

Environmental Management System (EMS) Manual

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Approved By: PRESIDENT / CEO

Maintained By: DIRECTOR OF TECHNOLOGY

Revision:

Issued: 09/27/2007

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QUALITY SYNTHETIC RUBBER, INC.
 MEDICAL ELASTOMER DEVELOPMENT, INC.

Environmental Management System (EMS) Manual

1. PURPOSE:

This manual sets forth the scope of Quality Synthetic Rubber and Medical Elastomer Development's **Environmental Management System (EMS)** and establishes the foundation for conformance to ISO 14001 Environmental Management System requirements.

2. SCOPE:

The Quality Synthetic Rubber / Medical Elastomer Development *Environmental Management System (EMS)* provides for the development and implementation of environmental policy and objectives that will; assure conformance to ISO 14001; assure conformance with our *Environmental Policy* and establish, implement, maintain and improve on our environmental management as it relates to the environmental aspects, which we can control, and/or influence.

3. REFERENCES:

| | QSR Reference Documents | MED Reference Documents |
|------|---|---|
| 3.1 | ISO 14001, Environmental management systems – Requirements with guidance for use | ISO 14001, Environmental management systems – Requirements with guidance for use |
| 3.2 | ISO 19011, Guidelines on Quality and/or Environmental Management Systems Auditing | ISO 19011, Guidelines on Quality and/or Environmental Management Systems Auditing |
| 3.3 | ISO 14004, Environmental management systems - General guidelines on principles, systems and support techniques | ISO 14004, Environmental management systems - General guidelines on principles, systems and support techniques |
| 3.4 | ISO 9001, Quality Management Systems – Requirements | ISO 9001, Quality Management Systems – Requirements |
| 3.5 | ISO/TS 16949 Quality management systems – Particular requirements for the application of ISO 9001 for automotive production and relevant service part organizations | ISO/TS 16949 Quality management systems – Particular requirements for the application of ISO 9001 for automotive production and relevant service part organizations |
| 3.6 | Environmental Aspects and Impact Determination, Procedure EM-09-001-P | Environmental Aspects and Impact Determination, Procedure EM-09-001-P |
| 3.7 | Environmental Objectives and Targets, Procedure EM-01-002-P | Environmental Objectives and Targets, Procedure EM-01-002-P |
| 3.8 | Management Review, Procedure AD-01-004-P | Management Representative and Management Review, Procedure QA-P-5 |
| 3.9 | Training System, Procedure ST-18-001-P | Training Needs Identification and Record Keeping, Procedure QA-P-28 |
| 3.10 | Document Control, QA-05-006-P | Control of Documents, QA-P-9 |
| 3.11 | Record Retention, Procedure QA-16-001-P | Control of Records, Procedure QA-P-26 |
| 3.12 | Corrective Action, Procedure QA-14-001-P | Corrective and Preventative Action, Procedure QA-P-22 |
| 3.13 | Internal Quality Audits, Procedure QA-17-001-P | Internal Audits, Procedure QA-P-27 |
| 3.14 | Calibration Control Procedure, DL-11-001-P | Inspection Equipment, Control, Maintenance and Calibration procedure QA-P-19 |
| 3.15 | Computer Network Security and Maintenance, Procedure MI-05-001-P | Control of Documents, QA-P-9 |
| 3.16 | EMS Responsibility Matrix, EM-01-002-F | EMS Responsibility Matrix, EM-01-002-F |
| 3.17 | EMS Legal and Other Requirements matrix, EM-09-002-F | EMS Legal and Other Requirements matrix, EM-09-002-F |
| 3.18 | Emergency preparedness and Response, matrix EM-09-004-F | Emergency preparedness and Response, matrix EM-09-004-F |
| 3.19 | Environmental Performance Measurement Indicators, matrix EM-09-005-F | Environmental Performance Measurement Indicators, matrix EM-09-005-F |
| 3.20 | Quality Record Matrix, form QA-16-001-I | Quality Record Matrix, form QA-16-001-I |

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4. ENVIRONMENTAL MANAGEMENT SYSTEM REQUIREMENTS:

4.1 GENERAL REQUIREMENTS:

Establish, document, implement, maintain and continually improve upon our *Environmental Management System (EMS)* in accordance with the requirements of ISO 14001 and the **Environmental Policy** of Quality Synthetic Rubber, Inc.

