SOUTHWEST RESEARCH INSTITUTE®

QUALITY SYSTEM MANUAL

July 2015

Revision 5

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1.0 PURPOSE

This Southwest Research Institute® (SwRI® or Institute) Quality System Manual (QSM) provides a foundation for implementation of the quality management system (QMS) at the Institute per SwRI's Operating Policy and Procedure (OPP) 10.1.1, *Quality Management System*.

The QSM supports SwRI's mission;

> *"Benefiting government, industry and the public through innovative science and technology."*

This manual serves as a general description of the top level processes of the Institute's QMS. It also provides a basis for a QMS within the Institute's cost centers. Cost centers consist of technical divisions (divisions) and administrative & general (A&G) groups.

Individual cost centers maintain the specific requirements within their documented quality system to address the various quality standards that are currently in use at the Institute:

- ISO 9001
- ISO 17025
- AS 9100
- ISO 13485
- ISO 17020
- API Q1
- GMP
- GLP
- NELAC
- CMMI
- 10 CFR 50, Appendix B
- ASME NQA-1

As changes are made to the above standards, this manual shall be reviewed and any necessary changes made.

2.0 SCOPE

This QSM provides a general description of the quality management process that is applied at the Institute. It also provides quality management policies and defines responsibilities for the implementation, maintenance and management of a QMS.

This QSM defines the SwRI mission, quality policy, quality objectives and system process requirements for basic quality related processes, such as the following:

- resource management;
- customer-related processes;
- work environment;
- customer communication;
- product realization;
- purchasing; and
- measurement, analysis and improvement.

Within the divisions or A&G groups, permissible exclusions to the QMS are limited to those requirements within the applicable standard that the cost center is addressing for their QMS. Such exclusions shall not affect the division's or A&G group's ability, or responsibility, to provide product that meets customer and applicable regulatory requirements.

Divisions or A&G groups within the Institute may use this QSM to develop operating procedures and instructions, or they may develop a specific quality manual that defines their QMS in relation to the applicable standard to be addressed. Specific quality manuals shall be based upon, and not be in conflict with, the contents of this QSM.

3.0 TERMS AND DEFINITIONS

A&G: Groups within the Institute providing administrative and general support; there are six (6) A&G groups which are then further divided into specific functions. A&G groups include:

- CFO and Vice President – Finance (Treasurer);
- Human Resources (HR);
- Legal;
- Operations;
- Facilities/Services; and
- Environmental, Safety and Quality Systems (ESQ)

Client/ Customer: Person or entity receiving a product from an organization

Division: The ten (10) technical divisions within the Institute, consisting of:

- Chemistry & Chemical Engineering, Division 01;
- Engine, Emissions & Vehicle Research, Division 03;
- Fuels & Lubricants Research, Division 08;
- Automation & Data Systems, Division 10;
- Applied Power, Division 11;
- Applied Physics, Division 14;
- Space Science & Engineering, Division 15;
- Signal Exploitation & Geolocation, Division 16;
- Mechanical Engineering, Division 18; and
- Geosciences & Engineering, Division 20

Executive Management: The highest level of management within an organization (top management)

Institute: Southwest Research Institute

I^2Net: The Southwest Research Institute intranet system

Process: System of activities that uses resources to transform inputs into outputs

Product:	The result of a process; products may include hardware, software, processed material, intellectual property, or a service
Product Realization:	The sequence of processes required to achieve the product
Outsourced Process:	Process needed for the organization's QMS but chosen to be performed by a party external to the organization
Supplier:	Person or entity providing a product/service to the organization
Validation:	Confirmation through the provision of objective evidence that the requirements for a specific intended use or application have been fulfilled
Verification:	Confirmation through testing or surveillance that specified requirements have been fulfilled

4.0 QUALITY MANAGEMENT SYSTEM

4.1 General Requirements

This manual documents the Institute's QMS and required processes. The sequence and interaction of these processes is shown in Appendix A.

The organization and the responsibilities of management are described in Section 5, *Management Responsibility*. An overview of the Institute organization is given in Appendix B for reference only. The most current organization chart can be located through the SwRI I^2Net.

The process of identifying and obtaining the resources necessary to support Institute operations is contained in Section 6, *Resource Management*.

The processes used to fulfill the goals and objectives of the Institute are identified in Section 7, *Product Realization*.

The systems and procedures used to measure, monitor and analyze the Institute's processes, as well as to implement appropriate actions necessary to achieve planned results and continually improve these processes, are described in Section 8, *Measurement, Analysis and Improvement*.

Where any division or A&G group chooses to outsource any process that could affect product conformity with requirements, they shall ensure control over such processes. The type and extent of control to be applied to these out-sourced processes shall be defined in the division's or A&G group's QMS or other appropriate documentation.

