Quality, Environmental, Health and Safety Manual

Toshiba International Corporation
Social Infrastructure Systems Group
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This document shall be considered “For Reference Only” when printed as a hardcopy. Revision status must be verified prior to use.
Toshiba International Corporation (TIC) Designs, Manufactures, and provides Sales and Service of Industrial Motors, Adjustable Speed Drives, Uninterruptible Power Supplies, Motor Controls, and Distribution Equipment. In addition, we manufacture and sell HEV Motors, sell and support Programmable Logic Controllers (PLC’s), Industrial Plant Systems, Magnetic Flow Meters, and Transportation Equipment.

As Sr. VP and Group President General Manager, I have responsibility for the Quality, Environmental, Health and Safety Management System (QEHS), which is comprised of methods, documents, and people producing products for our Customers. To support the QEHS Management System, we have compiled this QEHS Management System Manual as a tool to provide guidance to our employees and assure our Customers the System we have in place will provide the highest Quality, which meets requirements of ISO 9001:2008, ISO/TS 16949:2009, ISO 14001:2004, OHSAS 18001:2007 and ISO/IEC 17025:2005 UL Client Test Data Program (CTDP).

To ensure our processes and methods meet the needs of our Customers, we have put our concept of what Quality is into our Quality, Environmental, Compliance, and Occupational Health and Safety Policy. It is important everyone here at Toshiba International Corporation work together to meet this Policy, so we have identified measurable Objectives specific to various Departments and Work Centers throughout the Organization to support this Policy.

Additional Procedures, Work Instructions, and Records supplement this QEHS Management System Manual to ensure effective planning, operation, and control of the QEHS Management System. The QEHS Management System is planned to meet requirements of the referenced standards. Changes to the QEHS Management System are planned to maintain its integrity.

As part of the QEHS Management System, we have identified processes needed, how they are sequenced, and how they interact with each other. We have determined criteria and methods needed to ensure both operation and control of these processes are effective.

To ensure they continue to function at the highest level of Quality, Environmental Compliance, and Occupational Health and Safety, we monitor, measure, and analyze these processes, and when necessary, implement actions necessary to achieve planned results. Customer Satisfaction is very important to me, therefore we will ensure Customer Requirements are identified and met. We will collect and analyze Customer Satisfaction data to detect trends, so appropriate improvements can be made to our QEHS Management System.

I will show my commitment to our QEHS Management System by communicating to our employees the importance of meeting Customer, Statutory, Regulatory and Laboratory Requirements, and by approval and support of the Quality, Environmental, Health and Safety Policy and Key Objectives. We will regularly examine the QEHS Management System to evaluate its effectiveness and identify areas for improvement.

It is essential we provide resources and information for these processes so they function at a level necessary to provide our Customers with products of the highest Quality. Responsibilities and authorities are defined and communicated to the Organization. I have appointed members of Management who have responsibility and authority to promote the QEHS Management System. To ensure we have a good process for communication, I have established appropriate methods, including those needed regarding effectiveness of the QEHS Management System.

Kyle Kem
Sr. VP and Group President, General Manager
11/5/15

Date

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1.0 PURPOSE:
This section establishes the Scope of and requirements for the integrated Quality Management System, Environmental Management System, and Occupational Health and Safety Management System (QEHS Management System) in order to demonstrate Toshiba International Corporation's (TICs) ability to consistently provide product and services meeting Customer and applicable Legislative and Regulatory Requirements, and aims to enhance Customer Satisfaction through Continual Improvement. Policies and Objectives are formulated which take into account Legislative Requirements, information regarding Significant Environmental Impacts, and Occupational Health and Safety.

2.0 REFERENCE DOCUMENTS:
2.1 Quality Document Matrix – Doc. No. 2F-421-001
2.2 QEHS Manual, Section 5, QEHS Organizational Responsibilities
2.3 QEHS Manual, Section 6, Management Review
2.4 QEHS Manual, Section 8, Resource Management
2.5 QEHS Manual, Section 15, Monitoring, Measurement, Analysis, Improvement and Evaluation of Compliance
2.6 QEHS Manual, Section 16, Control of Non-conforming Product and Material
2.7 QEHS Manual, Section 17, Analysis of Data
2.8 QEHS Manual, Section 18, Improvement
2.9 QEHS Manual, Section 19.1, Additional Environmental Management System Requirements
2.11 ISO 9001:2008, Clauses 4.1, 4.2, 5.3, 5.4.1 and 6.4
2.12 ISO 14001:2004, Clauses 4.2, 4.3.3, 4.4.1 and 4.4.2
2.13 OHSAS 18001:2007, Clauses 4.2, 4.3, 4.4.1, and 4.4/2
2.14 Strategy Deployment Procedure – Doc. No. 2P-551
2.15 ISO/TS 16949:2009, Clauses 4.1.1, 5.4.1.1, and 7.4
2.16 Quality Management System – Doc. No. 4P-310
2.17 ISO/IEC 17025: 2005, Clause 4.2

3.0 DEFINITIONS:
3.1 See QEHS Manual, Section 21, Glossary (Terms and Definitions) for definitions of italicized terms.
3.2 ISO – International Organization for Standardization
3.3 OHSAS – Occupational Health and Safety Advisory Services
3.4 QEHS – Quality, Environmental, Health and Safety

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3.5 PLC – Programmable Logic Controller

4.0 QEHS MANAGEMENT SYSTEM REQUIREMENTS:

4.1 Scope:

4.1.1 Toshiba International Corporation Designs, Manufactures, and provides Sales and Service of Motors, Adjustable Speed Drives, Uninterruptible Power Supplies, Motor Controls, and Distribution Equipment. Toshiba also manufactures and provides sales on HEV Motors. In addition, Toshiba International Corporation sells and supports Programmable Logic Controllers (PLC’s), Industrial Plant Systems, Magnetic Flow Meters, and Transportation Equipment.

4.1.2 Toshiba International Corporation’s Senior Management has specified requirements for the QEHS Management System in order to demonstrate its:

4.1.2.1 ability to consistently provide product and services meeting Customer and applicable Regulatory Requirements;

4.1.2.2 aim to enhance Customer Satisfaction through effective application of the QEHS Management System, including processes for Continual Improvement of the System and assurance of conformity to Customer and applicable Regulatory Requirements;

4.1.2.3 commitment to reducing the Facility Impact on the Local Environment through pollution prevention activities on-site as well as cooperative initiatives with Local Organizations.

4.1.3 QEHS Policy and Objectives are formulated to comply with Legislative Requirements, and to consider information regarding Significant Environmental Impacts, and Occupational Health and Safety which are in control of Toshiba International Corporation or which Toshiba International Corporation can be expected to have an influence.

4.1.4 The Scope of the QEHS Management System applies to sites owned or controlled by Toshiba International Corporation. These sites include:

4.1.4.1 13131 West Little York Road, Houston, Texas 77041
4.1.4.2 48679 Alpha Drive, Wixom MI 48393
4.1.4.3 Okanella Warehouse:
   4.1.4.3.1 10510 Okanella St. Houston, Texas 77041
   4.1.4.3.2 10435 Okanella St. Houston, Texas 77041
   4.1.4.3.3 6355 Clara Rd, Houston, Texas 77041

4.2 Management System – General:


4.2.2 This established QEHS Management System is maintained by:

4.2.2.1 identifying processes needed for application throughout the Organization;

4.2.2.2 determining the sequence and interaction of these processes;

4.2.2.3 determining criteria and methods needed to ensure both operation and control of these processes are effective;
4.2.2.4 ensuring availability of resources and information necessary to support the operation and monitoring of these processes (Reference 2.4);
4.2.2.5 monitoring, measuring and analyzing these processes (Reference 2.5);
4.2.2.6 implementing actions necessary to achieve planned results and Continual Improvement of these processes (Reference 2.7 and 2.8).

4.3 Toshiba International Corporation Mission Statement:
4.3.1 To be the Leader in Production, Design, and Application of High Quality Competitive Electrical Products and Services. The foundation of Toshiba International Corporation success will be based on teamwork and a commitment to Quality, Environmental Preservation, and Safety.

4.4 Policy:
4.4.1 A policy governing operations at Toshiba International Corporation is communicated and posted.

4.4.1.1 Key QEHS Policy Features:
4.4.1.1.1 A summary of QEHS Management Systems is communicated to employees.

4.5 QEHS Policy Implementation:
4.5.1 Ways in which the QEHS Policy is implemented and maintained include:
4.5.1.1 ensuring the Policy has been implemented and maintained company-wide and all personnel (employees and persons working on our behalf) understand the Policy through training and/or orientation, and by posting the QEHS Policy;
4.5.1.2 providing a framework for establishing and reviewing the QEHS Management System and Environmental Objectives and Targets;
4.5.1.3 QEHS Management System Management Review and QEHS Policy to ensure continued relevance and suitability;
4.5.1.4 Audits of the QEHS Management System;
4.5.1.5 organization, responsibilities, and interfaces of various functions being defined and documented;
4.5.1.6 equipment and facilities being suited for their intended purpose;
4.5.1.7 employees possessing sound skills in their areas of responsibilities and being offered the opportunity for necessary training to ensure they are capable of achieving Quality in the work they perform;
4.5.1.8 all activities being characterized by Quality, Environmental, and Occupational Health and Safety sensitivity as set forth in our QEHS Management System;
4.5.1.9 steps to remedy any existing defects and deficiencies, either internally or externally;
4.5.1.10 appointment of QEHS Management Representatives;
4.5.1.11 commitment to comply with relevant Legislation and Regulations;
4.5.1.12 ensuring availability of the QEHS Policy to interested parties.

4.6 QEHS Management System Objectives and Associated Targets:
4.6.1 It is the responsibility of Toshiba International Corporation, Senior Management to ensure QEHS Objectives, including those needed to meet work related requirements, and in support of the Organizational Objectives are established and documented at relevant levels and functions within operations of Toshiba International Corporation.
These Objectives are measurable and consistent with the QEHS Policy. In establishing these Objectives, the Legal Requirements, Significant Environmental Aspects, Occupational Health and Safety Risks and Hazards, Technological Options, Laboratory Requirements and Financial, Operational, and Business Requirements as well as views of interested parties are considered.

4.6.2 Programs have been established and are maintained for achieving Objectives and Targets, which include the designation of responsibility at each relevant function, and the means and timeframe by which they shall be achieved.

4.6.3 The overall general QEHS Objectives are:


4.6.3.2 serve and respond to needs of our Customers through Continual Improvement of processes;

4.6.3.3 establish and nurture a culture which is focused on Quality, the natural Environment, and the impact of work processes on Occupational Health and Safety;

4.6.3.4 to create and maintain an Environment encouraging teamwork, cooperation, innovative thinking, initiative, leadership, problem solving, decision making, and a commitment to Continual Improvement;

4.6.3.5 to continually review and improve Systems and Procedures;

4.6.3.6 to operate consistent with Environmental, and Occupational Health and Safety Legislation and Regulations;

4.6.3.7 to fulfill stated Objectives relative to selected Significant Environmental Aspects and associated Impacts;

4.6.3.8 to prevent pollution by waste minimization and Reduce/Reuse/Recycle Programs where applicable, and eliminate releases or disposal to the Environment.

4.6.4 In addition, QEHS Objectives, including those needed to meet requirements for product, have been established within relevant levels and functions within Toshiba International Corporation.

4.7 Key Toshiba International Corporation Operation Objectives are:

4.7.1 Quality – Offering the best products and services resulting in superior Customer Satisfaction.

4.7.2 Environment – Promoting and advancing Environmental efforts including the reduction, reuse, recycling, and conservation of natural resources within all possible fiscal and technical capabilities, in activities such as but not limited to: construction, facility and process management, product design, and external operations.

4.7.3 Health and Safety – Providing a safe working Environment, free of recognized hazards, reducing the risk of harm to employees, visitors, properties, and ensuring appropriate controls and contingencies exist to address unforeseen events.

4.7.4 Competency – Providing all employees with necessary training and tools to successfully implement the QEHS Policy and perform their work competently.

4.7.5 Corporate Social Responsibility – Ensuring our actions positively affect, protect, and sustain the communities where we work and live.
5.0 RESPONSIBILITY:

5.1 It is the responsibility of Toshiba International Corporation, Senior Management, to ensure the QEHS Policy is implemented and understood by all employees and to commit resources necessary to establish, implement, maintain, and improve the Quality, Environmental, Health and Safety Management System and Organizational Infrastructure.

5.2 It is the responsibility of Management at all levels of the Organization to establish and communicate the Quality, Environmental, and Occupational Health and Safety Objectives to employees.

5.3 All employees are responsible for Product Quality, Environmental Aspects under their control, and Occupational Health and Safety.

5.4 Organizational responsibilities for the QEHS Management System are stated in 2.2 above, including the interrelation of all personnel who manage, perform and verify work which affects Quality.