4.2 ENVIRONMENTAL POLICY:

We are committed to improving our environment through effective and efficient implementation of an Environmental Management System. This commitment applies to all persons working for or on behalf of the organization and requires that we continually improve our environmental impact through:

- An understanding and commitment to comply with legal and other requirements that relate to the environmental aspects of our business;
- The establishment of environmental objectives and targets that pursue pollution prevention and waste reduction;
- The review and taking of proactive steps toward the achievement of these targets.

4.3 PLANNING:

4.3.1 ENVIRONMENTAL ASPECTS:

An assessment of the environmental aspects shall take place in accordance with **Environmental Aspects and Impact Determination, Procedure EM-09-001-P**. This procedure has been established to facilitate the process of identifying the environmental aspects, and their impact on the environment, that exist as a result of our business activities.

- As a result of this process, we will identify those activities and products that have a significant impact on the environment, and take these into account in the establishment, implementation and maintenance of the *Environmental Management System (EMS)* and the setting forth of objectives, goals and targets within the organization as they relate to prevention of pollution and the preservation of our natural resources.

4.3.2 LEGAL AND OTHER REQUIREMENTS:

Quality Synthetic Rubber / Medical Elastomer Development have identified and obtained accesses where needed to the latest legal requirements and other requirements relating to our Environmental aspects. **EMS Legal and Other Requirements, matrix EM-09-002-F** has been established for the purpose of tracking, identifying and communicating legal and other requirements (i.e., EPA requirements, customer requirements, QSR policy requirements, etc.) that are applicable to our facility.

4.3.3 OBJECTIVES and TARGETS PROGRAM:

Quality Synthetic Rubber / Medical Elastomer Development has established environmental objectives and targets based on the requirements of the Objectives and Targets procedure (**ref.: Environmental Objectives and Targets, Procedure EM-01-002-P**). These objectives and targets define, the performance objectives (*Investigate, Control or Improve*), specific quantified targets, responsible parties and the means and time frame by which objective are to be achieved.

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The following areas shall be taken into account when establishing and reviewing Objective and targets:

- Our significant environmental aspects;
- Legal and other requirements;
- Technological Options;
- Financials;
- Operational requirements;
- Business requirements;
- Views of other interested parties.

Objectives and Targets shall be reviewed, at a minimum, once annually as a part of the **Management Review**. This review shall be conducted in harmony with, the objectives set forth in our Environmental Policy, and a commitment to continual improvement.

4.4 IMPLEMENTATION AND OPERATION:

4.4.1 RESOURCES, ROLES, RESPONSIBILITY AND AUTHORITY:

Roles, responsibilities and authorities are defined at relevant functions and levels within the organization (*ref.: EMS Responsibility, matrix EM-01-002-F*). The President / CEO with the assistance of the Environmental Management coordinator provides the resources essential to the implementation and control of the environmental management system, including: training, human resources, specialty services, financial resources, technical and informational services. The Environmental Management Coordinator has primary responsibility for establishing, operating and maintaining the **Environmental Management System (EMS)**. Cross Functional Teams (**EMS Steering Committee**) are used wherever possible to provide routine EMS support to the Environmental Management Coordinator.

4.4.2 COMPETENCE, TRAINING AND AWARENESS:

Quality Synthetic Rubber, Inc. / Medical Elastomer Development Inc. jointly identifies, plans, monitors and records training needs for personnel whose work may create a significant impact upon the environment. We provide employees training at each relevant function and level so they are aware of the environmental policy, significant environmental aspects, their roles and responsibilities in achieving conformance with the policy and procedures, and with the requirements of the environmental management system. The Human Resource Manager is responsible for maintaining employee training records (*ref.: Training System, procedures ST-18-001-P and QA-P-28 and Training Needs Identification and Record Keeping, Procedure QA-P-28*).

