

QUALITY SYNTHETIC RUBBER, INC.

## Quality Synthetic Rubber's

# Testing Facility Laboratory Manual

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# QUALITY SYNTHETIC RUBBER, INC.

## 1. SCOPE:

1.1 The Laboratory Manual communicates the policies, procedures and practices of Quality Synthetic Rubber's Material Testing Laboratory both internally and to it's customers. This manual having been established to meet both the needs and requirements of our clients and those of ISO/IEC 17025.

## 2. LABORATORY MANUAL DISTRIBUTION AND APPROVAL:

2.1 QSR electronically accesses the Laboratory Manual. Printed copies for Sales and Auditor distribution are marked Uncontrolled. The methods for control and distribution are explained in procedure QA-05-001-P, *Control of QSR Policy Manuals*.

2.2 The President / CEO and Technical Director approve policy changes to the Laboratory Manual. QSR records the revision level, issue date and authorized signatures in the master Laboratory Manual.

## 3. QUALITY POLICY STATEMENT

3.1 Quality Synthetic Rubber is committed to providing "World Class" precision molded Elastomeric components. This commitment is a company wide dedication to continuous improvement and customer satisfaction.

The Materials Laboratory and its personnel, in keeping with this policy are committed to:

- Maintaining a quality system that will allow us to meet or exceed the requirements of our customers.
- Maintaining a quality system that will allow us to meet or exceed the requirements of ISO/IEC 17025.
- Maintaining a working knowledge of the quality systems involved and implementing them in our work.
- Performing all testing in conformance with customer requirements and stated test methods.
- Providing "WORLD CLASS" testing services, in the most professional manner possible, to our customers and clients.

## 4. MANAGEMENT REQUIREMENTS

### 4.1 ORGANIZATION:

4.1.1 The Material Testing Laboratory managerial staff has the authority and resources needed to discharge their duties. The Material Laboratory is equipped with superior facilities and staff. Laboratory Management is supported by and reports directly to the President / CEO. The organizational structure enables the Laboratory to perform the technical and quality functions for which it is responsible.

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4.1.2 In the absence of the Technical Director, the Laboratory Manager will assume the duties of the technical Director. In the absence of the Laboratory Manager the Technical Director will assume the duties of the Laboratory manager these duties including quality management responsibility. In the event of both the Technical Director and the Laboratory Manager absence, the Quality Manager for Quality Synthetic Rubber's manufacturing facility, having knowledge of Laboratory systems, will assume these necessary management positions until the return of these key personnel.

4.1.3 Internal communications are directed through the Laboratory Manager or Director of Technology to prevent adverse influence. Gifts or favors from suppliers, customers or internal activities that may benefit from "in-spec" test results are prohibited to avoid the perception of conflict of interest.

4.1.4 The Technical Director and Laboratory Manager share joint responsibility for the development and implementation of the Laboratory Manual. The process for updating the Laboratory Manual, and methods for determining the revision history and responsibilities are detailed in procedure QA-05-001-P, *Control of QSR Policy Manuals*.

4.1.5 The Laboratory Manager is responsible for being familiar with the test methods, procedures, test objectives and the assessment of test results. The Laboratory Manager also has the responsibility to maintain the "Quality Management Systems" within the Material Laboratory to ISO/IEC 17025 and has the authority to institute corrective action and procedures consistent with these quality goals. The Laboratory Manager reports to the Director of Technology.

4.1.6 QSR's Quality Assurance Manager has the responsibility to maintain the Quality Systems integrated with the Material Laboratory as specified within this Manual, and to maintain the overall Quality System to ISO/TS-16949. The Quality Assurance Manager reports directly to the President / CEO.

4.1.7 The Director of Technology has overall responsibility for technical operations. The Director of Technology shall have the ultimate responsibility to assure that the Laboratory remains in compliance with ISO/IEC 17025 at all times. The Director of Technology and President / CEO are the highest level of Management at which Laboratory policy and resource decisions are made (ref.: Organization Chart).

4.1.8 It shall be the responsibility of all laboratory employees to conduct themselves in a manner that does not diminish the confidence in our competence, impartiality, judgment or operational integrity as viewed by both Q.S.R. employees and our customers. This responsibility includes activities both in and outside of normal operations at Quality Synthetic Rubber (ref.: *Employee Hand Book / Plant Rules and Termination Notification Procedure AC-05-001-P*).

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4.1.9 Job descriptions will be maintained for all Laboratory Personnel detailing responsibility, education and training requirements (ref.: *Job Description Program*).

4.1.10 Proprietary rights and confidential information for both Quality Synthetic Rubber and customers are adequately secured (ref.: *Computer Network Security & maintenance, procedure MI-05-001-P*).

4.1.11 The Organizational Chart can be obtained on the Quality Synthetic Rubber web sight by entering <http://www.qsr-inc.com>.