6.0 RECORDS:

6.1 None
HEV Plant Process Map and Interactions

MANAGEMENT PROCESS

- 1. Environmental Policy
- 2. Risk Management
- 3. Environment
- 4. Resource Planning
- 5. Quality Management
- 6. Training
- 7. Workforce Planning
- 8. Safety Management
- 9. Health Management
- 10. Information Management
- 11. Management Review
- 12. Continual Improvement

SUPPORT PROCESSES

- 13. Infrastructure
- 14. Human Resources
- 15. Purchasing
- 16. Maintenance & Engineering
- 17. Calibration
- 18. ISO Support
- 19. QIC Quality Assurance

Customer Requirements → 1. Sales

Build to Schedule → 6. Build to Schedule

Quality Management → 5. Quality Management

Information Management → 10. Information Management

Human Resources → 14. Human Resources

Purchasing → 15. Purchasing

Calibration → 17. Calibration

ISO Support → 18. ISO Support

QIC Quality Assurance → 19. QIC Quality Assurance

Service Management → 12. Continual Improvement

Continual Improvement Projects → 12. Continual Improvement

Workforce Planning → 4. Workforce Planning

Safety Management → 8. Safety Management

Health Management → 9. Health Management

Training → 3. Training

Information Management → 11. Information Management


Quality Management → 4. Quality Management


Environment → 2. Environment

Environmental Policy → 1. Environmental Policy

Customer Satisfaction → 13. Customer Satisfaction

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1.0 PURPOSE:

This Section establishes QEHS Management System Planning, identifying how activities are coordinated to direct and control the QEHS Management System of Toshiba International Corporation (TIC).

2.0 REFERENCE DOCUMENTS:

2.1 QEHS Manual, Section 2, QEHS Management System
2.2 QEHS Manual, Section 9, Product Realization
2.3 ISO 9001:2008, Clause 5.4.2
2.4 ISO 14001:2004, Clause 4.3
2.5 OHSAS 1800:2007, Clause 4.3
2.6 Environmental Aspects Identification, Management and Performance Procedure
2.7 Hazard Assessment Procedure
2.8 Job Safety Analysis Procedure (JSA)
2.9 Strategy Deployment Procedure –Doc. No. 2P-551
2.10 ISO/TS 16949:2009

3.0 DEFINITIONS:

3.1 See QEHS Manual, Section 21, Glossary (Terms and Definitions) for definitions of italicized terms.
3.2 EMS – Environmental Management System
3.3 ISO – International Organization for Standardization
3.4 OHSAS – Occupational Health and Safety Advisory Services
3.5 QEHS – Quality, Environmental, Health and Safety

4.0 QEHS MANAGEMENT SYSTEM REQUIREMENTS:

4.1 QEHS Management System Overall Planning:

4.1.1 Toshiba International Corporation’s Management plans and defines processes needed to effectively and efficiently meet Quality, Environmental, and Occupational Health and Safety Policies, Objectives, and Requirements, ensuring:

4.1.1.1 QEHS Management System Planning is performed to meet specified requirements, as well as QEHS Objectives and Targets (Reference 2.1);

4.1.1.2 QEHS Management System integrity is maintained when changes are planned and implemented;

4.1.1.3 procedures are established and maintained to identify Environmental Aspects activities which Toshiba International Corporation can control and can be expected to influence to determine those which have or can have Significant Environmental Impacts (Reference 2.6);

4.1.1.4 procedures are established and maintained for ongoing identification of Occupational Health and Safety Hazards, assessment of associated Risks, and implementation of
necessary control measures. These include routine and non-routine activities and activities of all personnel having access to the workplace in addition to facilities at the workplace (Reference 2.7 and 2.8);

4.1.5 Aspects related to Significant Environmental Impacts are considered when establishing Environmental Objectives; results of Occupational Health and Safety Risks assessments and effects of related controls are considered when establishing Occupational Health and Safety Objectives;

4.1.6 resource availability and information necessary to support operation and monitoring of processes is provided;

4.1.7 knowledge gained from previous experience and other sources of information which identify improvement opportunities are considered.

4.1.2 Management systematically reviews effectiveness and efficiency of Organizational processes.

4.2 Planning for Meeting Customer Specified Requirements:

4.2.1 Where appropriate, Toshiba International Corporation gives consideration to the following activities, in addition to preparation and maintenance of the QEHS Plan meeting specified Customer requirements (Reference 2.2):

4.2.1.1 identification and acquisition of any controls including Monitoring, Measurement, Analysis, Processes, Production Equipment, Inspection and Test Equipment, Fixtures, Resources, and Skills necessary to achieve Quality requirements;

4.2.1.2 ensuring compatibility of the Customer Design, Production Process, Installation Requirements, Inspection and Test Procedures, and applicable documentation;

4.2.1.3 updating, as necessary, Quality Control and Inspection/Testing Techniques, including the development of new Measuring and Test Equipment;

4.2.1.4 identification of any measurement requirement exceeding known state of the art capability in sufficient time to be made available;

4.2.1.5 identification and implementation of suitable Inspection and Checks at appropriate stages in the manufacture of product;

4.2.1.6 clarification of all Inspection criteria for all features and requirements of the product, including any containing a subjective element.

4.3 Planning for Occupational Health and Safety Hazard Identification and Risk Assessment:

4.3.1 Toshiba International Corporation Occupational Health and Safety Hazard identification and Risk assessment methodology is proactive and includes:

4.3.1.1 classification and identification of risks to be eliminated or controlled;

4.3.1.2 ensuring consistency with operating experience and capabilities of risk control measures employed;

4.3.1.3 provision of input into determination of facility requirements, identification of training needs and/or development of operational controls;

4.3.1.4 provision for monitoring required actions to ensure both the effectiveness and timeliness of their implementation;

4.3.1.5 establishing and documenting Occupational Health and Safety Objectives.
4.4 Planning for Meeting Environmental Requirements:

4.4.1 Toshiba International Corporation recognizes development, implementation, and maintenance of an effective Environmental Management System (EMS) are not possible without appropriate planning. At a minimum, such planning includes:

4.4.1.1 identifying Environmental Aspects and evaluating associated Impacts for each production process which can be controlled;

4.4.1.2 determining all Legal Regulatory Requirements;

4.4.1.3 establishing and documenting Facility Environmental Objectives and Targets;

4.4.1.4 creating Environmental Procedures, Plans and Programs;

4.4.1.5 establishing Internal Environmental Performance Criteria and Measurement Systems.

5.0 RESPONSIBILITY:

5.1 Toshiba International Corporation Management, Design Engineering, Quality Control, Manufacturing Engineering, and Marketing are responsible for QEHS Management System Planning within their respective functions.

6.0 RECORDS:

6.1 Records associated with Planning are identified throughout the QEHS Management System and associated documentation.
1.0 **PURPOSE:**
This Section establishes Management’s Responsibilities with regard to Continual Improvement of the QEHS Management System and enhancement of Customer Satisfaction.

2.0 **REFERENCE DOCUMENTS:**
2.1 QEHS Manual, Section 2, QEHS Management System
2.2 QEHS Manual, Section 3, QEHS Management System Planning
2.3 QEHS Manual, Section 5, QEHS Organizational Responsibilities
2.4 QEHS Manual, Section 6, Management Review
2.5 QEHS Manual, Section 8, Resource Management
2.6 QEHS Manual, Section 10, Customer-Related Processes
2.7 ISO 9001:2008/ISO/TS16949, Clauses 5.1, 5.2, 5.5.2.1, 5.5.3 and 6.1
2.8 ISO 14001:2004, Clauses 4.4.1 and 4.4.3
2.9 OHSAS 18001:2007
2.10 Internal and External Communication Procedure – Doc. No. 2P-553
2.11 Quality Representative Procedure – Doc. No. 4P-5511
2.12 Customer Representative Procedure – Doc. No. 4P-5521
2.13 Confidentiality Procedure – Doc. No. 4P-713
2.14 ISO/IEC 17025:2005
2.15 Management Review Procedure – Doc. No. 2P-560-002

3.0 **DEFINITIONS:**
3.1 See QEHS Manual, Section 21, Glossary (Terms and Definitions) for definitions of italicized terms.
3.2 ISO – International Organization for Standardization
3.3 OH&S – Occupational Health and Safety
3.4 OHSAS – Occupational Health and Safety Advisory Services
3.5 QEHS – Quality, Environmental, Health and Safety
3.6 TS – Technical Specification
3.7 APQP – Advance Product Quality Planning

4.0 **QEHS MANAGEMENT SYSTEM REQUIREMENTS:**
4.1 Roles, responsibilities and authorities of personnel who manage, perform, and verify activities having an effect on Toshiba International Corporation (TIC) facilities and processes are defined, documented, and communicated to facilitate effective Quality, Environmental, and Occupational Health and Safety Management.
4.1.1 Management Commitment:

4.1.1.1 Management provides evidence of its commitment to development, implementation, and continual improvement of the QEHS Management System by:

4.1.1.1.1 communicating to all employees the importance of meeting Customer requirements as well as Statutory and Regulatory Requirements;

4.1.1.1.2 establishing a QEHS Policy and ensuring the Policy is understood by all employees (Reference 2.1);

4.1.1.1.3 ensuring the QEHS Policy and Objectives are established and reviewed for continuing suitability and adequacy, and when necessary, the need for change (Reference 2.2);

4.1.1.1.4 conducting Management Reviews (Reference 2.4);

4.1.1.1.5 ensuring availability of resources (human, specialized skills, technology, laboratory and financial) essential for implementation and control of the QEHS Management System (Reference 2.1 and 2.5);

4.1.1.1.6 appointment of specific QEHS Management Representatives (Reference 2.1).

4.1.2 Customer Focus:

4.1.2.1 Management ensures Customer Requirements are determined. These requirements are met with the aim of enhancing Customer Satisfaction (Reference 2.6).

4.1.2.2 Management shall designate personnel with responsibility and authority to ensure the customer requirements are addressed efficiently/effectively. This includes selection of special characteristics, setting quality objectives and related training, corrective and preventive actions, product design and development.

4.1.2.3 HEV Plant/TS16949: Management has designated personnel with responsibility and authority to ensure that customer requirements are addressed through the use of the business planning process and the APQP process.

4.1.2.4 ISO/IEC 17025 - Validation Lab: The Laboratory management’s commitment to good professional practice and to the quality of testing and calibration in servicing customer.

4.1.3 Consultation and Communication:

4.1.3.1 Management has established communication processes within Toshiba International Corporation to ensure communication takes place regarding the QEHS Management System. These processes are documented in procedures and are maintained for:

4.1.3.1.1 OH&S pertinent information and Environmental related communications between various levels and functions of the Organization and other interested parties (Reference 2.10);

4.1.3.1.2 Receiving, documenting, and responding to QEHS communications related to external interested parties. Processes for external communication are considered relative to Significant Environmental Aspects and Occupational Health and Safety; the decision of which is recorded (Reference 2.10).

4.1.3.2 Employee involvement and consultation arrangements are documented. Employees are involved in development and review of Policies and Procedures to manage risks and consulted when there are any changes affecting Occupational Health and Safety.
Employees are also represented on Occupational Health and Safety matters and informed of their OH&S Representatives.

5.0 **RESPONSIBILITY:**

5.1 It is the responsibility of *Management* to ensure Customer Focus and QEHS related communication throughout Toshiba International Corporation.

5.2 External communications to interested parties relative to Environmental Aspects and their significance, and Occupational Health and Safety Risks is the responsibility of the VP of Human Resources of Toshiba International Corporation.

6.0 **RECORDS:**

6.1 Records include Job Descriptions, Organization Charts, and External Environmental Aspects related communications.
1.0 PURPOSE:
This Section establishes responsibilities and authorities of Toshiba International Corporation (TIC) personnel for implementing and maintaining the QEHS Management System.

2.0 REFERENCE DOCUMENTS:
2.1 QEHS Manual, Section 6, Management Review
2.2 ISO 9001:2008/ISO/TS16949, Clauses 5.5.1, 5.5.1.1 and 5.5.2
2.3 ISO 14001:2004, Clause 4.4.1
2.4 OHSAS 18001:2007
2.5 Job Descriptions
2.6 Management Review Procedure – Doc. No. 2P-560-002
2.7 Organization Charts
2.8 FMC CSR
2.9 Quality Representative Procedure – Doc. No. 4P-5511
2.10 Customer Representative Procedure – Doc. No. 4P-5521
2.11 ISO/IEC 17025:2005, Clause 4.1.5 a), f), h) and i)

3.0 DEFINITIONS:
3.1 See QEHS Manual, Section 21, Glossary (Terms and Definitions) for definitions of italicized terms.
3.2 TGEA – Toshiba Group Environmental Audit
3.3 FMC CSR – Ford Motor Company Customer-Specific Requirements
3.4 ISO – International Organization for Standardization
3.5 OHSAS – Occupational Health and Safety Advisory Services
3.6 QEHS – Quality, Environmental, Health and Safety
3.7 STA – Supplier Technical Assistance
3.8 TS – Technical Standard
3.9 VPP – Voluntary Protection Program
3.10 APQP – Advanced Product Quality Planning

4.0 QEHS MANAGEMENT SYSTEM REQUIREMENTS:
4.1 Roles, responsibilities and authorities of all employees within the Organization are defined, and communicated by Management to facilitate effective Quality, Environmental, and Occupational Health and Safety Management. Organizational relationships within the company are described in the Organization Charts. Specific responsibilities and authorities for such activity affecting Quality,
Environmental Impacts, and Occupational Health and Safety are defined in the respective Job Descriptions, Procedures, and Work Instructions.

4.2 Responsibility and authority of Toshiba International Corporation personnel related to the QEHS Management System are as follows:

4.2.1 VP and Group Presidents, General Manager is Responsible for:

4.2.1.1 the QEHS Management System at Toshiba International Corporation, including Regulatory Compliance. Toshiba International Corporation Management Team assists by providing direction and guidance;

4.2.1.2 Management Review Meetings for Toshiba International Corporation to ensure the QEHS Management System remains effective;

4.2.1.3 approval of the QEHS Management System Manual and Policy Statements resides with the Toshiba International Corporation VP and Group President, General Managers and Management Team;

4.2.1.4 establishing QEHS Objectives and Targets for Toshiba International Corporation.