4.2 Documentation Requirements

4.2.1 General

This QSM contains the Institute's quality policy and quality objectives. Additional procedures, as appropriate, shall be identified and documented within each division or A&G group.

The quality system documentation and quality records required by this manual shall ensure effective planning, operation and control of the Institute's processes. The Institute ensures that employees have access to QMS documentation and are made aware of relevant procedures in accordance with management responsibility, authority and communication.

4.2.2 Quality Manual

This document has been established as the Institute-level QSM. Divisions and A&G groups may maintain lower-tier QMS manuals. When these documents are established, they shall contain the detail necessary to address the requirements of the applicable quality standard.

The quality policy and requirements in this QSM supersede the lower-tier manuals should there be conflict in content.

Division and A&G group-specific quality management systems are detailed on the I^2Net.

4.2.3 Control of Documents

Documents required for the QMS shall be controlled. The Institute ensures the review and approval of quality documents prior to use. Divisions and A&G groups shall establish a procedure to define the required controls.

There shall be control over the review, update and re-approval of documents. Any changes and the current revision status shall be identified and only relevant versions shall be available for use. Documents shall be available electronically or in printed form to ensure legibility, ready identification, and accessibility to applicable staff.

If any documents of external origin are used, they shall be identified and their distribution controlled. Obsolete documents shall be suitably identified if retained for any purpose and controls shall be in place to prevent the unintended use of obsolete documents.

4.2.4 Control of Records

Records required for the QMS shall be controlled within each division and A&G group and shall remain legible, readily identifiable and retrievable. Such records shall be maintained to provide evidence of conformance to requirements and of effective operation of the QMS. A documented

procedure shall be established for the identification, storage, retrieval, protection, retention time and disposition of records.

Unless otherwise documented, record retention and disposal for divisions and A&G groups are controlled in accordance with the Institute Operating Policy and Procedure (OPP) 4.2.1, *Record Retention and Disposal*.

5.0 MANAGEMENT RESPONSIBILITY

5.1 Management Commitment

Management provides evidence of its commitment to the QMS through the following;

a) the Institute's quality policy;
b) ensuring clear channels of responsibility, authority and communication;
c) QMS; and
d) conducting management reviews of the QMS.

The executive management of the Institute shall ensure there is

a) communication to the organization on the importance of meeting customer, statutory and regulatory requirements; and
b) adequate resource availability to fulfill customer, regulatory and statutory requirements.

5.2 Customer Focus

At an Institute level, customer requirements are determined via the contract review process. Individual procedures may be developed within divisions and A&G groups to address specific division actions with customers.

In addition, contractually required deliverables for government, government sub-contracts, internal research, development projects and deliverables required by Institute management are tracked through SwRITracker. SwRITracker may also be used for commercial projects at the request of the division.

5.3 Quality Policy

The SwRI quality policy is posted on the Institute's external website and available to our clients. The policy is:

> "SwRI® strives to provide clients with creative and efficient research, engineering, and testing services at a reasonable cost and in a manner that reflects high professional and ethical standards. Our operations and products shall conform to contractual, statutory, and regulatory requirements and meet or exceed customer expectations."

Each staff member is expected to understand and to perform quality-related work in accordance with the documented procedures and instructions or take formal actions to amend the procedures or instructions prior to commencing work.

Personnel at all levels are expected to

a) identify quality problems and adverse trends;
b) initiate, recommend, or provide solutions; and

c) facilitate the implementation of corrective and preventive measures.

The priority of each staff member is the attainment of quality through personal development, continual improvement, and the use of efficient processes that satisfy customer expectations. Continual improvement shall be accomplished through setting quality system objectives and measuring performance toward those objectives.

Divisions, departments, A&G groups, or project teams may have individual quality policies that are specific for their purpose. Individual quality policies shall include a commitment to comply with the requirements and continually improve the QMS. The quality policy shall be communicated and understood by all relevant parties within the organization. The quality policy provides a framework for establishing and reviewing quality objectives and shall be reviewed for continuing suitability.

Metrics shall be established to monitor quality policy implementation and effectiveness. These may include but not limited to:

a) contract performance;
b) financial performance;
c) client quality awards;
d) client survey results;
e) product performance;
f) technical society participation/recognition;
g) personnel or product awards;
h) patent awards;
i) process capability and efficiency; and
j) error/uncertainty analyses.

5.4 Planning

5.4.1 Quality Objectives

Divisions and A&G groups shall establish quality objectives. The objectives shall be appropriate to the work performed by the division or A&G group and shall be measurable and consistent with the defined quality policy.

5.4.2 Quality Management System Planning

QMS planning is performed in conjunction with the Institute's Advisory Committee for Quality Improvement (ACQI). This group is responsible for

a) advising and informing executive management on the quality management program to support business operations;
b) recommending best practices that provide for efficient, effective and continually improved quality management;
c) promoting systematic approaches to quality management processes; and

d) advising executive management on future trends in quality management.