## 4.2 QUALITY SYSTEM

4.2.1 The Quality System Manual, Laboratory Manual and referenced Procedures along with Work, Process and Testing Instructions comprise QSR's Quality System. Methods and policies specific to the Material Testing Laboratory are detailed in the Laboratory Manual, Laboratory Procedures and Testing Instructions. The document structure of the Laboratory Quality System is outlined below:

- Level 1 - Quality System Manual & Laboratory Manual
- Level 2 - Quality Procedures & Laboratory Procedures
- Level 3 - Work Instructions, Gage Instructions & LP Testing Instructions
- Level 4 - Records (Reports, Tags, Miscellaneous Documents)

The Laboratory Quality System is available to all Laboratory Personnel electronically on the Quality System Directory. The Quality System Directory, managed by the Quality Assurance Manager, maintains the current Laboratory Manual and relevant documents per *Document Control, procedure QA-05-006-P* and *Control of QSR Policy Manuals, procedure QA-05-001-P*.

## 4.3 DOCUMENT CONTROL

4.3.1 Procedures for document control ensure:

- Those current issues of documents are available at all essential locations, and invalid or obsolete documents are promptly removed from points of issue.
- That obsolete documents retained for reference are identified as "Obsolete".
- That master lists identifying the current revision status are established and readily available (ref.: Quality System Directory).

4.3.2 The laboratory will institute the requirements of the following procedures in the administration of document control:

- QA-05-006-P, Document Control
- QA-05-001-P, Control of QSR Policy Manuals
- QA-05-003-P, Procedure and Work Instruction Control
- QA-05-007-P, Control of Process Inspection and Testing Instructions
- QA-05-010-P, Standards Control Procedure
- QA-05-008-P, Form Control Procedure
- MG-05-002-P, Customer Drawing Control

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- MI-05-002-P, Software Control
- QA-16-001-P, Record Retention
- QA-05-005-P, Document Identification Control

4.3.3 The Director of Technology and Laboratory Manager share joint responsibility for the development, implementation and maintenance of the Laboratory Manual, Laboratory Procedures and Test Instructions. The Laboratory Manual and Laboratory Procedures will be reviewed annually as a part of "Management Review". Revision recommendations may be made by any Quality Synthetic Rubber Employee. *Control of QSR Policy Manuals, procedure QA-05-001-P and Procedure & Work instruction Control, procedure QA-05-003-P* detail the steps for revising the Laboratory Manual, Procedures and Instructions.

4.3.4 Changes to documents are reviewed and approved by the same functions that performed the original review and approval unless specifically designated otherwise. Approval functions have access to pertinent information to base their review and approval. The approval functions are listed on the documents or referenced. A description of the change is listed on the document or attachments and the obsolete document is retained in the signature files.

4.3.5 Calibration and Testing Instructions are part of the Document Control System. These documents are maintained up-to-date and readily available to the staff. Laboratory Procedures and Instructions detail the use and operation of all relevant equipment, including the handling and preparation of items for calibration or test (ref.: *Control of Process, Inspection & Testing Instructions, procedure QA-05-007-P*).

## 4.4 CONTRACT / NEW WORK REVIEW

4.4.1 Quality Synthetic Rubber's testing laboratory is not a contract testing facility. The testing performed in Q.S.R. is a part of the "Production Part Approval Process" (PPAP), and also in many cases is performed as a periodic confirmation that materials used to produce product conform to specification requirements.

4.4.2 New work is reviewed by the Director of Technology as a part of the *Simultaneous Advanced Planning (SAP), Procedure QA-02-002-P*. A feasibility review is conducted and documented (ref.: *form SA-03-002-F*) for non-standard inquiries as required by the *Advanced Quality Planning Procedure QA-02-001-P* and the *Feasibility Review Procedure SA-02-001-P*. Issues of concern that arise as a result of a feasibility review are resolved with QSR's customers prior to acceptance of a contract. Acceptable Feasibility Review's are processed in accordance with the Simultaneous Advanced Planning Process.

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4.4.3 As a part of *Simultaneous Advanced Planning*, consideration is given to job requirements as they pertain to the assignment and testing of materials to be used for the product. Prints and all related specifications are evaluated for material and test requirements. The selection of appropriate test methods is made and consideration is given to laboratory capabilities and resources to assure that we can meet the job requirements. If an area of concern is noted or there is a need to deviate from customer requirements these concerns are discussed and reported in the SAP meeting and appropriate measures are taken before job commencement. Evidence of this review and appropriate actions are indicated on the *Simultaneous Advanced Planning monitoring form QA-02-011-F*.

4.4.4 QSR's laboratory does not subcontract testing for which it maintains accreditation. Consideration is however given to test capabilities as part of job review. Decisions are made at this time with regard to placing work, that is not within our scope of accreditation, with outside laboratories for completion.