4.2.2 Business Unit Managers are Responsible for:

4.2.2.1 coordination of processes related to a given product (i.e. Motors, Drives, UPS, Solutions, HEV Motors, etc.);

4.2.2.2 identifying and monitoring Business Unit Goals and Objectives in support of Toshiba International Corporation Goals and Objectives.

4.2.3 Plant Managers are Responsible for:

4.2.3.1 QEHS Management System implementation at the Plant Level;

4.2.3.2 any Management Review Meetings over their respective areas to assure the QEHS Management System remains effective for their Plant;

4.2.3.3 complying with Toshiba International Corporation QEHS Objectives and Targets.

4.2.3.4 Identifying and advising regulatory authorities of changes in Production and Quality Representatives.

4.2.3.5 Following regulatory compliance rules.

4.2.4 Customer Representatives are Responsible for:

4.2.4.1 Ensuring that customer requirements are addressed through the use of the business planning process and the APQP process.

4.2.5 Management Representatives are Responsible for:

4.2.5.1 Toshiba International Corporation Management has appointed four Management Representatives {{Quality Management System (1), and Environmental, and Occupational Health and Safety Management Systems (1), and Automotive Quality Management System (1), and Laboratory Quality Management System (1)}} who have responsibility and authority including:


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Program (CTDP), TGEA Requirements, and Voluntary Protection Program (VPP) Requirements;

4.2.5.1.2 Reporting QEHS Management System Performance to Executive Management for review, including any recommendations for improvement;

4.2.5.1.3 Ensuring promotion and awareness of Customer Requirements throughout the Organization;

4.2.5.1.4 Facilitating, guiding, and providing input to QEHS Objectives and Targets for Toshiba International Corporation.

4.2.5.1.5 Responsible for the Document Control Administration

4.2.5.2 In addition, the Management Representatives are responsible for acting as a liaison to Third Party Auditors and Registrars in regard to issues concerning the QEHS Management System.

4.2.6 The Chief Quality Executive is Responsible for Overall Development of the Quality Management System and Continual Improvement:

4.2.6.1 Additional responsibilities include:

4.2.6.1.1 Integration of division activities to create organizational clarity and focus in regards to Quality Assurance and Quality Control

4.2.6.1.2 Enhanced quality management planning providing guidance, expertise and coordination on Quality matters;

4.2.7 The Quality System Manager is Responsible for Overall Maintenance of the Quality Management System:

4.2.7.1 Additional responsibilities include:

4.2.7.1.1 Maintaining Corporate Quality Management System Policy and Procedures;

4.2.7.1.2 Facilitating Quality Management System Management Review Meetings;

4.2.7.1.3 Delivery coordination of Quality Training activities for Management and Employee Training and Development

4.2.7.1.4 Coordinating Procedures, Work Instructions, and related documentation in a consistent, uniform, and clear manner;

4.2.7.1.5 Providing guidance, expertise and coordination on Quality Management System matters;

4.2.7.1.6 Assuring proper Document Control, including review and coordination of all Quality Management System document releases;

4.2.7.1.7 Coordinating Internal and External Audits;

4.2.8 The Quality Assurance Manager is Responsible for:

4.2.8.1.1 Process support for vendor projects;

4.2.8.1.2 Maintaining the Voice of Customer feedback system

4.2.8.1.3 Development of Management Innovation

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4.2.9 The Environmental, Health and Safety Manager is Responsible for Overall Maintenance of the Environmental, and Occupational Health and Safety Management Systems, including Regulatory Compliance:

4.2.9.1 Additional responsibilities include:

4.2.9.1.1 maintaining Corporate Environmental Management System Policies and Procedures including compliance with TGEA Requirements;
4.2.9.1.2 conducting Environmental Management Systems and Occupational Health and Safety Management System Management Review Meetings;
4.2.9.1.3 providing Management and Employee Training and Development;
4.2.9.1.4 maintaining Corporate Occupational Health and Safety Management System Policies and Procedures;
4.2.9.1.5 coordinating Procedures, Work Instructions, and related documentation in a consistent, uniform, and clear manner;
4.2.9.1.6 providing guidance, expertise and coordination on Environmental and Occupational Health and Safety matters;
4.2.9.1.7 assuring proper Document Control, including the review and coordination of all Environmental Management System and all Occupational Health and Safety Management System document releases;
4.2.9.1.8 coordinating Internal and External Audits;
4.2.9.1.9 conducting Occupational Health and Safety related Training, and maintaining Training Records.

4.2.10 Material and/or Supply Chain Managers are Responsible for Procurement of Goods and Services, and:

4.2.10.1 monthly Supplier Delivery Performance Reporting and Review
4.2.10.2 following and enforcing rules contained in the Chemical Hazard Communication Program Procedure;
4.2.10.3 creation of action plans for poor performing suppliers

4.2.11 Document Control Administrators are Responsible for:

4.2.11.1 Effectively follow TIC’s standard operating procedures in the control of documents by:
4.2.11.1.1 assisting in the creation of documents
4.2.11.1.2 ensuring documents have no errors in filenames
4.2.11.1.3 ensuring reference documents contained within are current before releasing into InfoSource
4.2.11.1.4 assigning document numbers
4.2.11.1.5 reviewing documents for formatting compliance
4.2.11.1.6 communicating changes to plant/departments affected by the changes
4.2.11.1.7 ensuring documents are available to locations where operations are essential,
4.2.11.1.8 maintaining a master list of documents
4.2.11.1.9 performing annual audits of documents in order to ensure that all documents are controlled, approved and properly submitted to departments.

4.2.12 Quality Control Managers are Responsible for:

4.2.12.1 assisting and maintenance of Quality Control Plans and Quality Checklists for new products, monitoring and control of Process Parameters, assistance in maintenance of Work Instructions, Inspection and Test Plans, Inspection and Testing of Materials and Product, and control and disposition of Non-conforming Materials;
4.2.12.2 conducting monthly Plant Quality Operating System Meetings based on the Plant’s Quality Performance;
4.2.12.3 reporting the Warranty Plan.
4.2.12.4 Following regulatory compliance rules
4.2.12.5 ISO/IEC 17025 – PEP Validation Lab: managing technical operations, resources needed and verifying work of quality of the testing and/or calibration activities.

4.2.13 Material Control is Responsible for:

4.2.13.1 storage of Toshiba International Corporation product and materials in a way to prevent damage and deterioration, in compliance with documented procedures,
4.2.13.2 packaging and shipping of finished product; in compliance with documented procedures,
4.2.13.3 following and enforcing rules contained in the Chemical Hazard Communication Program Procedure.

4.2.14 Production Managers are Responsible for:

4.2.14.1 production, scheduling, prioritizing, and controlling processes to meet Customer Requirements;
4.2.14.2 following and enforcing rules contained in the Chemical Hazard Communication Program Procedure;
4.2.14.3 following Regulatory Compliance rules and Recycling efforts.

4.2.15 Inspectors are Responsible for:

4.2.15.1 Receiving, In-process, and Final Inspections of products in accordance with pre-determined Inspection Checklists, Procedures, etc.
4.2.15.2 Following regulatory compliance rules.

4.2.16 Maintenance Manager is Responsible for:

4.2.16.1 maintenance of machinery, equipment, and tooling used for product production and facilities use, including Preventive and Predictive Maintenance;
4.2.16.2 maintaining equipment used to monitor Environmental Aspects;
4.2.16.3 following and enforcing rules contained in the Chemical Hazard Communication Program Procedure;
4.2.16.4 Motor Plant - Responsible for storage of chemicals to meet Regulatory Compliance.

4.2.17 **Facilities Manager is Responsible for:**
- 4.2.17.1 maintaining equipment used to monitor Environmental Aspects;
- 4.2.17.2 following and enforcing rules contained in the Chemical Hazard Communication Program Procedure;
- 4.2.17.3 Contracting suppliers related to Environmental Regulatory Compliance.

4.2.18 **Field Service Manager is Responsible for:**
- 4.2.18.1 post-delivery support of products.

4.2.19 **Research and Development Managers are Responsible for:**
- 4.2.19.1 coordinating the Product Design;
- 4.2.19.2 following and enforcing rules contained in the Chemical Hazard Communication Program Procedure.

4.2.20 **Organizational Development and Training Manager is Responsible for:**
- 4.2.20.1 Delivery coordination of Quality and Environmental Training activities.
- 4.2.20.2 Monitor/oversee curriculum development, delivery and tracking of all Human Resources Training initiatives
- 4.2.20.3 Evaluate training offerings and assess the various trainings needed across the organization.

4.2.21 **General:**
- 4.2.21.1 All personnel are responsible for Product Quality under their control and for following applicable Environmental, and Occupational Health and Safety Rules and Regulations.
- 4.2.21.2 Additional Organizational responsibilities are shown in the Toshiba International Corporation Organization Chart (Reference 2.7) and in individual functional Job Descriptions (Reference 2.5).
- 4.2.21.3 All personnel are responsible for following QEHS Policy and Procedures.

5.0 **RESPONSIBILITY:**
5.1 Responsibilities are designated in the above paragraphs, Organization Chart, respective Job Descriptions, and as specified, in each Section of this QEHS Management System Manual; and Procedures and Work Instructions.
5.2 Managers with responsibility and authority for corrective action shall be promptly informed of products or processes which do not conform to requirements.
5.3 Personnel responsible for conformity to product requirements shall have the authority to stop production to correct quality problems.
5.4 Production operations across all shifts shall be staffed with personnel in charge of, or delegated responsibility for, ensuring product quality.

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5.5 HEV Plant/TS16949: FMC STA shall be notified within 10 working days of any changes to senior management responsible for Quality or company ownership.

6.0 RECORDS:

6.1 Records include Organization Charts, Job Descriptions, and Meeting Minutes.
1.0 **PURPOSE:**

This Section establishes requirements for Management’s review of the QEHS Management System to ensure its continuing suitability, adequacy and effectiveness.

2.0 **REFERENCE DOCUMENTS:**

2.1 QEHS Manual, Section 3, QEHS Management System Planning
2.2 QEHS Manual, Section 7, Documentation Requirements
2.3 QEHS Manual, Section 15, Monitoring, Measurement, Analysis, Improvement and Evaluation of Compliance
2.4 QEHS Manual, Section 16, Control of Non-conforming Product and Material
2.5 QEHS Manual, Section 18, Improvement
2.7 ISO 14001:2004, Clause 4.6
2.8 OHSAS 18001:2007
2.9 Corrective/Preventive Action Procedure – Doc. No. 2P-850-0012
2.10 Corrective and Preventive Action Procedure – Doc. No. 2P-850-003
2.112.10 Internal Audit for Environmental, Health and Safety Compliance Procedure
2.11 Internal Audit Procedure – Doc. No. 2P-822-001
2.12
2.13 Preventive Action Procedure – 2P-853
2.142.13 Records Management Procedure – Doc. No. 2P-424-001
2.152.14 Internal and External Communications Procedure – Doc. No. 2P-553-001
2.162.15 FMC CSR, Clauses 4.7, 4.8
2.172.16 ISO/IEC 17025:2005, Clause 4.15

3.0 **DEFINITIONS:**

3.1 See QEHS Manual, Section 21, Glossary (Terms and Definitions) for definitions of italicized terms.
3.2 FMC CSR – Ford Motor Company Customer-Specific Requirements
3.3 ISO – International Organization for Standardization
3.4 OHSAS – Occupational Health and Safety Advisory Services
3.5 QEHS – Quality, Environmental, Health and Safety
3.6 TS – Technical Specification
3.7 IEC – International Electrotechnical Commission

4.0 **QEHS MANAGEMENT SYSTEM REQUIREMENTS:**

4.1 Management Review – General:
4.1.1 Management reviews Toshiba International Corporation (TIC)’s the QEHS Management System at least once per fiscal year to ensure its continuing suitability, adequacy and effectiveness (Reference 2.12). This review includes assessing opportunities for improvement and the need for changes to the QEHS Management System, including the Policy, Objectives and Targets. Records from these Reviews are maintained (Reference 2.13 (See 6.0 below)).

4.1.2 The Management Review process ensures necessary information is collected to allow Management to perform this evaluation of QEHS Management System effectiveness and includes both Review Inputs and Outputs.

4.1.3 Plant management Management shall hold holds monthly QOS (Quality Operating System) performance meetings. The results of these QOS reviews shall be integral to the senior management reviews.

4.2 Review Inputs:

4.2.1 Management Review Inputs include information on the Cost of Quality and:

4.2.1.1 Audit Results and any associated trend information (Reference 2.10 and 2.11);

4.2.1.2 Customer Feedback (Reference 2.3);

4.2.1.3 process performance and product conformity to requirements (References 2.3 and 2.4);

4.2.1.4 status of Corrective and Preventive Actions, including trend information (Reference 2.5 and 2.9);

4.2.1.5 Follow-up actions from Previous Management Reviews (Reference 2.12);

4.2.1.6 changes affecting the QEHS Management System, including changes to the Policy, Objectives, Procedure or other elements of the QEHS Management System (Reference 2.1);

4.2.1.7 recommendations for improvement (Reference 2.12);

4.2.1.8 Legal and Regulatory Requirements relevant to the QEHS Management System;

4.2.1.9 communication from external parties, including complaints regarding Environmental matters.

