7.6 Control of Measuring and Monitoring Equipment

Machined Integrations identifies the measurements to be made as well as the measuring and monitoring equipment required to assure product conformity to specified requirements. Measuring and monitoring equipment used are controlled to ensure that measurement capability is consistent with the measurement requirements. Where necessary to ensure valid results, measuring and monitoring equipment is:

- a) calibrated or verified, or both, periodically or prior to use, against devices traceable to international or national standards; where no such standards exist, the basis used for calibration is recorded,
- b) adjusted or readjusted as necessary,
- c) identified in order to determine its calibration status,
- d) safeguarded from adjustments that would invalidate the calibration and
- e) protected from damage and deterioration during handling, maintenance and storage.

The company also assesses and records the previous measuring results when/if equipment does not conform, and takes immediate action on any affected product. Applicable records are maintained including results of calibration and verification.

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## 8.0 MEASUREMENT, ANALYSIS AND IMPROVEMENT

#### 8.1 General

Machined Integrations defines, plans and implements the measurement and monitoring activities needed to assure conformity and improvement processes needed

- a) to demonstrate conformity to product requirements,
- b) to ensure conformity of the QMS, and
- c) to continually improve the effectiveness of the QMS.

This includes determination of applicable methods, including statistical techniques, and the extent of their use.

## 8.2 Monitoring and Measurement

#### 8.2.1 Customer Satisfaction

Machined Integrations monitors information on Customer satisfaction and/or dissatisfaction as one of the measurements of performance of the quality management system. The method of obtaining and using this information has been determined and is addressed in other sections of Machined Integrations' QMS.

Note: Monitoring Customer perception can include obtaining input from sources such as Customer satisfaction surveys, Customer data on deliverables including service quality, user opinion surveys, lost business analysis, compliments, warranty claims and dealer reports.

#### 8.2.2 Internal Audit

Machined Integrations conducts internal audits to determine whether the quality management system conforms to the requirements of ISO 9001:2008 and has been effectively implemented and maintained.

Machined Integrations plans the audit program, taking into consideration the status

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and importance of the activities and areas to be audited as well as the results of previous audits. The audit scope, frequency and criteria are to be defined at that time. Audits are conducted by personnel other than those who perform the activity being audited therefore the audits shall be impartial and objective. Records of the audits and their results are maintained.

Management responsible for the area being audited ensures that any necessary corrections and corrective actions are taken immediately to eliminate detected nonconformities and their causes. Follow-up actions include the verification of the implementation of action taken, and the reporting of verification results. A documented procedure is established to define the responsibilities and requirements for planning and conducting audits, establishing records and reporting results.

ISO 19011 is utilized as needed for guidance.

### 8.2.3 Monitoring and Measurement of Processes

Machined Integrations applies suitable methods for monitoring and where applicable, measurement of the quality management system process. When planned results are not achieved, correction and corrective action is taken, as appropriate, to ensure conformity of product. These methods confirm the continuing ability of each process to satisfy its intended purpose.

Note: When determining suitable methods, Machined Integrations considers the type and extent of monitoring and measurement appropriate to each of its processes in relation to their impact on the conformity to service requirements and on the effectiveness of the OMS.

#### 8.2.4 Monitoring and Measurement of Product

Machined Integrations measures and monitors the characteristics of the product to verify that product requirements for the service are met. This is carried out at appropriate stages of the product realization process. Evidence of conformity with the acceptance criteria is documented and maintained.

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Records will indicate the authority responsible for release of product for delivery to the Customer.

The release of product and delivery of service to the Customer does not proceed until all the specified activities, including all planned arrangements, have been satisfactorily completed, unless otherwise approved by the Customer or other relevant authority.

#### 8.3 Control of Nonconforming Product

Machined Integrations ensures that product which does not conform to requirements is identified and controlled to prevent unintended use or delivery. A documented procedure is established to define the controls and related responsibilities and authorities for dealing with nonconforming product.

Where applicable, Machined Integrations deals with nonconforming issues in one or more of the following ways:

- a) by taking action to eliminate the detected nonconformity,
- b) by authorizing its use, release or acceptance under concession by a relevant authority and, where applicable, by the Customer,
- c) by taking action to preclude its original intended use or application and/or
- d) by taking action appropriate to the effects, or the potential effects, of the nonconformity when conforming issue is detected after delivery or use has started.

When a nonconforming issue is corrected, it is re-verified to demonstrate conformity to the requirements. Records of the nature of the nonconformities and any subsequent actions taken, including concessions obtained, are maintained.

## 8.4 Analysis of Data

Machined Integrations determines, collects and analyzes appropriate data to demonstrate the suitability and effectiveness of the quality management system and evaluates improvements that can be made. This includes data generated by measuring and monitoring activities and other relevant sources.

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Machined Integrations analyzes this data to provide information on:

- a) Customer satisfaction and/or dissatisfaction,
- b) conformance to product requirements,
- c) characteristics and trends of processes and services, including opportunities for preventive action and
- d) suppliers.

#### 8.5 Improvement

## 8.5.1 Continual Improvement

Machined Integrations plans and manages the processes necessary for the continual improvement of the quality management system.

Machined Integrations continually improves the effectiveness of the quality management system through the use of the quality policy, objectives, audit results, analysis of data, corrective and preventive action and management review.

#### 8.5.2 Corrective Action

Machined Integrations takes corrective action to eliminate the causes of nonconformities in order to prevent recurrence. Corrective action is to be appropriate to the impact of the problems encountered.

The documented procedure for corrective action is:

- a) reviewing nonconformities (including Customer complaints),
- b) determining the causes of nonconformity,
- c) evaluating the need for actions to ensure that nonconformities do not recur,
- d) determining and implementing action needed,
- e) recording results of action taken and
- f) reviewing the effectiveness of corrective action taken.

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#### 8.5.3 Preventive Action

Machined Integrations identifies preventive action to eliminate the causes of potential nonconformities from occurring. Preventive actions taken are appropriate to the impact of the potential problems. The documented procedure for preventive action is:

- a) determining potential nonconformities and their causes,
- b) evaluating the need for action to preventive occurrence of nonconformities,
- c) determining and implementing action needed,
- d) recording results of action taken and
- e) reviewing the effectiveness of preventive action taken.