4.4.5 Records of review are maintained as a part of QSR's network computer system as a part of the SAP process. Records of customer correspondence as it relates to laboratory testing will be maintained in writing in the appropriate job file.

4.4.6 The SAP process is an on-going process of job review. This process continues until the customer is submitted all required documentation as such any amendments to requirements that take place after work has commenced is and will be communicated to all affected parties. If changes to work that falls out-side the realm of the SAP process take place they will be documented in writing by the Technical Director or the Laboratory Manager and communicated to all affected parties. The SAP process is concluded with the customer's approval of the PPAP.

## **4.5 SUBCONTRACTED TESTING:**

4.5.1 It is not the policy of QSR's laboratory to subcontract testing for which it maintains accreditation. However if it should become necessary to subcontract work for some unforeseen circumstance the following policies will apply:

- Work is only to be placed with laboratories that comply with ISO/IEC 17025 for the testing to be performed.
- QSR will inform its client, if work is being performed at the request of a customer out-side of QSR, in writing of the arrangement to subcontract.
- If appropriate, QSR will obtain customer approval to subcontract.
- QSR will maintain responsibility for subcontracted work and do whatever is required to assure that it's clients are satisfied with the work performed.

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- Test results from subcontractors will be submitted to QSR's customers "as received" by the subcontractor (The full subcontracted test report is submitted to the customer).

4.5.2 A file is maintained for all "subcontractors" and a copy of their "scope of accreditation is kept in said file. A list of Approved Vendors is maintained which includes approved Laboratories (ref.: *Vendor Control Procedure, PR-06-002-P*).

## 4.6 PURCHASING:

4.6.1 QSR's purchasing department maintains approved suppliers for the purchase of supplies and services that have a direct effect on the quality product and testing performed (ref.: *Purchasing Procedure, PR-06-001-P*). The methods used to select and classify vendors can be found in the *Vendor Control Procedure, PR-06-002-P*. A list of Approved Vendors is maintained by the Purchasing department, which includes approved suppliers used by the Laboratory (ref.: *Vendor Control Procedure, PR-06-002-P*). Materials used for specification testing, "Consumable Materials", by the Laboratory are controlled via the *Consumable Materials Procedure, ML-06-001-P*.

4.6.2 In addition to the policies as stated in the *Vendor Control Procedure*, the following requirements shall apply to the purchase and selection of supplies and services for the laboratory:

- Consumable materials shall, whenever possible, be obtained by a source that has obtained a minimum of ISO 9000 accreditation (ref.: *Consumable Materials, procedure ML-06-001-P*).
- Calibration and Testing services shall, whenever possible, be obtained from laboratories accredited to ISO/IEC 17025 by A2LA or another accredited body recognized by A2LA under the reciprocal recognition agreement, (ref.: *Calibration Control, procedure DL-11-001-P; Purchasing Procedure, PR-06-001-P*).

4.6.3 Whenever QSR's Material Lab does not use a calibration or reference standard source that is ISO/IEC 17025 accredited, the source will be evaluated for meeting the intent of ISO/IEC 17025 per the *Vendor Control Procedure, PR-06-002-P*.

## 4.7 SERVICE TO THE CLIENT:

4.7.1 The laboratory will do everything possible to assure that Quality Synthetic Rubber and it's customers receive the best possible service while maintaining the utmost in confidentiality when required. This may include, however is not limited to:

- Cooperating with customers in the clarification of test requests and the performance of said tests.
- Affording customers access to the laboratory to witness testing when requested.

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- Prepare, package and dispatch test items as may be required by our customers for the purpose of verification, etc..
- Advise, guide and communicate with our clients in technical matters, opinions and interpretations in regard to testing performed or to be performed.
- Communicate to the client any major deviations in testing being performed.
- Communicate with the client with regard to any delays that may result in the customer not receiving their testing in a timely manner.
- Clients will be notified of any event that casts doubt onto the validity of results supplied to them.

## 4.8 COMPLAINTS:

4.8.1 Complaints against the Laboratory's activities, both verbal and written, are documented in accordance with *Technical Complaint, procedure, ML-14-001-P* which covers the methods for documenting, investigating and resolving complaints.

4.8.2 Whenever a complaint raises doubt concerning the Testing laboratory's compliance with Laboratory procedures, policies or ISO/IEC 17025, a prompt audit of the quality system will occur. Consideration of suitable preventative action will be an integral part of this process. The *Corrective Action, procedure QA-14-001-P* will be used to assign root cause and implementing irreversible corrective action.

## 4.9 CONTROL OF NONCONFORMING TESTING / CALIBRATION WORK:

4.9.1 In the event that a nonconformance is identified with regard to any aspect of testing or the results of the testing performed do not conform with laboratory procedure or the agreed requirements of our customers, the Technical Director or the Laboratory Manager will act to contain the nonconformance and to initiate corrective action per the *Control of Nonconforming Testing, procedure ML-13-001-P*.