5.5 Responsibility, Authority and Communication

5.5.1 Responsibility and Authority

The Institute-level organization chart is provided in Appendix B.

Vice presidents are responsible for areas of business as defined on the Institute-level organization chart. Each division and A&G group shall maintain organization charts for all levels and areas within their responsibility. Current organization charts are posted on the I^{2}Net to ensure communication of responsibility and authority assignments.

5.5.2 Management Representative

At the Institute level, the director of Institute Quality Systems (IQS) shall serve as the management representative.

Vice presidents and executive management of divisions and A&G groups shall appoint a management representative for their QMS as appropriate. The management representatives are typically members of the ACQI.

5.5.3 Internal Communication

The president of the Institute shall ensure appropriate communication processes are established between the various levels, divisions and functions within the Institute and that communication takes place regarding the effectiveness of the QMS.

Several communication methods may be used; including, but not limited to, the following:

- meetings
- e-mails
- newsletters
- I^{2}Net

5.6 Management Review

5.6.1 General

The QMS shall be reviewed annually by top management to ensure its continuing suitability, adequacy and effectiveness. The review shall include assessing opportunities for improvement and the need for changes to the organization's QMS, including quality policy and quality objectives.

The Institute-level review is performed by the ACQI and executive management. The agenda for this meeting contains the following:

1. ACQI committee activities may include but not be limited to:
   - summary report on status of quality programs;
   - summary report on improvement methodologies for efficient and effective quality management; and
   - performance metrics of the quality program.
2. ACQI committee quality management objectives, including:
   - review of current ACQI committee quality management objectives and their status; and
   - establishment of ACQI committee quality management objectives for the next year.

Following the review meeting, an annual report shall be prepared by the ACQI and distributed to the Institute president.

In addition, reviews of division and A&G group QMS's are periodically performed and reported to the responsible vice president.

5.6.2 Review Input

Inputs to management review shall include information related to the following:

a) results of audits;
b) customer feedback;
c) process performance and product conformity;
d) status of preventive and corrective actions;
e) follow-up actions from earlier management reviews;
f) legal and other standard requirements affecting the QMS; and
g) recommendations for improvement.

Additional inputs as required by the various quality standards shall also be included as defined in the cost center's QMS.

5.6.3 Review Output

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

a) improvement of the effectiveness of the QMS and its processes;
b) improvement of product related to customer requirements; and
c) resource needs.

Additional outputs as required by the various quality standards shall also be included as defined in the cost center's QMS.

6.0 RESOURCE MANAGEMENT

6.1 Provision of Resources

The Institute shall determine and provide the necessary resources to:

a) implement and maintain the QMS and continually improve its effectiveness, and
b) enhance customer satisfaction by meeting customer requirements.

Product realization resource requirements are determined by project managers and are submitted to management via the Institute forms, PC-5, *Contract Action Form* and PC-2, *Project Cost Estimate Worksheet*.

6.2 Human Resources

6.2.1 General

The Institute ensures that personnel performing work affecting conformity to product requirements are competent on the basis of appropriate education, training, skills and experience. Records are maintained by the Human Resources Department demonstrating initial competence for previous employment and relevant experience. Job requirements for each position at the Institute are documented in the SwRI Career Ladders and Job Guidelines available on the I^2Net.

6.2.2 Competence, Training and Awareness

Evidence of job specific competence is maintained by the division or A&G group and management is responsible for identifying training requirements for employees. Employees are responsible for completing the required training and providing objective evidence of completion.

The Employee Development Office (EDO) maintains Institute training courses and records of completion, both online and classroom based. Specific job-related training may be maintained by the divisions and A&G groups.

6.3 Infrastructure

Infrastructure includes the buildings, workspace, associated utilities, process equipment (hardware and software) and supporting services such as transportation and communications.

The infrastructure requirements for the Institute are determined by the divisions and A&G groups. These requirements are approved by top Institute management. Several support functions on site are responsible for providing and maintaining the required infrastructure, these functions include, but are not limited to the following:

- Facilities/Services;
- Environmental, Safety and Quality Systems;
- Human Resources;

- Legal;
- Operations; and
- Financial.

6.4 Work Environment

The Institute determines and manages the work environment needed to achieve conformity to product requirements. Specific requirements are identified and maintained by divisions and A&G groups.

In addition, as part of the Institute's commitment to providing a healthy and safe work environment, it supports the Environmental and Safety Systems (ESS) department certified to ISO 14001, a medical facility and safety points of contact throughout the Institute. The Safety Policies and Procedures Manual, environmental policy and objectives are maintained on the I^{2}Net.

7.0 PRODUCT REALIZATION

An outline of the product realization process is given in Appendix A. When applicable, per contract or regulatory requirement, the customer shall be afforded the right to witness and/or approve any process described in the following sections.