4.2.1.10 HEV Plant/FMC CSR: Management Review Input must also include the Q1 Manufacturing Site Assessment results

4.2.1.11 ISO/IEC 17025 – PEP Validation Lab: Results of interlaboratory comparisons or proficiency tests.

4.2.1.12 ISO/IEC 17025 – PEP Validation Lab: Changes in volume and type of work.

4.3 Review Output:

4.3.1 Management Review Outputs include all decisions and actions related to:

4.3.1.1 improvement of adequacy and effectiveness of the QEHS Management System and its processes;

4.3.1.2 improvement of product related to Customer Requirements;

4.3.1.3 continued suitability of the QEHS Policies and Objectives;

4.3.1.4 Resource needs;

4.3.1.5 possible need for changes to the QEHS Policies, Objectives and other elements of the QEHS Management System;
4.3.1.6 Management Review Records.

4.3.1.7 ISO/IEC 17025 – PEP Validation Lab: Quality Control Activities, Resource and Staffing.

5.0 RESPONSIBILITY:

5.1 Individual responsibilities associated with Management Review are stated in the Management Review Procedure (Reference 2.12). Overall responsibility for Management Review resides with Management. Ensuring Scheduling Management Reviews and Quality Operating System Meetings are scheduled and conducted is the responsibility of the Management Representatives.

6.0 RECORDS:

6.1 Management Review Records are documented as determined by the respective Management Representatives or designee in accordance with Section 7 of this QEHS Management System Manual, and includes minutes and associated data (Reference 2.13).
### 1.0 PURPOSE:
This Section establishes Documentation Requirements of the QEHS Management System.

### 2.0 REFERENCE DOCUMENTS:

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<th>Reference Document</th>
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<td>2.6 OHSAS 18001:2007, Clauses 4.3.1, 4.3.2, 4.4.2, 4.4.3, 4.4.4, 4.4.5, 4.4.6, 4.4.7, 4.5.1, 4.5.2, and 4.5.4</td>
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<tr>
<td>2.7 Document and Data Control Procedure – Doc. No. 2P-423-001</td>
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<td>2.8 Records Management Procedure – Doc. No. 2P-424-001</td>
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<td>3.4 OHSAS – Occupational Health and Safety Advisory Services</td>
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<td>3.5 QEHS – Quality, Environmental, Health and Safety</td>
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<td>3.6 STA – Supplier Technical Assistance</td>
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<td>3.10 CTDP – Client Test Data Program</td>
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<td>3.11 IEC – International Electrotechnical Commission</td>
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### 4.0 QEHS MANAGEMENT SYSTEM REQUIREMENTS:

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<tr>
<td>4.1 Documentation Requirements – General:</td>
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<td>4.1.1 Toshiba International Corporation (TIC) has established and maintains documented procedures to control documents and data relating to requirements of the QEHS Management System.</td>
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</tbody>
</table>
4.1.2 QEHS Management System documentation includes:
   4.1.2.1 documented statements of a QEHS Policy and QEHS Objectives (Reference 2.4);
   4.1.2.2 this QEHS Management System Manual (See Subsection 4.2 below);
   4.1.2.4 documents needed by Toshiba International Corporation to ensure effective planning, operation, and control of its processes;
   4.1.2.5 information describing the Core Elements of the QEHS Management System and their interaction;

4.1.3 Documentation may be in the form of hardcopy or electronic media (Reference 2.8).

4.1.4 PEP Validation Lab/CTDP system: The laboratory shall establish and maintain procedures to control all documents that form part of its management system (internally generated or from external sources), such as regulations, standards, other normative documents, test and/or calibration methods, as well as drawings, software, specifications, instructions and manuals.
   4.1.4.1 The laboratory must have the technical documents (standards and datasheets) to conduct tests.

4.2 QEHS Management System Manual:
   4.2.1 This QEHS Management System Manual provides an overall description of the QEHS Management System Scope. It also includes the QEHS Policy, QEHS Objectives, documented procedures (Referenced by this QEHS Management System Manual) and a description of interactions between processes of the QEHS Management System. This QEHS Management System Manual also is used to instruct and guide all Toshiba International Corporation personnel and to inform Customers of controls implemented to assure Product Quality, Environmental Compliance, and Occupational Health and Safety.
   4.2.2 This established and maintained QEHS Management System Manual includes:
      4.2.2.1 requirements of the QEHS Management System (See Subsection 4.0 within each Section of this QEHS Management System Manual) as it applies to product and services. No exclusions are claimed under ISO 9001:2008, Clause 1.2; We are not responsible for performing service on HEV parts once delivered.
      4.2.2.2 inclusion or reference to documented procedures established for the QEHS Management System (See Subsection 2.0 within each Section of this QEHS Management System Manual);
      4.2.2.3 a description of interactions between processes of the QEHS Management System (Reference Section 2 of this QEHS Management System Manual).
      4.2.2.4 the applicable clauses of ISO/IEC 17025:2005 standard to meet UL Client Test Data Program (CTDP) in PEP Validation Lab.

4.3 Control of Documents:
   4.3.1 Documents required by the QEHS Management System are controlled as defined in the Document and Data Control Procedure (Reference 2.7), which defines the controls needed for:

This document shall be considered “For Reference Only” when printed as a hardcopy. Revision status must be verified prior to use.
4.3.1.1 approval of documents for adequacy prior to issue;
4.3.1.2 review and update as necessary and re-approval of documents;
4.3.1.3 ensuring changes, and current revision status of documents are identified;
4.3.1.4 ensuring relevant versions of applicable documents are available at points of use;
4.3.1.5 ensuring documents remain legible, readily identifiable, and can be located;
4.3.1.6 ensuring documents of external origin are identified and their distribution is controlled;
4.3.1.7 preventing unintended use of obsolete documents, and applying suitable identification if retained for any purpose.

4.3.2 Documented procedures have been established and maintained to cover situations where their absence could lead to deviations from the QEHS Policies, Objectives and Targets. Current operating criteria are stipulated in the associated procedures.

4.3.3 Records are a special type of document and are controlled {Reference 2.8 and 2.9 (See Subsection 4.4 below)}.

4.3.4 HEV/TS16949: Customer engineering standards/ specifications and changes based on customer required schedule will be reviewed, distributed and implemented in a timely manner, not to exceed two working weeks.

4.3.5 HEV/TS16949: TIC shall maintain a record of the date on which each change is implemented in production. The implementation includes updated documents.

4.3.6 HEV/TS16949: A change in these standards/specifications requires and updated record of customer production part approval when these specifications are referenced on the design record or if they affect documents of production part approval process, such as control plan, FMEAs, etc.

4.3.7 PEP Validation Lab/CTDP system - Test and calibration methods and method validation:

4.3.7.1 The laboratory shall use appropriate methods and procedures for all tests and/or calibrations within its scope. These include sampling, handling, transport, storage and preparation of items to be tested and/or calibrated, and, where appropriate, an estimation of the measurement uncertainty as well as statistical techniques for analysis of test and/or calibration data. The laboratory shall have instructions on the use and operation of all relevant equipment, and on the handling and preparation of items for testing and/or calibration, or both, where the absence of such instructions could jeopardize the results of tests and/or calibrations. Current - UL specifies the methods to be used. All instructions, standards, manuals and reference data relevant to the work of the laboratory shall be kept up to date and shall be made readily available to personnel. As Jan. 1, 2009 other supporting documentation required. Deviation from test and calibration methods shall occur only if the deviation has been documented, technically justified, authorized, and accepted by the customer. Current - Deviations from published methods are to be authorized by UL.

4.3.8 PEP Validation Lab/CTDP system - Selection of methods:

4.3.8.1 The laboratory shall use test and/or calibration methods, including methods for sampling, which meet the needs of the customer and which are appropriate for the tests and/or calibrations it undertakes. Methods published in international, regional or national standards shall preferably be used. Current - UL specifies the test methods. The laboratory shall ensure that it uses the latest valid edition of a standard unless it is not appropriate or possible to do so.
When necessary, the standard shall be supplemented with additional details to ensure consistent application. When the customer does not specify the method to be used, the laboratory shall select appropriate methods that have been published either in international, regional or national standards, or by reputable technical organizations, or in relevant scientific texts or journals, or as specified by the manufacturer of the equipment. Laboratory-developed methods or methods adopted by the laboratory may also be used if they are appropriate for the intended use and if they are validated. The customer shall be informed as to the method chosen. Current - UL is to be notified of test plans and must approve deviations. The laboratory shall confirm that it can properly operate standard methods before introducing the tests or calibrations. If the standard methods change, the confirmation shall be repeated.

4.4 Control of Records:

4.4.1 Records have been established and maintained to provide evidence of conformity to requirements and effective operation of the QEHS Management System. Records are maintained legible, readily identifiable and retrievable. Controls are needed for identification, storage, protection, retrieval, retention time and disposition of records (Reference 2.8 and 2.9).

4.4.2 Records may be in the form of any type of media, such as hardcopy or electronic media.

4.4.3 Records will be maintained for a specified amount of time to satisfy regulatory and customer requirements. Customer requirements do not supersede any regulatory requirements. (HEV Reference FMC CSR 4.4 and 4.33)

4.4.4 HEV/TS16949: Production part approvals, tooling records, purchase orders and amendments shall be maintained for the length of time that the part (or family of parts) is active for production and service requirements plus one calendar year unless otherwise specified by FMC.

4.4.5 HEV/TS16949: Records of inspection shall be maintained for each customer specification, unless waived in writing by STA. The actual test results (variable or attribute) shall be recorded. Simple pass/fail records are not acceptable for variable measurements.

4.4.6 HEV/TS16949: Specific records requirements specified by FMC (CSR4.4) will be included in the Records Management Procedure.

4.4.7 PEP Validation Lab/CTDP system: Calculations and data transfers shall be subject to appropriate checks in a systematic manner. Requirement as of Jan 1, 2009. When computers or automated equipment are used for the acquisition, processing, recording, reporting, storage or retrieval of test or calibration data, the laboratory shall ensure that: Requirement as of Jan 1, 2009.

4.4.7.1 Computer software developed by the user is documented in sufficient detail and is suitably validated as being adequate for use; Requirement as of Jan 1, 2009.

4.4.7.2 Procedures are established and implemented for protecting the data; such procedures shall include, but not be limited to, integrity and confidentiality of data entry or collection, data storage, data transmission and data processing; Requirement as of Jan 1, 2009.

4.4.7.3 Computers and automated equipment are maintained to ensure proper functioning and are provided with the environmental and operating conditions necessary to maintain the integrity of test and calibration data.
5.0 **RESPONSIBILITY:**

5.1 Department Managers are responsible for ensuring issues of appropriate documents are available for use in their area which is pertinent and periodically reviewed for removal of all obsolete issues. It is the responsibility of Department Managers to ensure required documented records from their functional areas are also created and maintained as specified {See Subsection 4.3 (4.3.1.1, 4.3.1.2, 4.3.1.4 and 4.3.1.7)}.

5.2 Management Representatives are responsible for establishment, identification and maintenance of QEHS documentation.

5.3 Document Control Administrators are responsible for controlling and maintaining Master Copies and Master Lists of hardcopy and electronic QEHS documents {See Subsection 4.3 (4.3.1.3, 4.3.1.5 and 4.3.1.6)}.

6.0 **RECORDS:**

6.1 QEHS Management System Records are identified in each Section of this QEHS Management System Manual and within each Procedure or Work Instruction.
1.0 **PURPOSE:**
This Section establishes requirements for Resources Management essential to implementation and continual improvement of the QEHS Management System.

2.0 **REFERENCE DOCUMENTS:**
2.1 QEHS Manual, Section 7, Documentation Requirements  
2.3 ISO 14001:2004, Clauses 4.4.1 and 4.4.2  
2.4 OHSAS 18001:2007, Clauses 4.4.1and 4.4.2  
2.5 Competency, Awareness and Training Procedure – Doc. No. 2P-622-002  
2.6 Records Management Procedure – Doc. No. 2P-424-001  
2.7 FMC CSR, Clauses 4.9, 4.10  
2.8 HEV Staff Quality Training Procedure – Doc. No. 4P-6222-1  
2.9 HEV Operator Training Procedure – Doc. No. 4P-6222-2  
2.10 Inspector Authorization Registration Procedure – Doc. No. 4P-6222-3  
2.11 Facility Maintenance Procedure – Doc. No. 4P-630  
2.12 Contingency Response Procedure – Doc. No. 4P-632  
2.13 Skill Matrix Procedure –Doc. No. 2P-622-001  
2.14 ISO/IEC 17025:2005, Clause 5.2.1 and 5.2.4  

3.0 **DEFINITIONS:**
3.1 See QEHS Manual, Section 21, Glossary (Terms and Definitions) for definitions of italicized terms.  
3.2 ISO – International Organization for Standardization  
3.3 OHSAS – Occupational Health and Safety Advisory Services  
3.4 QEHS – Quality, Environmental, Health and Safety  
3.5 DAP – Data Acceptance Program  
3.6 CTDP – Client Test Data Program  

4.0 **QEHS MANAGEMENT SYSTEM REQUIREMENTS:**
4.1 **Provision of Resources – General:**
4.1.1 Toshiba International Corporation (TIC) Management determines and provides resources needed to implement and maintain the QEHS Management System and continually improve its effectiveness, and to enhance Customer Satisfaction by meeting Customer Requirements.  
4.1.2 Any employee may identify requirements for additional resources (equipment, services, and personnel). Management is responsible to evaluate and provide for such resources to ensure continuing capability and all Customer Requirements are consistently met.
4.2 Human Resources – General:

4.2.1 Personnel (employees or persons performing tasks on our behalf) whose work may affect Product Quality, or cause or create a Significant Environmental Impact have been determined to be competent on the basis of appropriate education, training, skills and experience. All employees receive instruction in the QEHS Management System applicable to their specific work assignments. They also receive training on the consequences of departing from all relevant procedures.