4.9.2 In the event that a nonconformance is identified with regard to calibration work performed the *Calibration Control procedure DL-11-001-P* will be followed and corrective action taken accordingly. The Laboratory Manager evaluates at risk equipment and takes appropriate corrective action.

## 4.10 CORRECTIVE ACTION:

4.10.1 *Corrective Action procedure QA-14-001-P* describes the methods for implementing corrective action as well as action to prevent reoccurrence and includes a process for the recording of relevant information for Management review.

4.10.2 As a part of "containment" management must decide if the nonconformance requires notification of the client('s) in regard to the

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nonconformance or work performed that may come into question as a result of the nonconformance. If such notification is deemed necessary a record of said notification shall be present in the "CONTAINMENT" section of the Corrective Action report.

4.10.3 If a serious issue or risk to business is identified as a result of a nonconformance, that has cast doubt on laboratory compliance with policy, procedure or compliance with ISO/IEC 17025, an audit shall be conducted on the area of nonconformance to assure the effectiveness of the corrective action (Ref.: *Internal Quality Audits*, Procedure QA-17-001-P).

## 4.11 PREVENTIVE ACTION:

4.11.1 The following procedures and policies are utilized in the process of "Preventive Action" as it applies to a proactive approach to quality improvement and the identification of potential sources of nonconformance:

- Corrective Action, procedure QA-14-001-P
- Preventive Action, procedure QA-14-002-P
- Internal Quality Audits, procedure QA-17-001-P
- Continuous Improvement Project (CIP), procedure AD-02-001-P
- Laboratory Proficiency Testing, procedure ML-11-002-P
- Gage Evaluation Procedure, procedure DL-11-002-P
- Statistical Process Control, procedure QA-20-001-P
- Laboratory Statistical Process Control, procedure ML-20-001-P
- Management Review, procedure AD-01-004-P
- Test Quality Monitoring, ref. Form ML-10-013-F

4.11.2 The above procedures and policies describe the methods used to detect, analyze and eliminate potential causes of nonconformities. Appropriate sources of information such as customer complaints, audit results, SPC, Gage Repeatability & Reproducibility, replicate tests, trend reports on quality and Laboratory Proficiency Testing are used.

4.11.3 The procedures include instructions for determining the steps needed to deal with problems requiring preventive action. The controls for initiating and applying preventive actions are also defined to ensure their effectiveness.

4.11.4 Relevant information on actions taken is submitted for Management Review from the Continuous Improvement Process, internal audits, and corrective / preventive action records.

## 4.12 CONTROL OF RECORDS:

4.12.1 QSR has established procedures for the identification, collection, indexing, access, filing, storage, maintenance and disposal of quality and technical records. The following procedures have been established to facilitate the control of records as they relate to specific areas of concern:

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- Document Control, procedure QA-05-006-P
- Document Identification, procedure QA-05-005-P
- Record Retention, procedure QA-16-001-P
- Standards Control, procedure QA-05-010-P
- Control of QSR Policy Manuals, procedure QA-05-001-P
- Form Control, procedure QA-05-008-P
- Computer Network Security and Maintenance, procedure MI-05-001-P
- Software Control, procedure MI-05-002-P
- Procedure and Work Instruction Control, procedure QA-05-003-P
- Control of Process, Inspection and Testing, procedure QA-005-007-P

4.12.2 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 *Computer Network Security & Maintenance, procedure MI-05-001-P*. Records are made available to the customer or the customer's representative when agreed to contractually. All records are held secure and in confidence.

4.12.3 Reference *Record Retention, procedure QA-16-001-P* for retention times by record type. Customer specific retention periods are adhered to as contractually required. Retention times are considered minimums and records are eventually disposed.

4.12.4 Obsolete documents are promptly removed from all points of issue including operating locations. Obsolete documents are destroyed, or identified as "Obsolete" if retained for reference, to assure against unintended use. Electronic media is immediately replaced with updates upon reissue (ref. *Document Control, procedure QA-05-006-P*).

4.12.5 The laboratory shall retain records of original observations, derived data and sufficient information to establish an audit trail, calibration records, staff records and a copy of each test report or calibration certificate issued, for a defined period.

4.12.6 The records for each test or calibration shall contain sufficient information to facilitate, if possible, identification of factors affecting the uncertainty and to enable the test or calibration to be repeated under conditions as close as possible to the original.

4.12.7 The records shall include the identity of personnel responsible for the sampling, performance of each test and/or calibration and checking of results.

4.12.8 Observations, data and calculations are recorded at the time they are made and are identifiable to the specific test being performed and maintained on file in the Materials Laboratory (ref. *Compound Evaluation Form, ML-02-003-F* and *Master Test Files*).

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4.12.9 When mistakes occur in records, each mistake shall be crossed out, not erased, made illegible or deleted, and the correct value entered alongside. In the case of electronically stored data a hard copy of the data will be produced and a brief note shall be added to the document specifying the nature of the mistake. All such mistakes / alterations to records and electronic data shall be signed or initialed by the person making the correction and maintained on file.