4.4.3 COMMUNICATION:

A variety of processes are used for internal communications on environmental-related matters. The effectiveness of the communications is evaluated via Management Review, audits, inspections and informal discussions.

Communication processes that are used include, however are not limited to:

- Plant wide employee meeting.
- Training
- Quality System Directory (manual and procedures, QSR Intranet).
- EMS Workbook (workbook available on the QSR intranet).
- Postings on the plant information boards.

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Requests for information regarding environmental-related matters from externally interested parties are forwarded to the Environmental Coordinator. The Environmental Coordinator determines if a response will be made, delegates response duties, determines if corrective action is required and maintains a record of the final response on file. The resulting records are to be review once annually as a part of the **Management Review** process.

Quality Synthetic Rubber / Medical Elastomer Development do not intend to communicate our Significant Environmental Aspects with external parties unless said communication(s) are required by law. If said law requires communications it will be the responsibility of the Environmental Coordinator to document and perform these duties.

4.4.4 DOCUMENTATION:

This Manual identifies policy, scope, documents and procedures relevant to the **Environmental Management System (EMS)**. This manual along with all associated procedures and instructions are maintained on the QSR/MED computer network and can be viewed from the various computer terminals within the QSR and MED facilities. An **EMS Directory** has been established on the QSR/MED computer network for the review and maintenance of the various "living documents" that are a part of the environmental management system (i.e., Environmental Impact Determinations, Aspects & Impacts, Significant Impacts Determination, Objectives & Targets Matrix, Legal & other matrix, etc.). The **EMS Directory** can also be viewed on various computer terminals throughout the QSR/MED network system. A copy of the various **Environmental Management System (EMS)** documents, other than visual aids and records, can be obtained from any member of the **EMS Steering Committee**.

4.4.5 CONTROL OF DOCUMENTS:

The **Environmental Management System (EMS)** will institute the requirements of the QSR and MED **Document control procedures, QA-05-001-P & QA-P-9**. The Document Control Procedures assures proper control of all documents relating to Policy Manuals, Work Instructions, Inspection and Test Instructions, Standards Control, Form Control, Software Control and Document Identification.

4.4.6 OPERATIONAL CONTROL:

As a part of the **Environmental Aspects and Impact Determination** process, the **EMS Steering Committee**, with the assistance of appropriate departmental representatives, will identify and plan operations and activities associated with Significant Environmental Aspects consistent with the QSR/MED Environmental Policy, Objectives and Targets.

Operational Controls will be established to define the mechanisms for the establishment, implementation and maintenance of operational controls as they apply to:

- Situations where the absence of controls could lead to deviation from environmental policy, objectives and targets;
- Stipulation of specific operating criteria;
- Environmental aspects of goods and services used by the organization;
- Communicating EMS requirements to suppliers and contractors.

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4.4.7 EMERGENCY PREPAREDNESS AND RESPONSE:

The **EMS Steering Committee** will, as a part of its activities and responsibilities, identify potential emergency and/or accident situations that can have an impact on the environment. The committee will then determine the emergency preparedness and response activities required to respond to, prevent and/or mitigate the associated adverse environmental impacts (**ref.: Emergency Preparedness and Response Matrix, form EM-09-004-F**). The **EMS Steering Committee** will review and where necessary revise the emergency preparedness and response procedures. This review will be performed annually and after the occurrence of accidents or emergency situations. Periodic tests of the emergency preparedness and response procedures will be performed where practicable. The **EMS Steering Committee** will coordinate these tests with the appropriate area managers to help facilitate and evaluate these activities.

4.5 CHECKING:

4.5.1 MONITORING AND MEASUREMENT:

Quality Synthetic Rubber / Medical Elastomer Development has established monitoring and measurement requirements for the key characteristics of its operations and activities that can have a significant impact on the environment (**ref.: Environmental Performance Measurement Indicators matrix, form EM-09-005-F**). These key characteristics are monitored and measured to determine how the organization is managing its significant environmental aspects, achieving its objectives and targets and improving environmental performance.