4.2.2 Training or other action is provided to address activities associated with Environmental Aspects and the Environmental Management System.

4.2.3 Personnel performing certain specialized activities identified and addressed in the QEHS Management System are formally qualified to perform those designated activities.

4.2.4 Toshiba International Corporation (TIC) incorporates processes to motivate employees to achieve quality objectives, to make continual improvements, and to create an environment to promote innovation. The process shall include the promotion of quality and technological awareness throughout the whole organization.

4.2.5 Toshiba International Corporation (TIC) incorporates processes to measure the extent to which its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives.

4.2.6 PEP Validation Lab/CTDP system:
   4.2.6.1 The laboratory must have competent personnel conducting testing and/or calibrations.
   4.2.6.2 The laboratory management shall ensure the competence of all who operate specific equipment, perform tests and/or calibrations, evaluate results, and sign test reports and calibration certificates.
   4.2.6.3 When using staff who are undergoing training, appropriate supervision shall be provided.
   4.2.6.4 Personnel performing specific tasks shall be qualified on the basis of appropriate education, training, experience and/or demonstrated skills, as required.
   4.2.6.5 The laboratory shall maintain current job descriptions for managerial, technical and key support personnel involved in tests and/or calibrations.

4.3 Infrastructure:

4.3.1 Management determines, provides and maintains the Infrastructure needed to achieve Environmental conformity, and product conformity to Customer Requirements. Infrastructure includes:
   4.3.1.1 buildings, workspace and associated utilities;
   4.3.1.2 process equipment (hardware and software);
   4.3.1.3 supporting services (such as transport, communication or information systems).

4.4 Work Environment:

4.4.1 Management determines and manages the Work Environment needed to achieve conformity to Environmental, Occupational Health and Safety, and Product requirements. Examples of Environmental control include special Work Environments with exhaust systems or requiring air conditioning.
5.0 **RESPONSIBILITY:**

5.1 Toshiba International Corporation (TIC) Management is responsible for provision of resources necessary to meet Customer Requirements, requirements of the QEHS Management System, and associated Work Environment and Infrastructure.

5.2 Management and Supervision are responsible for ensuring necessary training is provided to complete specific production tasks and to ensure competency of the employees to perform work affecting Product Quality and the Environment.

5.3 The Quality Systems Manager is responsible for Quality Management System related training.

5.4 Management and Supervision are responsible for ensuring training material is kept current.

5.5 The Environmental, Health and Safety Manager is responsible for Occupational Health and Safety related Training.

6.0 **RECORDS:**

6.1 Data on education, training, skills and experience is recorded and maintained in accordance with Section 7 of this QEHS Management System Manual (Reference 2.6).
1.0 **PURPOSE:**

This Section establishes requirements for planning and developing processes needed for *Product Realization*. Planning of Product Realization is consistent with requirements of all Sections of this QEHS Management System Manual.

2.0 **REFERENCE DOCUMENTS:**

2.1 QEHS Manual, Section 2, QEHS Management System
2.2 QEHS Manual, Section 3, QEHS Management System Planning
2.3 QEHS Manual, Section 7, Documentation Requirements
2.4 QEHS Manual, Section 8, Resource Management
2.5 QEHS Manual, Section 10, Customer-Related Processes
2.6 QEHS Manual, Section 11, Design and Development
2.7 QEHS Manual, Section 12, Purchasing
2.8 QEHS Manual, Section 13, Production and Service Provision
2.9 QEHS Manual, Section 14, Control of Monitoring and Measuring Devices
2.10 QEHS Manual, Section 15, Monitoring, Measurement, Analysis, Improvement and Evaluation of Compliance
2.12 ISO 14001:2004, Clauses 4.3.2 and 4.4.6
2.13 OHSAS 18001:2007, Clauses 4.4 and 4.4.6
2.14 Environmental Aspects Identification, Management and Performance Procedure
2.15 Hazard Assessment Procedure
2.16 Laws and Regulations Procedure
2.17 Records Management Procedure – Doc. No. 2P-424-001
2.18 FMC CSR, Clauses 4.14, 4.15

3.0 **DEFINITIONS:**

3.1 See QEHS Manual, Section 21, Glossary (Terms and Definitions) for definitions of italicized terms.
3.2 FMC CSR – Ford Motor Company Customer-Specific Requirements
3.3 ISO – International Organization for Standardization
3.4 PLC – Programmable Logic Controller
3.5 OHSAS – Occupational Health and Safety Advisory Services
3.6 QEHS – Quality, Environmental, Health and Safety
3.7 TS – Technical Specification
4.0 QEHS MANAGEMENT SYSTEM REQUIREMENTS:

4.1 Planning of Product Realization:

4.1.1 Toshiba International Corporation (TIC) Designs, Manufactures, and provides Sales and Service of Industrial Motors, Adjustable Speed Drives, Uninterruptible Power Supplies, Motor Controls, and Distribution Equipment. In addition, we manufacture and sell HEV Motors, sell and support Programmable Logic Controllers (PLC’s), Industrial Plant Systems, Magnetic Flow Meters, and Transportation Equipment.

4.1.2 Processes needed for Product Realization are planned and developed. Planning of Product Realization is consistent with requirements of other processes of the QEHS Management System (Reference 2.1).

4.1.3 Activities associated with identified Quality, Significant Environmental Aspects, and Occupational Health and Safety Risks in line with the Policy, Objectives and Targets are planned to ensure they are performed under specified conditions.

4.1.4 Planning is in the form of documented procedures to cover situations where their absence could lead to deviations from the QEHS Policy, Objectives and Environmental Targets.

4.1.5 The operational Procedures and Work Instructions, and other operation documentation ensure effective process control and communication between process elements.

4.1.6 In planning Product Realization, Management determines the following as appropriate:

4.1.6.1 QEHS Objectives and product requirements (Reference 2.1 and 2.5);

4.1.6.2 the need to establish processes, documents, and provide resources specific to the product (Reference 2.2, 2.3 and 2.5);

4.1.6.3 required Customer-Related Processes, Verification, Validation, Monitoring, Inspection and Test activities specific to the product and criteria for product acceptance (Reference 2.6, 2.7, 2.8, 2.9 and 2.10);

4.1.6.4 establishment of Monitoring, Measurement, Analysis and Improvement processes (Reference 2.10);

4.1.6.5 Legal and other related requirements as contained in the documented procedure have been established and are maintained. The procedure provides identification of and access to Legal and other requirements to which Toshiba International Corporation subscribes, and are applicable to Environmental, and Occupational Health and Safety Aspects of its activities and products (Reference 2.16);

4.1.6.6 establishment and maintenance of documented procedures related to identifiable Significant Environmental Aspects and identified Occupational Health and Safety Risks of goods and services to cover situations where their absence could lead to deviations from the QEHS Policy, Objectives and Targets (Reference 2.14 and 2.15). Procedures and requirements are communicated to suppliers and contractors as applicable;

4.1.6.7 stipulating operating criteria in procedures;

4.1.6.8 establishment and maintenance of procedures for the Design of workplace, process, installations, machinery, operating procedures and work organization, including their adaptation to human capabilities, in order to eliminate or reduce Occupational Health and Safety Risks at their source;

4.1.6.9 establishment and maintenance of documented Occupational Health and Safety Objectives at each relevant level and function at Toshiba International Corporation;
4.1.6.10 Records needed to provide evidence Product Realization processes and resulting product meet requirements (Reference 2.17).

4.1.7 Products of Toshiba International Corporation are based on contractual requirements and associated specifications, and are produced in accordance with those requirements. Product Realization planning is in accordance with these requirements. The Output of this planning is the defined process to successfully meet contractual requirements.

4.1.8 HEV/TS16949: Customer requirements and references to its technical specifications shall be included in the planning of product realization as a component of the control plan.

4.1.9 HEV/TS16949: Acceptance criteria shall be defined and approved by the customer. For attribute data sampling, acceptance-level shall be zero defects. (Reference FMC CSR Tables A and B)

4.1.10 HEV/TS16949: Toshiba International Corporation ensures the confidentiality of customer-contracted products and projects under development, and related product information.

4.1.11 HEV/TS 16949: For all product and manufacturing related changes that impact product realization, process control and action plan, including verification and validation activities are defined. The effects of any change, including those changes caused by any supplier, shall be assessed. Compliance with customer requirements is ensured, and changes will be validated and agreement made with the customer before implementation. For proprietary designs, impact on form, fit and function (including performance, and/or durability) shall be reviewed with the customer so that all effects can be properly evaluated. When required by the customer, additional verification/identification requirements, such as those required for new product introduction, shall be met.

5.0 RESPONSIBILITY:

5.1 Product Realization planning is the responsibility of Management, in conjunction with other involved parties, including but not limited to Production and Material Control, Supply Manufacturing Engineering, Quality Control, etc.

6.0 RECORDS:

6.1 Records for Product Realization are defined in associated procedures, check sheets, production schedules, control plans (as applicable), and those maintained electronically on the Toshiba International Corporation Network (Reference 2.17).
1.0 **PURPOSE:**

This Section is to determine, review, and communicate product requirements for Customer Related Processes.

2.0 **REFERENCE DOCUMENTS:**

2.1 QEHS Manual, Section 7, Documentation Requirements
2.2 ISO 9001:2008/ISO/TS16949:2009, Clauses 7.2, 7.2.2.1, 7.2.3.1 and 8.2.1
2.3 ISO 14001:2004, Clause 4.4.3
2.4 OHSAS 18001:2007
2.5 Change Request Procedure – Doc. No. 2P-723-001
2.6 Engineering Change Order Procedure – Doc. No. 2P-737-001
2.7 Internal and External Communication Procedure – Doc. No. 2P-553-001
2.8 Pricing Approval for Quotations – Doc. No. 2P-722-001
2.9 Procedure for Approving Special Projects and Quotes – Doc. No. CQA03.80
2.10 Project Quotation Policy – EDS
2.11 Records Management Procedure – Doc. No. 2P-424-001
2.12 FMC CSR, Clause 4.16, 4.17, 4.18, 4.19
2.13 Customer Claim Handling Procedure – Doc. No. 4P-7517
2.14 Control of Customer Requested Design Changes – Doc. No. 4P-714-1
2.15 Change Point Registration to Customer – Doc. No. 4P-714-3
2.16 RMA Process and Handling Procedure – Doc. No. 108P-830-001

3.0 **DEFINITIONS:**

3.1 See QEHS Manual, Section 21, Glossary (Terms and Definitions) for definitions of italicized terms.
3.2 FMC CSR – Ford Motor Company Customer-Specific Requirements
3.3 FSP – Ford Supplier Portal
3.4 ISO – International Organization for Standardization
3.5 OHSAS – Occupational Health and Safety Advisory Services
3.6 QEHS – Quality, Environmental, Health and Safety
3.7 TS – Technical Specification
3.8 PPAP – Production Part Approval Process
3.9 APQP – Advanced Product Quality Planning

4.0 **QEHS MANAGEMENT SYSTEM REQUIREMENTS:**

4.1 Procedures detailing methods for reviewing proposals and contracts have been established to ensure the capability to meet all Customers specified requirements are implemented (Reference 2.8, 2.9, 2.10, 2.12, 2.14 and 2.15).
4.1.1 Determination of Requirements Related to the Product:

4.1.1.1 Product related requirements are determined at the estimating and proposal stages of Product Realization with Inputs relative to scheduling, material and labor costing, and resource requirements from appropriate Manufacturing or Engineering functions responsible for Product Realization. The product related requirements are finalized at the contract stage and communicated throughout the Product Realization, contract distribution, and contract review processes.

4.1.1.2 Determination of product related requirements include:

- 4.1.1.2.1 Customer specified requirements, including requirements for delivery and post-delivery activities;
- 4.1.1.2.2 requirements not stated by the Customer but necessary for specified use or intended use, where known;
- 4.1.1.2.3 Statutory, Regulatory, and Environmental requirements related to the product;
- 4.1.1.2.4 any additional requirements determined by Toshiba International Corporation (TIC).

4.1.2 Review of Requirements Related to the Product:

4.1.2.1 Requirements related to Toshiba International Corporation’s product are reviewed prior to commitment to supply product to the Customer and ensure:

- 4.1.2.1.1 requirements are adequately defined and documented, and verbal order requirements are confirmed before their acceptance;
- 4.1.2.1.2 any differences in the accepted requirements and those quoted are resolved;
- 4.1.2.1.3 Toshiba International Corporation has the capability to meet defined requirements.

4.1.2.2 Toshiba International Corporation ensures results of Review records and actions arising from the Review are maintained {Reference 2.11 (See 6.0 below)}.

4.1.2.3 Where the customer provides no documentation statement of requirement, customer requirements are confirmed before acceptance.

4.1.2.4 Where product requirements are changed, relevant documents are amended and relevant personnel are made aware of the requirement changes, which are then distributed to the appropriate Manufacturing or Engineering function responsible for Product Realization.