## 4.13 INTERNAL AUDITS:

4.13.1 Periodic internal audits of the laboratory are performed in accordance with Quality Synthetic Rubbers *Internal Quality Audits, procedure QA-17-001-P*. Internal auditors are trained and independent of the area being audited. Audit activities verify that laboratory operations continue to comply with the requirements of the quality system and ISO/IEC 17025. The audits are intended to determine:

- Whether procedures described in the quality system are being followed;
- Whether objectives (as defined in the quality system) are being achieved;
- Whether designated duties are being carried out satisfactorily;
- And if there is opportunities for improvement.

4.13.2 When audit findings cast doubt on the effectiveness of the operations or the correctness or validity of the laboratory's test results, the laboratory shall notify clients in writing if investigations show that the laboratory results may have been affected.

4.13.3 The area of activity audited, audit findings, follow-up audit activities and corrective action are recorded in Quality Synthetic Rubber's computer system using the "*Internal Audit Program*".

## 4.14 MANAGEMENT REVIEW:

4.14.1 Management Review meetings for all QSR functions are held at defined intervals. Management Reviews assess the effectiveness and continuing suitability of the Quality System to satisfy the requirements of ISO/TS-16949, ISO/IEC-17025 Requirements, and QSR's stated Quality Policy and Objectives. The President / CEO is responsible for scheduling and conducting these reviews.

- 4.14.2 In addition to the Review requirements of the *Management Review, procedure AD-01-004-P*, once annually, the Technical Department reviews, evaluates and reports on the following elements of the Laboratory's Quality System as a part of the management Review process: Matters arising from the previous Management Review;
- Third-Party assessments, findings and corrective action (A2LA);

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- Customer on-site audits, findings and corrective action; (Client Feedback)
- Safety and environmental concerns;
- Future plans and projections for staff, training, equipment, Facility, etc.;
- Suitability of the Laboratory manual;
- Suitability of the Laboratory procedures;
- Supplier and internal corrective and preventative actions;
- Equipment maintenance;
- Equipment Validation;
- Results of internal audits, findings and corrective actions;
- Results of participation in proficiency testing;
- Results of in-house quality checks;
- Details of any complaints from customers;
- Changes in the volume and the type of work;
- Reports from managerial and supervisory personnel.

4.14.3 Conclusions of the reviews are documented. Detailed rules for scheduling, conducting and recording Management Reviews are specified in *Management Review, procedure AD-01-004-P*.

## 5. TECHNICAL REQUIREMENTS:

### 5.1 GENERAL:

5.1.1 Quality Synthetic Rubber's laboratory is a mechanical test laboratory. The testing performed is performed in accordance with specific ASTM procedures. Our laboratory takes into account many factors to assure the correctness and reliability of this testing and that testing is being performed in accordance with ASTM test requirements. The following factors are considered when test procedures are established for this testing:

- Personnel;
- Accommodations and Environmental conditions;
- TEST Methods and method validation;
- Equipment;
- Measurement traceability;
- Sampling;
- Handling of test items.

### 5.2 PERSONNEL:

5.2.1 QSR's Laboratory is assigned sufficient personnel with the necessary education, training, technical knowledge and expertise for their functions. All Laboratory Employees receive training, from a source affiliated with the *Rubber Division of the American Chemical Society*, in the compounding, processing and testing of elastomers. The level of expertise for Laboratory Personnel is documented in training records and on the "Laboratory Personnel Qualifications List" (ref.: *Laboratory Personnel*

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*Qualifications List, form ML-18-002-F and Laboratory Training, procedure ML-18-001-P*). The Laboratory Training procedure indicates how records covering the education, skills and technical experience of the Laboratory Personnel are maintained. The Laboratory Manager retains records detailing qualifications and completed training.

5.2.2 It is the policy of Quality Synthetic Rubber to evaluate the education and training needs of it's personnel, based on their level of expertise, as a part of the Management Review process (*ref., Management Review, Procedure AD-01-004-P and Management Review, section 4.14 of this manual*).

5.2.3 All personnel utilized within the laboratory are employed by or under contract to Quality Synthetic Rubber, Inc.. Where Additional personnel are utilized, that are not part of the technical department, the Laboratory Manager shall assure that said personnel are supervised, competent, and that they work in accordance with laboratory quality systems.

5.2.4 Each Laboratory position, including senior staff, has a job description identifying relevant qualifications, position title, minimum job requirements for the position, responsibilities, reporting relationship, and supervisory responsibilities (*ref.: Job Description Program*).

## 5.3 ACCOMMODATIONS AND ENVIRONMENTAL CONDITIONS:

5.3.1 Environmental controls for the Material Laboratory are appropriate for the type of testing being performed. A temperature-controlled environment is maintained as required by the ASTM procedures being performed. Human factors relating to light, ventilation and space are considered with respect to performing required tasks safely, effectively.