7.1 Planning of Product Realization

Planning of product realization begins with proposals and contract bids that are prepared by the divisions and coordinated through the Central Proposal Office (CPO). This process is documented and approved through the use of form PC-7, *Proposal Brief/COI & Business Risk Review*. Records of this process are retained and, except where the proposal contains classified information, the records are posted on the I^{2}Net.

Following the award of a contract and in accordance with Institute, customer, regulatory and statutory requirements, the program/project manager and contracts department determine the following:

a) the need to establish processes, documents and provide resources specific to the product;
b) the required verification, validation, monitoring, inspection and test activities specific to the product; and
c) the identification of resources necessary to support operation and maintenance of the product.

These requirements are documented on Institute form PC-5, *Contract Action Form* and, where required, may be further described in a quality plan specific to the product. These records provide evidence that the realization processes and resulting product will meet requirements.

PC-7 and PC-5 forms are controlled, documented and retained electronically through the FDS Forms Manager application.

7.2 Customer-Related Processes

7.2.1 Determination of Requirements Related to the Product

Determination of requirements related to the product shall be accomplished through the contract review process. The Contracts department, in conjunction with the division and other A&G groups, considers the following requirements:

a) those specified by the customer, including delivery and post-delivery activities which may include warranty provisions, maintenance services or contractual obligations;
b) if known, those not specified by the customer but necessary for the specified or intended use;
c) statutory and regulatory requirements related to the product; and
d) additional requirements determined by the Institute.

7.2.2 Review of Requirements Related to the Product

The initial review process of requirements related to the product shall be performed via the Central Proposal Office. This review shall be conducted prior to submission of a proposal to a customer. This involves liaison between the division and A&G groups, as shown in Appendix A and described in Section 7.1. This process ensures there is no conflict of interest in submitting the proposal and that the organization has the ability to meet the defined requirements.

Further review shall occur at the contract phase where the Contracts department ensures that product requirements are defined and any requirement differences are resolved prior to contract approval. Any subsequent changes to product requirements shall be subject to an equivalent review and approval.

The proposal and contract review processes are controlled and documented on forms PC-7, *Proposal Brief/COI & Business Risk Review* and PC-5, *Contract Action Form*.

7.2.3 Customer Communication

Institute product information is available through press releases, promotional materials, on the Internet and via Institute publications such as Technology Today.

The Institute has a system for handling customer inquiries to ensure they are directed to the most appropriate area. Initial inquiries are directed through the Business Development Office or alternatively through contact information posted on the Institute's Internet site (www.swri.org).

Divisions and A&G groups are responsible for identifying and implementing effective arrangements for communicating with customers

including: customer inquiries, product information and customer feedback, including customer complaints.

7.3 Design and Development

7.3.1 Design and Development Planning

Design and development planning shall be performed by the divisions. To ensure that customer requirements are satisfied, the project managers plan and control the design and development of product.

The stages of design and development and results of progress are monitored through program status reports filed periodically. The review, verification and validation stages appropriate to the design and development are determined during the initiation of the project. Where appropriate, additional requirements and/or internal controls will be documented and approved in a project quality plan. The responsibilities, authorities and approvals of various groups are contained in or attachments to the Institute form PC-5, *Contract Action Form*.

7.3.2 Design and Development Inputs

Inputs relating to product requirements shall be determined by the divisions and records shall be maintained.

Inputs may include, but are not limited to the following:

a) project quality plans;
b) manufacturing process sheets;
c) requirements specifications;
d) project/program plans;
e) project/program deliverables;
f) statutory and regulatory requirements, where applicable; and
g) review of related research and literature review.

7.3.3 Design and Development Outputs

Outputs of design and development, such as drawings and product specifications, shall be provided by the divisions in a form that enables verification against the design and development input and shall be approved prior to release.

Divisions shall ensure the design and development outputs

a) meet the design and development input requirements;
b) provide appropriate information for purchasing, production and service operations;
c) contain or reference product acceptance criteria;
d) specify the characteristics of the product that are essential to its safe and proper use; and
e) meet startory/regulatory requirements for engineering design.

7.3.4 Design and Development Review

At suitable stages, the divisions shall conduct systematic reviews of design and development in accordance with planned arrangements to

a) evaluate the ability of the results of design and development to fulfill requirements; and
b) identify any problems and propose necessary actions.

Participants in such reviews shall include representatives of functions concerned with the design and development stage(s) being reviewed. Records of the results of the reviews and any necessary actions shall be maintained by the divisions.

7.3.5 Design and Development Verification

Design and development verification shall be performed in accordance with planned arrangements to ensure that the outputs meet the design and development input requirements. Records of the results of the verification and any necessary actions shall be maintained by the divisions as quality records.