4.1.2.5 Waiving the requirements stated above for a formal review shall require customer authorization.

4.1.3 Customer Communication:

4.1.3.1 Primary Customer communications are handled by Customer Service, Marketing, and Sales relative to product information, inquiries, estimates, proposals, contract review, contracts, order handling, including amendments and contract related feedback, including but not limited to complaints.

4.1.3.2 With regard to Environmental Aspects and Occupational Health and Safety Risks, in relation to the Customer and Customer Related Processes, Management has established and maintains procedures for:
4.1.3.2.1 internal communication between various levels and functions of the Organization (Reference 2.7);

4.1.3.2.2 receiving, documenting, and responding to relevant Environmental, and Occupational Health and Safety communication from external interested parties including but not limited to Customers (Reference 2.7).

4.1.3.3 HEV Plant/FMC CSR: Ford requires all manufacturing sites to report all materials per WSS-M99P999-A1, as noted in PPAP, Ford Specific Instructions. These requirements are detailed on FSP (environmental).

4.1.3.4 HEV Plant/FMC CSR: The customer authorization for waiving formal review may be obtained from the Buyer, and when appropriate, Ford Engineering.

4.1.3.5 HEV Plant/FMC CSR: Manufacturing feasibility reviews, e.g. APQP appendix E, shall include all supplier and Ford Engineering organizations, as appropriate. Product volume change requests from FMC increasing volume by 20% or more over the previously verified volume capability shall require full volume feasibility studies (APQP appendix E, or capacity verification may be required).

4.1.3.6 All necessary information, including data, will be communicated in a customer-specified language and format; e.g. computer-aided design data, electronic data exchange (HEV: Reference FMC CSR 4.19).

4.1.4 Customer Satisfaction:

4.1.4.1 Toshiba International Corporation monitors information related to Customer perception by the following method(s) regarding whether Toshiba International Corporation or Product Group has met Customer Requirements:

4.1.4.1.1 Customer Complaints;

4.1.4.1.2 Customer Satisfaction.

5.0 RESPONSIBILITY:

5.1 Subsections 4.1.1 and 4.1.2 above specify the responsibility for determination and review of requirements related to the product.

5.2 Subsection 4.1.3 above specifies the responsibility for Product Realization related Customer communication.

6.0 RECORDS:

6.1 Results of Review requirements related to the product and actions arising from the Review are recorded and maintained in accordance with Section 7 of this QEHS Management System Manual (Reference 2.11).
1.0 **PURPOSE:**

This Section establishes requirements for Design and Development of product as performed at Toshiba International Corporation (TIC).

2.0 **REFERENCE DOCUMENTS:**

2.1 QEHS Manual, Section 7, Documentation Requirements
2.2 QEHS Manual, Section 10, Customer-Related Processes
2.3 ISO 9001:2008/ISO/TS16949:2009, Clause 7.3 and 7.3.1.1
2.4 ISO 14001:2004, Clause 4.4.6
2.5 OHSAS 18001:2007, Clauses 4.4, 4.3.1 and 4.4.6
2.6 Change Request Procedure – Doc. No. 2P-723-001
2.7 Design Control General Procedure – Doc. No. 2P-731-001
2.8 Design Control New Product Development Procedure – Doc. No. 2P-734-001
2.9 Engineering Change Order Procedure – Doc. No. 2P-737-001
2.10 Product Safety Manual – Doc. No. DOD1000
2.11 Records Management Procedure – Doc. No. 2P-424-001
2.12 FMC CSR, Clauses 4.22, 4.23
2.13 Configuration Management Procedure – Doc. No. 2P-714-001
2.14 Multi-Disciplinary Team Operation – Doc. No. 2P-7311-002
2.15 Control of Customer Requested Design Changes – Doc. No. 4P-714-1
2.16 Internal Change Point Control Procedure – Doc. No. 4P-714-2
2.17 Change Point Registration to Customer Procedure – Doc. No. 4P-714-3
2.18 HEV Notice/Instruction Procedure – Doc. No. 4P-714-4
2.19 HEV QC Notice Procedure – Doc. No. 4P-714-5
2.20 FMEA Procedure – Doc. No. 4P-731
2.21 Special Characteristics Procedure – Doc. No. 4P-7323
2.22 Control Plan – Doc. No. 4P-7511

3.0 **DEFINITIONS:**

3.1 See QEHS Manual, Section 21, Glossary (Terms and Definitions) for definitions of italicized terms.
3.2 FMC CSR – Ford Motor Company Customer-Specific Requirements
3.3 FSP – Ford Supplier Portal
3.4 GPDS – Global Product Development System
3.5 ISO – International Organization for Standardization
3.6 OHSAS – Occupational Health and Safety Advisory Services

This document shall be considered “For Reference Only” when printed as a hardcopy. Revision status must be verified prior to use.
3.7 QEHS – Quality, Environmental, Health and Safety
3.8 SDS – System Design Specification
3.9 TS – Technical Specification
3.10 VDS – Vehicle Design Specification
3.11 FEMA – Failure Mode and Effects Analysis

4.0 QEHS MANAGEMENT SYSTEM REQUIREMENTS:

4.1 Design and Development Planning:

4.1.1 Product Development is planned and controlled through a Design and Development planning process, in which the following is determined:

4.1.1.1 Design and Development stages;
4.1.1.2 Review, Verification, and Validation appropriate to each Design and Development stage;
4.1.1.3 responsibilities and authorities for Design and Development.

4.1.2 Interfaces are managed between different groups involved in Design and Development to ensure effective communication and clear assignment of responsibility.

4.1.2.1 HEV/TS16949: Multidisciplinary Approach
Product realization shall be prepared using multidisciplinary approach (involving design, manufacturing, engineering, quality, production, etc.), including:
- Development/finalization and monitoring of special characteristics
- Development and review of FMEAs including actions to reduce potential risks
- Development and review of control plans

4.1.3 Planning Output is updated as Design and Development progresses.

4.2 Design and Development Inputs:

4.2.1 Inputs relating to product requirements are determined and records maintained {Reference 2.7 and 2.11 (See 6.0 below)}.

4.2.2 Design and Development Inputs include:

4.2.2.1 functional and performance requirements (including reliability of the product over time, availability of service parts, ease of maintenance, etc.);
4.2.2.2 applicable Statutory and Regulatory requirements;
4.2.2.3 where applicable, information derived from previous similar Designs;
4.2.2.4 other requirements essential for Design and Development;
4.2.2.5 Environmental Aspects and Occupational Health and Safety Risks associated with the resulting product or service.
4.2.2.6 HEV/TS16949: Conformity to customer requirements for designation, documentation and control of special characteristics.

4.2.3 These Inputs are reviewed for adequacy to ensure requirements are complete, unambiguous, and not in conflict with each other.
4.3 Design and Development Outputs:

4.3.1 The Outputs of Design and Development are provided in a form enabling Verification against Design and Development Inputs and are approved prior to release.

4.3.2 Design and Development Outputs include:

4.3.2.1 meeting Input requirements for Design and Development;
4.3.2.2 provide appropriate information for Purchasing, Production and Service Provision;
4.3.2.3 contain or reference product acceptance criteria;
4.3.2.4 specify characteristics of the product essential for safe and proper use, preservation and disposal.

4.4 Design and Development Review:

4.4.1 At suitable stages, systematic Design and Development Reviews are performed in accordance with planned arrangements (See 4.1 above):

4.4.1.1 to evaluate the ability of the Design and Development results to fulfill requirements;
4.4.1.2 to identify any problems and propose necessary actions.

4.4.2 Participants in such Reviews include Representatives of functions concerned with Design and Development stage(s) being reviewed. Records of the reviews are maintained (Reference 2.11)

4.4.3 HEV Plant/FMC CSR: GPDS shall be used when reviewing product design and development stages. Information on GPDS is available through FSP.

4.5 Design and Development Verification:

4.5.1 Design and Development Verification is performed in accordance with planned arrangements (See 4.1 above) to ensure Design and Development Outputs have satisfied Design and Development Input requirements. Records of verification results and any necessary actions are maintained (Reference 2.11).

4.5.2 HEV Plant/FMC CSR: Design verification shall be performed to show conformance with the appropriate VDS and SDS. Verification methods shall be recorded with the test results. VDSs and SDSs are available from Ford Engineering.

4.6 Design and Development Validation:

4.6.1 Design and Development Validation is performed in accordance with planned arrangements (See 4.1 above) to ensure the resulting product is capable of meeting specified application requirements or intended use, where known. Wherever practicable, Validation is completed prior to delivery or implementation of the product. Records of Validation results and any necessary actions are maintained (Reference 2.11).

4.7 Control of Design and Development Changes:

4.7.1 Design and Development changes are identified and records maintained. Changes are reviewed, verified, and validated, as appropriate, and approved before implementation. Design and Development Review changes include evaluation of the effect the changes have on constituent parts and product already delivered. Records of Validation and any necessary actions are maintained (Reference 2.11).
5.0 **RESPONSIBILITY:**

5.1 Research and Development is responsible for Design and Development activities of new product development.

5.2 Plant Design Engineering Departments are responsible for Design and Development activities of existing products.

6.0 **RECORDS:**

6.1 Records associated with product Design and Development are maintained (Reference 2.11 above).
1.0 **PURPOSE:**

This Section establishes requirements for verifying purchased material conforms to specified purchasing requirements.

2.0 **REFERENCE DOCUMENTS:**

2.1 QEHS Manual, Section 7, Documentation Requirements
2.3 ISO 14001:2004, Clause 4.4.6
2.4 OHSAS 18001:2007, Clause 4.4.6
2.5 Approved Supplier List (Baan IV)
2.6 Capital Appropriation Procedure – Doc. No. CQA03.40
2.7 Purchase Order Approval Authority Procedure – Doc. No. 2P-742-001
2.8 Supplier Quality Evaluation Procedure – Doc. No. 2P-741-003
2.9 Purchasing Procedure for Outsourced Finished Product – Doc. No. 2P-741-001
2.10 Purchasing Procedure – Doc. No. 2P-740-001
2.11 Records Management Procedure – Doc. No. 2P-424-001
2.12 FMC CSR, Clause 4.28
2.13 Procurement Quality Standard – Doc. No. 4P-741
2.14 Receiving Inspection Procedure – Doc. No. 4P-743
2.15 Supplier Monitoring Procedure – Doc. No. 4P-7432
2.16 Purchasing Procedure – Doc. No. 108P-740-001
2.17 ODM-Purchasing Development – Doc. No. 108S-740-005

3.0 **DEFINITIONS:**

3.1 See QEHS Manual, Section 21, Glossary (Terms and Definitions) for definitions of italicized terms.
3.2 FMC CSR – Ford Motor Company Customer-Specific Requirements
3.3 ISO – International Organization for Standardization
3.4 OHSAS – Occupational Health and Safety Advisory Services
3.5 QEHS – Quality, Environmental, Health and Safety
3.6 TS – Technical Specification
3.7 FMEA – Failure Mode and Effects Analysis

4.0 **QEHS MANAGEMENT SYSTEM REQUIREMENTS:**

4.1 Toshiba International Corporation (TIC) has established and maintains documented procedures which define controls for purchasing of production related product and materials.
4.1.1 Purchasing Process:

4.1.1.1 The Purchasing process ensures purchased material conforms to specified purchasing requirements. The type and extent of control applied to the supplier and the purchased material is dependent upon its effect on subsequent Product Realization or final product.

4.1.1.2 Suppliers are evaluated and selected based on their ability to supply material in accordance with Toshiba International Corporation requirements (Reference 2.8, 2.9 and 2.10). Criteria for selection, evaluation, and re-evaluation of suppliers are established (Reference 2.8).

4.1.1.3 HEV/FMC CSR: When required by the contract with Ford, subcontractor approval shall be obtained from the FMC buyer, and concurred by the STA.

4.1.2 Purchasing Information:

4.1.2.1 Purchasing documents contain data clearly describing material to be purchased including requirements for approval of material, procedures, processes, qualification of personnel and equipment, where applicable (Reference 2.6, 2.7 and 2.8).

4.1.2.2 Purchasing documents, in conjunction with Engineering documents, contain technical requirements, accept/reject criteria, and QEHS Management System requirements, and are provided to Receiving Inspection. The adequacy of specified purchase requirements is ensured through Verification prior to their communication with the supplier.

4.2 Verification of Purchased Material:

4.2.1 Inspection or other activities necessary for ensuring purchased material meets specified purchasing requirements are established and implemented. Where Toshiba International Corporation personnel or Customer intends to perform Verification at the supplier’s facility, the intended Verification arrangements and method of material release in the purchasing information are stated.

4.2.2 Purchase Orders, in conjunction with relevant procedures and specifications, provide information determining the nature, extent, and method of Receiving Inspection as well as for Verification records to ensure no key component is used or processed until it has been Inspected or otherwise verified as conforming to specified requirements.

5.0 RESPONSIBILITY:

5.1 Purchasing is responsible for purchasing materials conforming to specified purchasing requirements.

5.2 Purchasing is responsible for coordinating the evaluation and approval of potential new suppliers and arranging for additions to the Approved Supplier List. They are also responsible for maintaining the Approved Supplier List and performing certain supplier approval processes, such as sending and receiving supplier self-assessments, participating in on-site Audits, and maintaining supplier records.

5.3 Toshiba International Corporation maintains responsibility for ensuring the quality of purchased products from customer-designated sources, including tool/gauge suppliers.