5.3.2 Environmental factors that may adversely affect measurements are controlled to the degree necessary so as not to invalidate test results or increase the measurement uncertainty. Areas of sample preparation, preconditioning, testing and storage are of adequate size and free from degrading factors that could affect the integrity of the samples. *Environmental Control, procedure ML-11-004-P, Laboratory Test Instructions and ASTM Procedures* address environmental requirements.

5.3.3 A calibrated temperature monitoring device is available and operating, whenever testing or specimen conditioning necessitating temperature control is being performed. The Laboratory room temperature is recorded and maintained on file in the Material Laboratory and is readily accessible. Laboratory Management has the power and responsibility to stop testing in the laboratory any time conditions become such that the test results of said testing comes into question as to validity, including conditions that may arise due to the environment.

5.3.4 Effective separation is maintained for incompatible test areas, or when potentially adverse influence or cross-contamination needs to be

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avoided. This is accomplished by segregating the Laboratory into specific work areas indicative to the testing operations.

5.3.5 QSR's building layout segregates the Material Laboratory from other manufacturing functions to limit access. The Material Laboratory is secured when Laboratory Personnel are not on duty.

5.3.6 It is the policy of Quality Synthetic Rubber to maintain all areas in a clean and orderly manner. Tools, equipment and materials are stored in their proper location at the end of each workday, unless extended or continuous testing requires use of the equipment. Desktops, countertops, etc. are cleaned as needed by the Laboratory Personnel. QSR's Building Maintenance maintains floors. Housekeeping is included as an audit item (ref.: *Internal Auditing, procedure QA-17-001-P*).

## 5.4 TEST METHODS AND METHOD VALIDATION:

5.4.1 Test Instructions are part of the Document Control System, are maintained up-to-date and readily available to the staff (ref.: *Control of Process, Inspection & Testing Instructions, procedure QA-05-007-P and Document Control, procedure QA-05-006-P*). *Laboratory Procedures and Gage Instructions* detail the use and operation of all relevant equipment, including the handling and preparation of items for testing. Laboratory Test Procedures are written for tests performed by Laboratory personnel in order to maintain consistency of the measurement process. Laboratory Test Instructions are clear and unambiguous and are electronically accessed from the Quality System Directory. Where Appropriate, an estimation of measurement uncertainty and / or statistical techniques are used for the analysis of test data.

5.4.2 Laboratory Procedures contain the following information:

- The title,
- Unique procedure number (LP-#),
- Instruction effective date and revision level,
- Applicable references and published consensus standards,
- Scope,
- Apparatus used,
- Known testing limitations,
- The number of significant figures to be reported,
- The instruction and any other needed information.

5.4.3 Where a testing method is not specified by the customer, the Director of Technology will select a published international or national standard. If a consensus standard is not available, then methods might be found in professional scientific texts or journals. Methods that have not been established as a standard are fully documented, statistically validated and agreed to by the involved parties. Non-standard methods are made available to the customer and other recipients of the report.

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5.4.4 Confirmation, of the laboratories ability to use equipment and perform testing, is completed prior to introducing the test into laboratory systems for use. Confirmation of ability to properly perform testing is also performed as a part of the review process whenever specification changes are received and introduced into the laboratory systems. Customers, when appropriate, will also be informed if methods proposed are considered inappropriate or out of date.

5.4.5 When sampling is a requirement of the test method, the Material Testing Laboratory uses documented procedures and appropriate statistical techniques to select a sample. The sampling techniques are specified in Laboratory Instruction and ASTM procedures.

5.4.6 Manual calculations and handwritten data transfers are subject to checks by someone other than the Technician performing the work, prior to reporting the data to the customer. The individual checking the work, initials the data as evidence of the review.

5.4.7 The Material Testing Laboratory utilizes computers and automated equipment for the capture, processing, manipulation, recording, reporting, storage and retrieval of test data. The Laboratory maintains supporting evidence that the equipment is capable of performing within the boundaries of the test method specification.

5.4.8 The laboratory and support functions to the laboratory help ensure:

- Computer software is documented and adequate for use, (ref.: *manufacturer's manuals* for purchased software and *Software Control, procedure MI-05-002-P* for internal software);
- *Computer Network Security & Maintenance, procedure MI-05-001-P*, documents the procedures for ensuring the security, maintenance and integrity of data entry, capture, storage, transmission and processing in the computer system;
- Equipment is maintained and calibration verified to ensure proper functioning, (ref. *Calibration Control, procedure, DL-11-001-P*);

5.4.9 All laboratory equipment and testing performed by the laboratory is evaluated to determine if the estimation of uncertainty of measurement is needed (ref.: *Estimation of Uncertainty of Measurement, procedure ML-11-007-P* and *Calibration Control, procedure, DL-11-001-P*).