7.3.6 Design and Development Validation

Design and development validation shall be performed in accordance with planned arrangements to ensure that the resulting product is capable of meeting the requirements for the specified application or intended use where known. Wherever practicable, validation shall be completed prior to delivery or implementation of the product.

Records of the results of the validation and any necessary actions shall be maintained by the divisions as quality records.

7.3.7 Control of Design and Development Changes

Design and development changes shall be identified and records maintained by the divisions. The changes shall be reviewed, verified and validated as appropriate and approved before implementation. The review shall include evaluation of the effect of the changes on constituent parts and delivered products.

Records of the results of the review of changes and any necessary actions shall be maintained by the divisions.

7.4 Purchasing

7.4.1 Purchasing Process

Purchasing of product for the Institute is centralized through the purchasing support function. This process is controlled through the Purchasing Department Quality System Manual. The purchasing group ensures purchased products meet specified requirements.

The Purchasing department acts on behalf of the Institute in activities related to the following:

a) source selections;
b) commitments to a supplier;
c) procurement negotiation;
d) delivery and expediting; and
e) record maintenance.

In addition, the Institute maintains an approved supplier list (ASL) for the purchase of all quality, environmental and safety critical supplies/services. The ASL is maintained by IQS on behalf of the divisions and other A&G groups and is made available to all staff via the I^{2}Net. Additional controls, when required by quality system specifications, are implemented by the applicable division.

A Counterfeit/Fraudulent Items mitigation program is in place at the Institute to prevent counterfeit or fraudulent parts, components or materials being acquired and used. Details regarding this program are contained in Appendix C.

7.4.2 Purchasing Information

Information relating to purchasing decisions is controlled and maintained by the purchasing department as described in the Purchasing Policies and Procedures Manual.

The Institute identifies commonly used quality requirements through the use of standard quality clauses known as ‘Q-Codes.’ The Q-Codes are posted on the I^{2}Net and are used by divisions and A&G groups to notify purchasing of any special requirements for critical purchases.

7.4.3 Verification of Purchased Product

Verification of purchased product may be performed at a number of levels. Initial verification is performed upon receipt by the Shipping and Receiving department, in accordance with their procedures. The division or A&G group ensures the purchased product meets the specified purchase requirements and that any required certificates of compliance have been received.

As required by contract or quality plan, additional inspection is performed by IQS to verify the purchased product conforms to specified requirements.

Where verification is to be performed on the supplier’s premises, information regarding verification arrangements and method of product release shall be included in the purchasing information.

7.5 Production and Service Provision

7.5.1 Control of Production and Service Provision

The SwRI divisions or A&G groups, as applicable, shall plan and carry out production and service provision under controlled conditions. Controlled conditions shall include, as applicable, the following:

a) the availability of information that specifies the characteristics of the product;
b) where necessary, the availability of procedures and/or work instructions;
c) the use of suitable equipment;
d) the availability and use of monitoring and measuring equipment;
e) the implementation of monitoring and measuring; and
f) the implementation of product release, delivery and post-delivery activities.

7.5.2 Validation of Processes for Production and Service Provision

The SwRI divisions or A&G groups, as applicable, shall validate any product and service processes where the resulting output cannot be verified by subsequent measurement or monitoring and, as a consequence, deficiencies become apparent only after the product is in use or the service has been delivered.

Validation shall demonstrate the ability of these processes to achieve planned results.

The divisions shall establish arrangements for these processes including, as applicable, the following:

a) defined criteria for review and approval of the processes;
b) approval of equipment and qualification of personnel;
c) use of specific methods and procedures;
d) requirements for records; and
e) re-validation.

7.5.3 Identification and Traceability

Each division or A&G group, as applicable, shall identify the product through suitable means throughout product realization. The status of product with respect to monitoring and measurement requirements shall be identified. Where traceability is a requirement, the division or A&G group shall control the unique identification of the product and maintain records.

7.5.4 Customer Property

The Institute divisions, as applicable, shall exercise care with customer property while such property is under the division's control or being used by the division. Each division or A&G group is responsible for identification, verification, protection and safeguarding of customer property. If any property is lost, damaged or otherwise found to be unsuitable for use, the Institute shall report the matter to the customer and maintain records. Guidance for the protection of intellectual property and personal data is contained within the SwRI compliance manual and OPPs.

Specific requirements exist for the control of government property. These are addressed in operating policy and procedure, OPP 4.1.1, *Government Property Administration*.

7.5.5 Preservation of Product

The divisions shall preserve the product during internal processing and delivery to the intended destination in order to maintain conformity to requirements. This preservation shall include identification, handling, packaging, storage and protection. Preservation shall also apply to the constituent parts of a product.

7.6 Control of Monitoring and Measuring Equipment

Monitoring and measurement equipment are identified and controlled to provide evidence of conformity of product to determined requirements. The ability of computer software to satisfy the intended application, when used in monitoring and measurement of specified requirements, shall be confirmed, verified, and under configuration control.