5.4 Purchasing reviews and approves purchasing documents for adequacy of the specified requirements prior to release.

5.5 Receiving Inspection is responsible for Verification of incoming material.

6.0 RECORDS:

6.1 Results of supplier evaluations and any necessary actions arising from the evaluation are maintained (Reference 2.11 above).

6.2 Records of acceptable suppliers have been established and are maintained (Reference 2.11 above).
1.0 **PURPOSE:**

This Section establishes requirements for Production Provision related to the Manufacture, Sales and Service of Industrial Motors, Adjustable Speed Drives, Uninterruptible Power Supplies, Motor Controls, and Distribution Equipment. In addition, we manufacture and sell HEV Motors, sell and support Programmable Logic Controllers (PLC’s), Industrial Plant Systems, Magnetic Flow Meters, and Transportation Equipment.

2.0 **REFERENCE DOCUMENTS:**

2.1 QEHS Manual, Section 7, Documentation Requirements
2.2 QEHS Manual, Section 8, Resource Management
2.3 QEHS Manual, Section 10, Customer-Related Processes
2.4 QEHS Manual, Section 14, Control of Monitoring and Measuring Devices
2.5 QEHS Manual, Section 15, Monitoring, Measurement, Analysis, Improvement and Evaluation of Compliance
2.6 ISO 9001:2008/TS16949:2009, Clauses 7.5, 7.5.1.1, 7.5.1.2, 7.5.1.3, 7.5.1.4, 7.5.1.5, 7.5.3.1, 7.5.4.1, 7.5.5.1
2.7 ISO 14001:2004, Clauses 4.3.2, 4.4.5 and 4.4.6
2.8 OHSAS 18001:2007, Clause 4.3.2
2.9 Capital Appropriation Procedure – Doc. No. CQA03.40
2.10 Customer Supplied Product Procedure – Doc. No. 2P-754-001
2.11 Laws and Regulations Procedure – Doc. No. 2P-560-003
2.12 Product Identification and Traceability Procedure – Doc. No. 2P-753-002
2.13 Production Cycle – Doc. No. CQA02.80
2.14 Records Management Procedure – Doc. No. 2P-424-001
2.15 Shipping – Doc. No. CQA02.30
2.16 FMC CSR, Clause 4.31, 4.34
2.17 Incoming receipt of product and Material Procedure - Doc. No. 2P-754-001
2.18 Cycle Count procedure – Doc. No. 4P-7551-2
2.19 Verification of Job Set ups – Doc. No. 4P-7513
2.20 Material replenishment from Okanella Warehouse to HEV plant– Doc. No. 4P-7551-1
2.21 Facility Maintenance Procedure – Doc. No. 4P-630
2.22 Traceability control procedure – Doc. No. 4P-7513
2.23 Product Identification – Doc. No. 4P-753

3.0 **DEFINITIONS:**

3.1 See QEHS Manual, Section 21, Glossary (Terms and Definitions) for definitions of italicized terms.
3.2 FMC CSR – Ford Motor Corporation Customer-Specific Requirements
3.3 ISO – International Organization for Standardization
3.4 MMOG – Material Management Operation Guideline
3.5 MP&L – Material Planning and Logistics
3.6 OHSAS – Occupational Health and Safety Advisory Services
3.7 QEHS – Quality, Environmental, Health and Safety
3.8 TS – Technical Specification
3.9 CTDP – Client Test Data Program

4.0 QEHS MANAGEMENT SYSTEM REQUIREMENTS:

4.1 Control of Production Provision:

4.1.1 Production Provision is planned and performed under controlled conditions which include, as applicable:

4.1.1.1 availability of information describing characteristics of the product (Reference 2.3);
4.1.1.2 availability of documented Procedures and Work Instructions identifying the manner of production where the absence of such Procedures or Work Instructions could adversely affect Quality, Environmental Impact, or Occupational Health and Safety (Reference 2.1);
4.1.1.3 use of suitable equipment and working Environment (Reference 2.3 and 2.13);
4.1.1.4 availability and use of Monitoring and Measuring Devices (Reference 2.5);
4.1.1.5 compliance with reference Standards/ Codes, Quality Plans and/or documented Procedures;
4.1.1.6 monitoring and measurement of suitable process parameters and product characteristics (Reference 2.4 and 2.21);
4.1.1.7 criteria for workmanship is available in a clear practical manner (e.g. representative samples, written standards, or illustrations);
4.1.1.8 release, delivery, and post-delivery activities (References 2.1, 2.3 and 2.5);
4.1.1.9 suitable equipment maintenance to ensure continued process capability (Reference 2.21);
4.1.1.10 approval of processes and equipment, as appropriate;
4.1.1.11 establishment and maintenance of a procedure to identify and have access to Legal and other subscribed requirements applicable to Environmental Aspects, and Occupational Health and Safety Risks of production activities (Reference 2.11);
4.1.1.12 identification of operations and activities associated with identified Significant Environmental Aspects, and Occupational Health and Safety Risk in line with the QEHS Policy, Objectives and associated Targets.
4.1.1.13 HEV Plant/TS16949: control plans at the system, subsystem, component and/or material level, for the product supplied, including those for processes producing bulk materials as well as parts.
4.1.1.14 HEV Plant/TS16949: control plan for pre-launch and production that take into account the design FMEA and manufacturing process FMEA outputs.
4.1.1.15 HEV Plant/TS16949: Control plans are reviewed and updated when any change occurs affecting product, manufacturing process, measurement, logistics, supply sources or FMEA.
4.1.2 The requirement for any qualification of process operations, equipment, and personnel is specified in written procedures.

4.2 **Validation of Processes for Production Provision:**

4.2.1 Processes for Production Provision are validated where subsequent monitoring or measurement cannot verify the resulting Output. This includes any processes where deficiencies become apparent only after the product is in use or the service has been delivered. Validation demonstrates the ability of these processes to achieve planned results.

4.2.2 Established arrangements for these processes include, as applicable:

4.2.2.1 defined criteria for review and approval of the processes;
4.2.2.2 approval of equipment and qualification of personnel;
4.2.2.3 use of specific methods and procedures;
4.2.2.4 requirements for records (Reference 2.3);
4.2.2.5 re-validation of the process when a process parameter is changed (i.e. material, equipment, initial run of a job, material changeover, or job change, etc.).

4.2.3 Toshiba International Corporation has identified key process equipment and provide resources for machine/equipment maintenance and develop an effective planned total preventive maintenance system, which includes:

- Planned maintenance activities
- Packaging and preservation of equipment, tooling and gauging
- Availability of replacement parts for key manufacturing equipment
- Documenting, evaluating and improving maintenance objectives

4.2.4 Toshiba International Corporation utilizes preventive and predictive maintenance methods to continually improve the effectiveness and the efficiency of production equipment.

- This includes timely review of planned maintenance activities and a documented action plan, included in the Management Review process, to address any backlog.
- Predictive maintenance requires studies to predict maintenance requirements (Statistical Process Control study, etc.) and consideration of cost of quality prior to implementation.

4.2.5 Toshiba International Corporation has determined resources for tool and gauge design, fabrication and verification activities, as well as a system for production tooling management, including:

- Maintenance and repair facilities and personnel
- Storage and recovery
- Set-up
- Tool-change programs for perishable tools
- Tool design modification documentation, including engineering change level
- Tool modification and revision to documentation
- Tool identification, defining the status, such as production, repair or disposal
4.2.6 Job set-ups shall be verified whenever performed, such as an initial run of a job, material changeover, job change. The organization shall use statistical methods of verification where applicable.

4.2.7 Documented work instructions shall be prepared for all employees having responsibilities for the operation of processes that impact conformity to product requirements. These instructions shall be accessible for use at the work-station. These instructions shall be derived from sources such as the quality plan, the control plan and the product realization process.

4.2.8 Operators shall use the most current work instructions, unless otherwise authorized in writing.

4.3 **Identification and Traceability:**

4.3.1 Toshiba International Corporation (TIC) maintains Systems and Procedures for identifying product and material by suitable means (Reference 2.12). Suitable identification from receipt, during all stages of production, storage, and delivery to the Customer is maintained.

4.3.2 Where and to the extent traceability is a specified Customer Requirement, Toshiba International Corporation has established and maintains procedures for unique identification of product and material (Reference 2.12). This identification is recorded (Reference 2.14 (See 6.0 below)).

4.4 **Customer Property:**

4.4.1 Toshiba International Corporation has established and maintains documented procedures to identify, verify, protect, and safeguard Customer Property; and for storage, and maintenance of Customer Supplied Property which are provided for incorporation into supplies of the facilities or related activities (Reference 2.10).

4.4.2 Customer Supplied Product, which falls under the procedure (Reference 2.10), which is lost, damaged, or is found to be unsuitable for use is recorded and reported to the Customer for disposition (Reference 2.3 and 2.10).

4.4.3 HEV Plant/TS16949: Customer-owned tools, manufacturing, test, inspection tooling and equipments are permanently marked so that the ownership of each item is visible, and can be determined.

4.5 **Preservation of Product:**

4.5.1 Toshiba International Corporation maintains Preservation of Product and materials during internal processing, and delivery to the intended destination. This preservation includes identification, handling, packaging, storage and protection of all tangible aspects of our product. Preservation also applies to the constituent parts of the product.

4.5.2 Toshiba International Corporation assesses the condition of product in stock at planned intervals in order to detect deterioration, as well as use an inventory management system to optimize inventory turn-over time and assure stock rotation. Obsolete products are controlled in a similar manner to nonconforming product.

4.5.3 HEV/CSR: Toshiba International Corporation meets all logistics requirements as specified by MP&L, compliance to MMOG, including:

- Annual assessment
- Adherence to customer delivery rating requirements
- Part identification and tracking
- Lot traceability through shipping
- Prevention of damage or deterioration
- Maintenance of returnable dunnage
Use of customer packaging requirements from 1121R

4.6 **Operational Control:**

4.6.1 Toshiba International Corporation identifies operations and activities associated with the identified Significant Environmental or Occupational Health and Safety Aspects. Toshiba International Corporation plans these activities, including maintenance, to ensure they are performed under specified conditions by:

4.6.1.1 establishing and maintaining documented procedures to cover situations where their absence could lead to deviations from the QEHS Policy, Objectives and Targets;
4.6.1.2 stipulating operating criteria in the procedures;
4.6.1.3 establishing and maintaining procedures related to the identifiable Significant Environmental and Occupational Health and Safety Aspects and Risk of Hazards associated with goods and services used by the Organization and communicating relevant procedures and requirements to suppliers and contractors.

5.0 **RESPONSIBILITY:**

5.1 Assembly Departments are primarily responsible for control of handling and storage of materials, and packaging.
5.2 Manufacturing and Material Control are responsible for product preservation, as defined in 4.5 above.
5.3 The Customer Service Manager is responsible for Shipping.
5.4 Production Engineering is responsible for Validation of Processes. The responsibility for the control of Customer Supplier Product is identified in the procedure (Reference 2.10).
5.5 Manufacturing Engineering is responsible for Validation of production processes.
5.6 Quality Control is responsible for monitoring and measurement, identification, and traceability.
5.7 Each Manufacturing facility is responsible for Operational Control with respect to the Environment and Occupational Health and Safety.

6.0 **RECORDS:**

6.1 Records of Customer Supplied Product which is lost, damaged, or otherwise found unsuitable for use are maintained (Reference 2.3 above).
1.0 **PURPOSE:**

This Section establishes requirements for monitoring and measuring, and the Control of Monitoring and Measuring Devices needed to provide evidence of conformity of product, materials, and Environmental activities to determined requirements.

2.0 **REFERENCE DOCUMENTS:**

2.1 QEHS Manual, Section 7, Documentation Requirements
2.2 QEHS Manual, Section 10, Customer-Related Processes
2.3 ISO 9001:2008/ISO/TS16949:2009, Clause 7.6, 7.6.1, 7.6.2, 7.6.3.1
2.4 ISO 14001:2004, Clause 4.5.1
2.5 OHSAS 18001:2007
2.6 Calibration, Control of Inspection, Measuring and Test Equipment Procedure – Doc. No. 2P-760-001
2.7 Monitoring and Measurement of QEHS Performance Procedure – Doc. No. 2P-840-001
2.8 Records Management Procedure – Doc. No. 2P-424-001
2.9 FMC CSR, Clause 4.35, 4.36
2.10 Facility Maintenance and Jigs and Tools Control Procedure – Doc. No. 4P-630
2.11 Calibration Control of IM&TE Procedure – Doc. No. 4P-760
2.12 Measurement System Analysis Procedure – Doc. No. 4P-761
2.13 ISO/IEC 17025:2005, Clause 5.6.2.2
2.14 Validation Test QC Procedure – Doc. No. 9P-736-001

3.0 **DEFINITIONS:**

3.1 See QEHS Manual, Section 21, Glossary (Terms and Definitions) for definitions of italicized terms.
3.2 FMC CSR – Ford Motor Corporation Customer-Specific Requirements
3.3 ISO – International Organization for Standardization
3.4 OHSAS – Occupational Health and Safety Advisory Services
3.5 QEHS – Quality, Environmental, Health and Safety
3.6 TS – Technical Specification
3.7 CTDP – Client Test Data Program

4.0 **QEHS MANAGEMENT SYSTEM REQUIREMENTS:**

4.1 Monitoring and measurement to be undertaken and monitoring and measuring devices needed to provide evidence of product, process and material conformity to determine requirements have been determined (Reference 2.6).