### 5.5 EQUIPMENT:

5.5.1 QSR's Laboratory is furnished with all items of sampling, measurement and test equipment required to correctly perform all testing specified in our scope of accreditation. In those cases where laboratory personnel need to use equipment outside of the laboratories permanent control such equipment use must first be approved by the Technical Director and said equipment must be investigated to assure that the requirements of both the test specification and ISO/IEC17025 are meet.

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5.5.2 To assure that equipment used for testing complies with specification requirements and are capable of achieving the accuracy required for each test performed The following procedures, and the systems associated with them, have been instituted to assure compliance with specifications relevant to the tests concerned:

- *Laboratory Equipment Validation, procedure ML-11-006-P;*
- *Calibration Control, procedure DL-11-001-P;*
- *Preventative Maintenance System, procedure MT-09-003-P;*
- *Software Control, procedure, MI-05-002-P;*

5.5.3 Laboratory equipment is only operated by authorized personnel. Instructions on the use and maintenance of laboratory equipment is kept up to date and available via QSR's computer system (ref. QSD, Lab Pro's., Cal. Program, PM Program).

5.5.4 Gages, measuring and test equipment are labeled with a calibration sticker that identifies the date of the last calibration, the due date for the next calibration and the initials of the personnel responsible for such activities. Intermediate checks are performed in house per the calibration control procedure.

5.5.5 Records for measuring, test and operational equipment are maintained per the respective procedures: *Calibration Control, procedure DL-11-001-P, Preventative Maintenance System, procedure MT-09-003-P and Laboratory Equipment Validation, procedure ML-11-006-P. Equipment validation records are maintained in the equipment files located in the laboratory. Records include the following information:*

- Equipment identity;
- Manufacturer's name, type, and serial number or other unique identification;
- Equipment validation;
- Date received and date placed in service;
- Current location;
- Condition when received (e.g. new, used, reconditioned);
- Manufacturer's instructions, where available;
- Dates and results of calibrations and/or verifications and date of the next calibration and/or verification;
- Details of maintenance carried out to date and planned for the future;
- History of any damage, malfunction, modification or repair;

5.5.7 Equipment that has been damaged, overloaded, shown by verification or otherwise found to be producing suspect or defective results is removed from service. Equipment removed from service is identified as such to prevent equipment from being used. Before reintroducing equipment following a repair, the performance and calibration is evaluated to ensure proper performance. Defective equipment activities are evaluated for any affect the equipment may have had on previously reported test results.

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Appropriate action is taken in accordance with the *Test Reporting, procedure ML-16-001-P and Calibration Control, procedure DL-11-001-P.*

## 5.6 MEASUREMENT TRACEABILITY AND CALIBRATION:

5.6.1 All measuring and test equipment having an effect on the accuracy or validity of tests are calibrated and/or otherwise verified prior to being placed into service. Confirmations, using a positive recall system, are performed at prescribed intervals to ensure the capability of the equipment. Calibration certificates and reports, wherever applicable, provide traceability to National Standards (NIST) and contain the "as found" condition of the instruments, measurement results and the associated uncertainties (ref.: *QSR's "Gage Program" and the Calibration Control, procedure, DL-11-0001-P.*)

5.6.2 Where traceability to a National Standard of measurement is not applicable other evidence is used to satisfactorily correlate evidence such as:

- Proficiency testing or inter laboratory comparisons;
- Internationally accepted standard in the field concerned;
- Suitable reference materials;
- Ratio or reciprocity-type measurements;
- Mutual consent standards (clearly specified and agreed to by all parties).

5.6.3 The Calibration Control Program provides for the calibration and verification of reference standards. The reference standards are calibrated by a National Standards Laboratory that ensures traceability to the primary standard at NIST. The Dimensional Laboratory maintains the integrity of the standards.

5.6.4 Select standards and measuring equipment requiring service checks between calibrations to monitor for unacceptable drift are identified in the gage program and specific instructions provided via *Laboratory Procedures* or *Gage Instructions*. Required checks are scheduled and the results recorded (ref.: *Calibration Control, procedure, DL-11-001-P.*)

5.6.5 Reference materials are not applicable to any testing performed at QSR. Policy will be established if reference materials become a specified or contractual requirement for a testing procedure.

## 5.7 SAMPLING, HANDLING AND STORAGE OF TEST ITEMS:

5.7.1 Quality Synthetic rubber's laboratory does not perform testing on a contract basis. Testing is performed on Quality Synthetic rubber materials for Quality Synthetic rubber to supply to the customers it fabricates products for, therefore we do not receive samples/test items from customers for testing.