Calibrated equipment is controlled and maintained through Institute divisions. The Institute Calibration Laboratory provides calibration services to the Institute divisions and is accredited to ISO 17025, *General requirements for the competence of testing and calibration laboratories*.

8.0 MEASUREMENT, ANALYSIS AND IMPROVEMENT

8.1 General

The Institute shall continually monitor the effectiveness of the service provided and conformity to product requirements. The Institute shall strive to improve service and product conformity whenever practicable.

8.2 Measuring and Monitoring

8.2.1 Customer Satisfaction

The Institute shall monitor information relating to customer perception as to whether the Institute has met customer requirements. The methods for obtaining and using this information shall be determined by the divisions.

8.2.2 Internal Audit

Internal audits of SwRI divisions and A&G groups shall be conducted at planned intervals to determine whether the QMS

a) conforms to the planned arrangements (see 7.1);
b) conforms to the requirements of this manual and to the quality management requirements established by the division or A&G group; and
c) is effectively implemented and maintained.

Internal audits shall be conducted in accordance with IQS-OP-822, *Audit and Surveillance Program Management*. An annual internal audit schedule is prepared, updated regularly and is available for review on the I²Net.

8.2.3 Monitoring and Measurement of Processes

The Institute monitors, measures and analyzes its quality processes through the Institute Quality System and in accordance with operating policy and procedure, OPP 10.1.1, *Quality Management System*. Corrective and preventive actions and their effectiveness may be tracked through the Institute quality reporting system (QRS) program. The status of corrective and preventive actions is reviewed within the division or A&G group.

8.2.4 Monitoring and Measurement of Product

The Institute inspects the characteristics of the product at appropriate stages of product realization to verify product requirements have been met.

Inspection of product is performed by IQS and records are maintained. Inspection is performed according to division procedures or by use of IQS-OP-742, *Purchasing Information and Verification*.

8.3 Control of Nonconforming Product

The organization shall ensure that product that does not conform to product requirements is identified and controlled to prevent unintended use or delivery. Nonconforming product is controlled through procedures specific to the division or by IQS procedure, IQS-OP-830, *Nonconformance Process*.

8.4 Analysis of Data

The ACQI, on behalf of the Institute, shall determine, collect and analyze appropriate data to demonstrate the suitability and effectiveness of the QMS and evaluate where continual improvements of the QMS can be made.

The Institute shall analyze the data to provide information on

a) customer satisfaction;

b) conformance to product requirements;
c) characteristics and trends of processes and product including opportunities for preventive action; and
d) supplier performance; and
e) audit, product, process or system nonconformities.

8.5 Improvement

8.5.1 Continual Improvement

The Institute shall continually improve the effectiveness of the QMS through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive action, and management review. Continual improvement is also effected and documented through the ACQI.

8.5.2 Corrective Action

SwRI shall take corrective action to eliminate the cause of nonconformities in order to prevent recurrence.

The QRS may be used to document and obtain appropriate approvals for corrective action, in accordance with IQS procedure, IQS-OP-850, *Corrective and Preventive Action Process*. Alternatively, divisions and A&G groups may develop an appropriate controlling procedure for their use of QRS or alternate problem tracking system.

For any system that is used, the division or A&G group shall define requirements for