Measurement gages may be used as a part of the monitoring and measuring process. Measurement equipment, when necessary to ensure valid results, will be calibrated and verified at specified intervals to ensure valid results in accordance with **Calibration Control Procedures, DL-11-001-P & QA-P-19**.

4.5.2 EVALUATION OF COMPLIANCE:

The EMS Steering Committee will conduct an annual review to identify the most current national, state and local legal requirements and other requirements to assure that Quality Synthetic Rubber / Medical Elastomer Development remains in compliance with the most current requirements. This review may include, however it is not limited to, information that may be found on federal, state and local web sites, in legal publications and on customer web sites. Changes and additions to regulation and requirements that are identified, shall be accessed to determine how they apply to our environmental aspects and were appropriate, changes to the *Environmental Management System (EMS)* shall be made and communicated to the organization. Records are maintained as a part of **Management Review**.

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4.5.3 NONCONFORMITY, CORRECTIVE ACTION AND PREVENTIVE ACTION:

Corrective Action procedures QA-14-001-P and QA-P-22 describe the methods for implementing corrective action as well as action to prevent reoccurrence and includes a process for the recording of relevant information for review. Corrective actions relevant to the environmental Management system shall be reviewed and approved by the Environmental Management Coordinator and/or one or more members of the EMS Steering Committee to ensure that actions taken are appropriate to the magnitude of the problem and the environmental impacts encountered And that any necessary changes are made to the environmental management system documentation.

Procedures and policies are utilized in the process of Corrective and Preventive Action as it applies to a proactive approach to *Environmental Management System (EMS)* improvement and the identification of potential sources of nonconformance. Relevant information on actions taken is reviewed at least once annually by the EMS steering committee as a part of the **Management Review**.

4.5.4 CONTROL OF RECORDS:

Record retention procedures and instructions have been established for the identification, collection, indexing, access, filing, storage, maintenance, retention and disposal of records (**ref.: Record Retention, procedures QA-16-001-P and QA-P-26 and Quality Record Matrix, form QA-16-001-I**).

Records are legible, stored in a suitable environment to prevent damage or deterioration and are readily retrievable. Electronic data is protected, backed-up, stored and access controlled per the **Computer Network Security & Maintenance procedure MI-05-001-P**.

4.5.5 INTERNAL AUDITS:

Periodic internal audits of the **Environmental Management System (EMS)** are performed in accordance with **Internal Quality Audits procedures QA-17-001-P and QA-P-27**. Internal auditors are trained and independent of the area being audited when practicable. Audit activities verify, that the environmental management system conforms with the this manual and its related documents and ISO 14001, and that the systems are properly implemented and maintained.

The audits are intended to determine whether the environmental management system(s):

- Conforms with the requirements of this manual;
- Conforms with the requirements of ISO 14001;
- Are properly implemented and maintained;
- Can be improved.

The area audited, audit findings, follow-up audit activities and corrective action are recorded in computer system using the *Internal Audit Program*.

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4.6 MANAGEMENT REVIEW:

Review of the Environmental Management Systems is conducted as a part of **Management Review, procedures AD-01-004-P and QA-P-5**. These reviews are conducted to ensure continued suitability, adequacy and effectiveness of the environmental management system. These reviews include the assessing of opportunities for improvement and the need for changes to the Environmental Management system, the Environmental Policy and the Environmental Objective and Targets.

The following areas shall be reviewed as a part of Management Review:

- Results of audits
- Evaluations of compliance with legal requirements and with other requirements;
- Communications with externally interested parties, including complaints;
- Organizational environmental performance;
- Objectives and targets;
- Corrective and preventative action;
- Follow-up actions as a result of the previous management review;
- New developments and circumstances (legal and other requirements relating to environmental aspects);
- EMS improvement recommendations.