5.7.2 The following documents and procedures have been established and shall be used in the determination of test item sampling, identification,

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handling, protection and storage requirements to ensure the validity of testing being performed by Quality Synthetic's laboratory:

- Compound Evaluation, form ML-02-003-F
- ASTM procedures.
- Laboratory "Test Procedures" (LP-procedures);
- Material Development, procedure ML-02-001-P
- Identification and Traceability, procedure MG-08-001-P
- Receiving Inspection, procedure QA-10-001-P
- In-Process Material Testing, procedure ML-10-002-P
- Environmental Control of the Materials Laboratory, procedure ML-11-004-P

5.7.3 ASTM procedures will be followed for the determination of sampling, handling and storage requirements for all testing reflected in our "Scope of Accreditation" that is performed for submittal to QSR's customers. When customers require deviations, additions or exclusions from documented sampling procedure, these shall be recorded in detail on test reports and shall be communicated to the appropriate personnel.

5.7.4 When Laboratory testing is complete, any remaining sample material is identified, stored and then disposed of in accordance with applicable government and environmental regulations.

5.7.5 Where test items need to be stored or conditioned under specific environmental conditions, the conditions are maintained, monitored and recorded. Security arrangements are followed as required to protect the condition and integrity of secured items.

5.7.6 Test items are examined by the Laboratory prior to testing to ensure that the test item has received all necessary preparation. Abnormalities or departures from normal conditions are logged in the comments section of the laboratories "Incoming Sample Log". Unacceptable or questionable test items are disposed of and replacement samples are obtained.

## 5.8 ASSURING THE QUALITY OF TESTS:

5.8.1 In addition to periodic audits the Material Laboratory implements Checks to ensure the quality of results provided to customers (ref.: Test Quality Monitoring Matrix form ML-10-013-F). Checks include as appropriate the items listed, but are not limited to the following list:

- Statistical techniques (ref.: *Laboratory Statistical Process Control, procedure ML-20-001-P; Gage Evaluation, procedure DL-11-002-P; and Statistical Process Control, procedure QA-20-001-P*);
- Inter-laboratory comparisons (ref.: *Laboratory Proficiency Testing, procedure ML-11-002-P*);

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- Regular use of certified reference materials and/or in-house quality Control using secondary reference materials;
- Replicate testing using the same or different methods;
- Re-testing of retained items;
- Correlation of results for different characteristics of an item;

5.8.2 Assuring the quality of testing performed is an ongoing process and is monitored and reviewed as a part of the management review process (ref. *Management Review, section 4.14*).

## 5.9 REPORTING OF RESULTS:

5.9.1 Material test results are reported accurately, clearly, unambiguously and objectively. Test data sent to the customer is handled in accordance with the *Test Reporting, procedure, ML-16-001-P*. Test data for QSR's process control is handled per procedures *In-Process Material Testing, procedure ML-10-002-P* and *Receiving Inspection, procedure QA-10-001-P*. The test reports include or reference all the information necessary for the interpretation of the test results. Customers will be notified in writing of any event that casts doubt onto the validity of results given in any test report or test report amendment.

5.9.2 Any amendments to a test report after issue shall be made only in the form of a further document. Amendments must contain the statement "Supplement to Test Report Serial No. 12345678..." with the serial number of the test report that is being supplemented. Clear differentiation between the two reports is made so that there is no mistake as to which report contains the correct results. Amendments will meet all the requirements of ISO/IEC 17025.

5.9.3 When the testing is not within QSR's scope of accreditation, the testing will be performed by an outside Laboratory. QSR ensures that testing service suppliers are competent to perform the testing and meet the requirements of ISO/IEC 17025. Testing service suppliers are selected based on historical data, scope of accreditation and an evaluation of the supplier. Records are maintained of the evaluations and data. A list of Approved Vendors is maintained which includes approved Laboratories (ref.: *Vendor Review, procedure PR-06-002-P*). Test results performed by out-side laboratories are not reported on QSR's test reports. The full supplier test report is submitted to the customer.

## 5.10 A2LA POLICIES

5.10.1 Quality Synthetic Rubber, Inc. will do everything in it's power to assure compliance with the requirements of A2LA's advisory policy

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"Laboratory Reference to A2LA Accreditation Stature". Procedures have been establish and shall be followed by all employees involved, in the use of the A2LA logo, or the presentation of our accreditation status, to assure that it is always presented in a manner that does not imply accreditation in areas out side our "Scope of Accreditation". If Quality Synthetic Rubber's A2LA accreditation should be discontinued or otherwise suspended the use of the "A2LA" logo and other references to A2LA accreditation will be discontinued (ref.: *Use of A2LA Logo and Accreditation Status, Procedure ML-05-002-P*).

5.10.2 The A2LA document "A2LA Policy on Measurement Traceability" shall be followed to assure that the laboratory applies sound principals in the application of measurement traceability. Procedures have been established and will be followed to assure consistent practices in the application of measurement traceability principals as they relate to the equipment and calibrations associated with the tests reflected in our "Scope of Accreditation" (ref, *Measurement Traceability, Technical Department Requirements, Procedure ML-11-008-P*).

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