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

8.5.3 Preventive Action

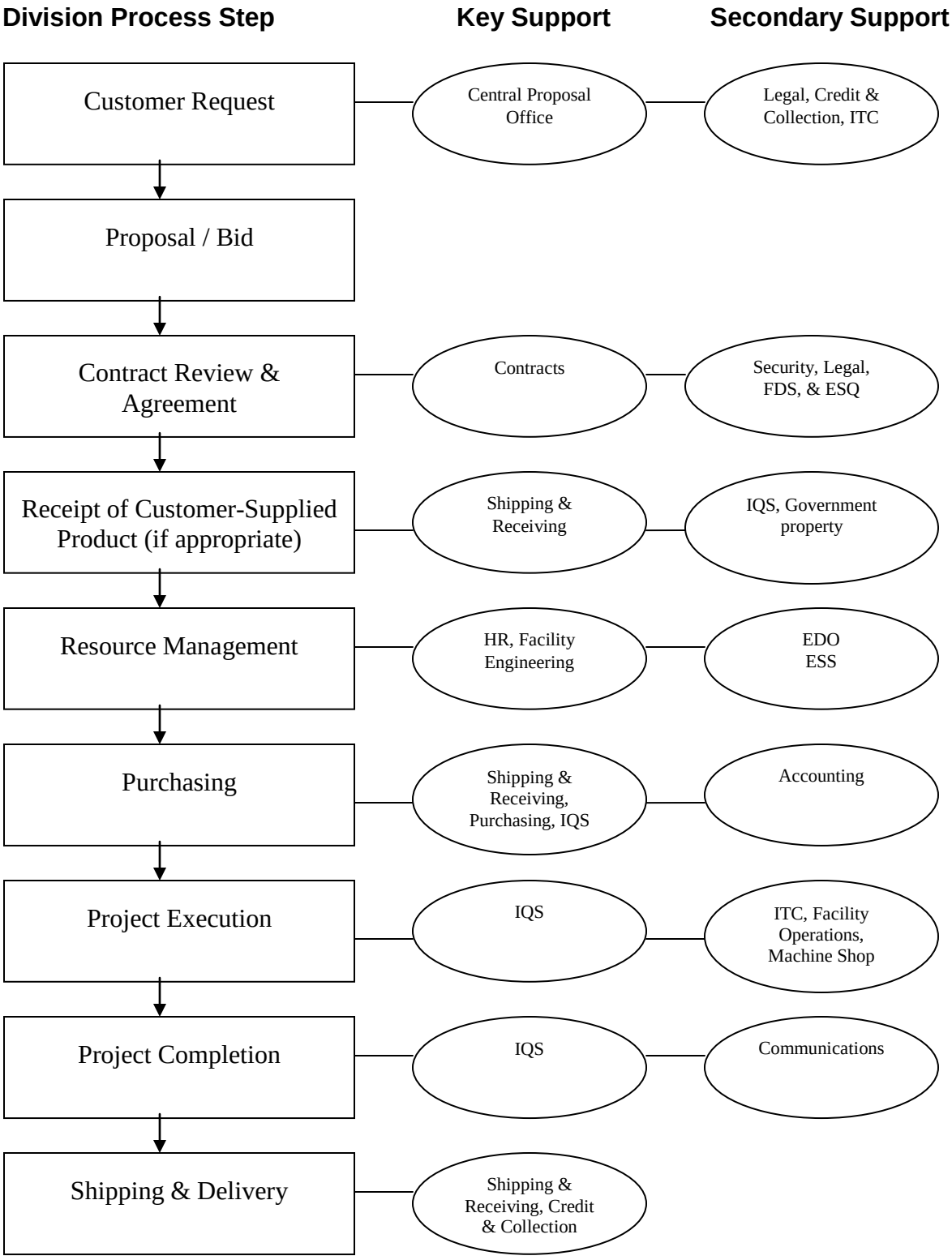
The divisions or A&G groups, as applicable, shall determine action to eliminate the causes of potential nonconformities in order to prevent occurrence.

The QRS may be used to document and obtain appropriate approvals for preventive action in accordance with IQS procedure, IQS-OP-850, *Corrective and Preventive Action Process*. Divisions and A&G groups may develop an appropriate controlling procedure for their use of QRS.

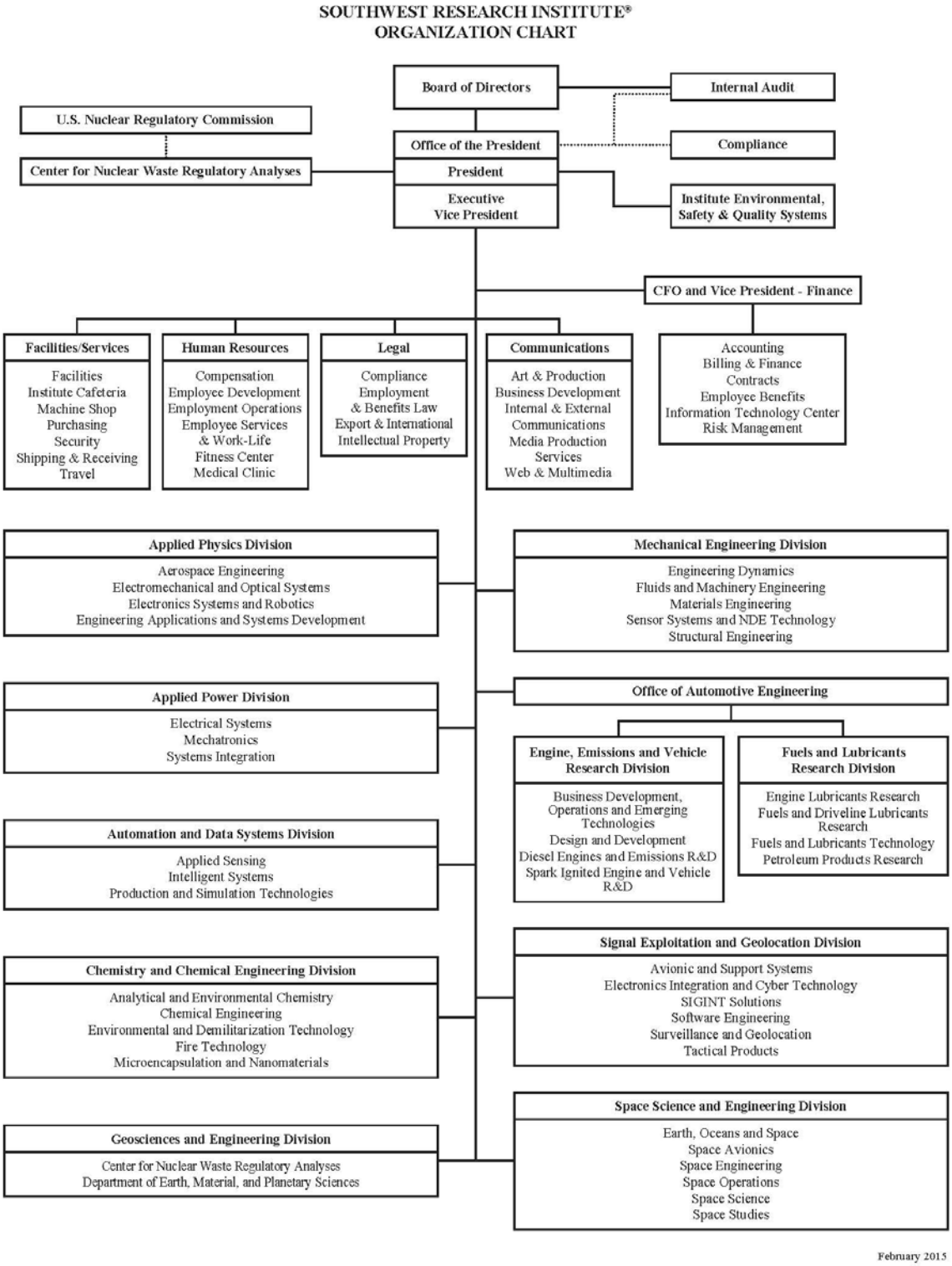
For any system that is used, the division or A&G group shall define requirements for

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

APPENDIX A: REALIZATION PROCESS – INTERACTION OF DIVISION AND A&G GROUPS



APPENDIX B: SWRI ORGANIZATION CHART (FOR REFERENCE ONLY)



APPENDIX C: SWRI COUNTERFEIT/FRAUDULENT ITEMS (CFI) MITIGATION PROGRAM

The purpose of the CFI program at SwRI is to:

- Prevent CFI from being acquired
- To inspect parts, components and materials received by SwRI in order to detect any suspected CFI
- To effectively control suspected CFI to prevent their use, and if determined to be counterfeit or fraudulent to dispose of appropriately
- To provide employee training at appropriate levels to ensure awareness of the program

Prevention

SwRI shall make every effort to procure parts, components and materials from reputable sources using good procurement practices. Orders, when possible, should be placed with the original manufacturer or from an authorized distributor. The approved supplier list (ASL) process in conjunction with the use of QA codes shall be used to mitigate the purchase of CFI.

Detection of CFI

Receiving inspection shall be performed prior to acceptance of critical parts, components or materials. CFI training shall be available for employees performing receipt inspection. If a part, component or any material is suspected to be counterfeit or fraudulent, the items shall be labeled, segregated to prevent unintended use, and management shall be notified.

Control and Disposition of CFI

Items suspected of being counterfeit or fraudulent shall be evaluated. If the items are determined to be counterfeit or fraudulent the nonconforming process should be used to document the issue. Suspected CFIs should not be returned to the supplier or source. Reports regarding CFI may be made to government and/or industry groups as appropriate.

Training

Web based training shall be available through the Employee Development Office. Training should be undertaken at a level appropriate to the role and function performed by the employee.

- CFI awareness (basic knowledge)
- Inspection (advanced)

Additional Information

Specific activities for employees regarding the CFI mitigation program shall be detailed in Division and Cost Center specific operating procedures and work instructions.

REVISION HISTORY

Revision 4: Remove Appendix C. Update/remove/add A&G groups and technical divisions in section 3.0. Update DMS to SwRITracker. Change ACQEI to ACQI. Added “top” to Institute Management and ESQ to list in section 6.3. Added final sentence in section 7.4.1. Add wording to include divisions or A&G group throughout section 7.5 and in section 8.5.3. Reference OPP section in first paragraph under Purpose. In section 4.1 note that Appendix B is for reference only for organization chart. Add “For Reference Only” on Appendix B. Add last paragraph under section 5.3 regarding metrics. In section 6.2.1 change “job” to “previous employment”. Revise wording regarding the calibration laboratory in the second paragraph in section 7.6. Revise list in section 8.4. Update Quality to IQS and add ESS in Appendix A. Minor word changes throughout document for clarification. In section 5.1, change QSM to QMS.

Revision 5: Remove reference to Division 09, Include reference to counterfeit parts prevention in section 7.4.1. Add details regarding the SwRI Counterfeit/Fraudulent Items (CFI) Mitigation Program as Appendix C.