4.2 Processes have been established to ensure monitoring and measurement can be performed, and are performed, in a manner consistent with monitoring and measurement requirements (Reference 2.7).
4.3 Where necessary, to ensure valid results, measuring equipment is:

4.3.1 calibrated or verified at specified intervals, or prior to use, against measurement standards traceable to International or National Measurement Standards. Where no such standards exist, the basis used for calibration or verification is recorded;

4.3.2 adjusted or re-adjusted as necessary;

4.3.3 identified to enable calibration status to be determined;

4.3.4 safeguarded from adjustments that would invalidate measurement results;

4.3.5 protected from damage and deterioration during handling, maintenance and storage.

4.4 In addition, the validity of previous measuring results are assessed and recorded when the equipment is found not to conform to requirements, and appropriate action is taken regarding the equipment and any product and/or materials affected.

4.5 When used in monitoring and measurement of specified requirements, the ability of computer software to satisfy the intended application is confirmed prior to initial use and reconfirmed as necessary.

4.6 HEV Plant/TS16949: Measurement System Analysis (MSA) is conducted to analyze the variation present in the results of each type of measuring and test equipment system. This requirement shall apply to measurement systems referenced in the control plan. The analytical methods and acceptance criteria used shall conform to those in customer reference manuals on MSA.

4.7 HEV Plant/TS16949: The customer is to be notified if suspect product or material has been shipped due to inaccurate monitoring and measuring devices.

4.8 HEV Plant/TS16949: the calibration lab at TIC is to have a defined scope that includes its capability to perform the required calibration services. The lab will specify and implement, as a minimum, technical requirements for:

- Adequacy of the procedures used in the lab,
- Competency of the lab personnel,
- Testing of the product,
- Capability to perform calibrations correctly, traceable to the relevant process standards,
- Review of the related records.

4.9 HEV Plant/TS16949: For calibrations performed by service providers, the provider is to have a defined scope that includes its capability to perform the required calibration services and be approved prior to use. Acceptance criteria is based on the latest ISO/IEC 17025 (or national equivalent).

4.10 HEV Plant/TS16949: When a qualified lab is not available for a given piece of equipment, calibration services may be performed by the equipment manufacturer. In such cases, TIC will ensure that the requirements listed in 4.7 above have been met.

4.11 PEP Validation Lab/CTDP system: For testing laboratories, equipment with measuring functions used, unless it has been established that the associated contribution from the calibration contributes little to the total uncertainty of the test result. When this situation arises, the laboratory shall ensure that the equipment used can provide the uncertainty of measurement needed.

4.12 PEP Validation Lab/CTDP system: Where traceability of measurements to SI units is not possible and/or not relevant, the same requirements for traceability to, for example, certified reference materials, agreed methods and/or consensus standards, are required as for calibration.
5.0 RESPONSIBILITY:

5.1 Quality Control is responsible for overseeing calibration requirements at Toshiba International Corporation (TIC).

5.2 The Maintenance Department is responsible for overseeing calibration requirements at Toshiba International Corporation for equipment used to verify Environmental and Occupational Health and Safety related requirements as applicable (Reference 2.6).

5.3 The Manufacturing Departments are responsible for using calibrated equipment to verify product or process characteristics.

5.4 The Water and Wastewater Contractor is responsible for overseeing calibration requirements at Toshiba International Corporation for equipment used to verify operational and permit requirements of the water supply system and the wastewater treatment system.

6.0 RECORDS:

6.1 Calibration records for and Verification results are maintained (Reference 2.6 and 2.8).

6.2 HEV/TS16949: Records of calibration are to include:

- Equipment identification, including the measurement standards against which the equipment is calibrated,
- Revisions following engineering changes,
- Any out-of-specification readings as received for calibration/verification,
- An assessment of the impact of out-of-specification condition,
- Statements of conformity to specification after calibration/verification,
- Notification to the customer if suspect product or material has been shipped
1.0 PURPOSE:

This Section establishes requirements for Monitoring, Measurement, Analysis and Improvement of the QEHS Management System and associated processes.

2.0 REFERENCE DOCUMENTS:

2.1 QEHS Manual, Section 6, Management Review
2.2 QEHS Manual, Section 7, Documentation Requirements
2.3 QEHS Manual, Section 9, Product Realization
2.4 QEHS Manual, Section 18, Improvement
2.5 ISO 9001:2008/ISO/TS16949:2009, Clauses 8.1, 8.1.1, 8.1.2, 8.2, 8.2.3.1, 8.2.4.1
2.6 ISO 14001:2004, Clauses 4.4.7, 4.5.1, 4.5.4 and 4.4.6
2.7 OHSAS 18001:2007, Clauses 4.4.7, 4.5.1, 4.5.2, 4.5.4 and 4.5.5
2.8 Corrective/Preventive Action Procedure – Doc. No.2P-850-001
2.9 Emergency Preparedness and Response Procedure
2.10 Environmental Aspects Identification, Management and Performance Procedure
2.11 Incoming Receipt of Material Procedure – Doc. No. 2P-754-001
2.12 Internal Audit for Environmental and Safety Compliance Procedure
2.13 Internal Audit Procedure – Doc. No. 2P-822-001
2.15 Records Management Procedure – Doc. No. 2P-424-001
2.16 FMC CSR, Clause 4.40, 4.41
2.17 Identification of Statistical Tools Procedure – Doc. No. 2P-811-001
2.18 QMS Audit Procedure – Doc. No. 4P-8221
2.19 Manufacturing Process Audit Procedure – Doc. No. 4P-8222
2.20 Product Audit Procedure – Doc. No. 4P-8223
2.21 Monitoring and Measurement of Processes Procedure – Doc. No. 4P-823
2.22 Product Release Procedure – Doc. No. 4P-824-1
2.23 Continual Improvement Procedure – Doc. No. 4P-851

3.0 DEFINITIONS:

3.1 See QEHS Manual, Section 21, Glossary (Terms and Definitions) for definitions of italicized terms.
3.2 ES – Engineering Specification
3.3 FMC CSR – Ford Motor Corporation Customer-Specific Requirements
3.4 ISO – International Organization for Standardization

This document shall be considered “For Reference Only” when printed as a hardcopy. Revision status must be verified prior to use.
3.5 OHSAS – Occupational Health and Safety Advisory Services
3.6 OH&S – Occupational Health and Safety
3.7 PFMEA – Process Failure Mode and Effect Analysis
3.8 QEHS – Quality, Environmental, Health and Safety
3.9 STA – Supplier Technical Assistance
3.10 TS – Technical Specification

4.0 QEHS MANAGEMENT SYSTEM REQUIREMENTS:

4.1 General:

4.1.1 Toshiba International Corporation (TIC) continually monitors its performance by measuring and evaluating production processes, determining capability of processes, and whether Objectives have been achieved to the Customer and other interested parties’ satisfaction. Process data is collected and analyzed based on the process control needs.

4.1.2 HEV/TS16949: Appropriate statistical tools for each process shall be determined during advance quality planning and included in the control plan.

4.1.3 HEV/TS16949: Basic statistical concepts, such as variation, control (stability), process capability and over-adjustment shall be understood and utilized. (Reference QEHS Section 8)

4.1.4 Results are provided as Inputs to Management and Supervision to provide information for improving Organization performance.

4.1.5 Monitoring, measurement, analysis and improvement processes are needed to demonstrate product conformity and ensure QEHS Management System conformity. This includes determination of applicable methods, including statistical techniques, as applicable, and the extent of their use (Reference 2.4).

4.1.6 Audit Results, Non-conformances, Corrective and Preventive Actions, and Customer Feedback are used to continually improve QEHS Management System effectiveness.

4.2 Customer Satisfaction:

4.2.1 As one of the QEHS Management System performance measurements, information relating to Customer Perception regarding whether the Organization has met Customer Requirements is monitored. Methods for obtaining and using this information have been determined and include:

4.2.1.1 Customer Complaints (on-line and manual);
4.2.1.2 Customer Scorecard;
4.2.1.3 Customer Feedback (E-mail, letters, phone calls);
4.2.1.4 continued repetitive purchases;
4.2.1.5 direct contact with Customers;
4.2.1.6 Customer Audits;
4.2.1.7 Customer Corrective Action Requests;
4.2.1.8 Customer Recognition;

4.3 Internal Audit:

4.3.1 Internal Audits are conducted at planned intervals to determine whether the QEHS Management System (Reference 2.12 and 2.13):

4.3.1.2 is properly and effectively implemented and maintained.

4.3.2 Information regarding results of QEHS Management System Audits is provided to Sr. Management for review (Reference 2.1).

4.3.3 An Audit Program is planned, taking into consideration the status and importance of processes and areas to be audited, including Environmental, and Occupational Health and Safety Risk importance, as well as results of previous Audits. Audit criteria, scope, frequency, and methods as well as responsibilities and requirements for conducting Audits, and reporting of results are defined (Reference 2.13 and 2.12). Selection of Auditors and conducting Audits ensure objectivity and impartiality of the Audit process. For ISO:9001, Auditors do not Audit their own work, or any other area where there may be a conflict of interest.

4.3.4 Management responsible for the area being audited ensures actions are taken without undue delay to eliminate detected non-conformities and their causes. Follow-up activities include verification of actions taken and reporting of verification results. Follow-up Audits are performed, as necessary, to verify and record possible Corrective and Preventive Actions have been completed and are effective (Reference 2.8).

4.4 Monitoring and Measurement of QEHS Processes:

4.4.1 Suitable methods for monitoring and, where applicable, measurement of the QEHS Management System processes are applied within Toshiba International Corporation operations to demonstrate the ability of business processes to achieve planned results. When planned results are not achieved, appropriate Corrective Action is taken.

4.4.2 Documented procedures to monitor and measure, on a regular basis, the key characteristics of operations and activities having a Significant Environment or Occupational Health and Safety Impact have been established and are maintained (Reference 2.14). Recorded information is included to track performance, relevant operational controls, and conformance with the QEHS Policy, Objectives and associated Targets. In addition, Toshiba International Corporation has established and maintains a documented procedure for periodically evaluating compliance with relevant Environmental, and Occupational Health and Safety Legislation and Regulations.

4.4.3 Emergency Preparedness and Response plans and procedures are reviewed and revised, where necessary, and in particular after the occurrence of accidents or emergency situations. These procedures are periodically tested (Reference 2.9).

4.4.4 Statistical techniques and other metrics, as applicable, are used to establish, monitor, control and improve processes, and to verify process capability for critical variables and product characteristics (Reference 2.4).

4.4.5 Toshiba International Corporation has also established procedures to monitor and measure Occupational Health and Safety performance on a regular basis. These procedures provide for:

4.4.5.1 monitoring the extent of which Occupational Health and Safety Objectives are met;

4.4.5.2 proactive measures of performance to monitor compliance with OH&S and QEHS requirements, operational criteria, and applicable Legislation and Regulatory requirements;

4.4.5.3 reactive measures of performance to monitor accidents, ill health, incidents (including near-misses) and other historical evidence of deficient OH&S performance;
4.4.5.4 recording monitoring and measurement data and results sufficient to facilitate subsequent Corrective and Preventive Action analysis.

4.4.6 Where monitoring equipment is required for Environmental and Occupational Health and Safety performance measurement and monitoring, Toshiba International Corporation has established and maintains procedures for calibration and maintenance of such equipment. Records of calibration, maintenance activities, and results are retained.

4.5 Monitoring and Measurement of Product and Material:

4.5.1 Product characteristics, to verify product requirements have been met, are monitored and measured. This is performed at appropriate stages of the Product Realization process in accordance with planned arrangements (Reference 2.3).

4.5.2 Evidence of conformity with acceptance criteria is maintained {Reference 2.3 (See 6.0 below)}.

4.5.3 These records indicate the person(s) authorizing release of product.

4.5.4 Product release and delivery do not proceed until all planned arrangements have been satisfactorily completed, unless otherwise approved by a relevant authority, and where applicable by the Customer (Reference 2.3).

4.5.5 Toshiba International Corporation Inspects and/or Tests all products and materials in accordance with documented procedures and established Quality Plans prior to use (Receiving Inspection), during manufacture (In-process Inspection), and prior to shipment (Final Inspection) to achieve conformance verification to Quality Requirements (Reference 2.4).

4.5.6 HEV Plant/TS16949: For any characteristics that are either not statistically capable or are unstable, a reaction plan is initiated from the control plan, which includes containment of product and 100% inspection as appropriate. Specific timing and assigned responsibilities are indicated until process becomes stable and capable. The plans are to be reviewed with and approved by the customer when so required.

4.5.7 HEV Plant/FMC CSR: If product does not meet specification, production shipments are stopped immediately and containment actions are taken. STA and direct customer facility is notified immediately, and test failure are analyzed, determined, corrected, and verified, at which point shipments may be resumed. Suspect products are not shipped without sorting or reworking to eliminate the cause of failure.

4.5.8 HEV Plant/FMC CSR: Product Validation Engineering Specification testing frequency requirements shall be clearly noted in the Control Plan and PFMEA. Any revisions to these frequencies require Ford Engineering approval and STA concurrence.

4.5.9 Records of Inspections and Tests performed are maintained as stated in these referenced procedures (Reference 2.3).

4.5.10 HEV Plant/TS16949: Records of significant process events such as tool change, machine repair or any process changes and their effective dates are recorded.

4.5.11 HEV Plant/TS16949: A layout inspection and a functional verification to applicable customer engineering material and performance standards are performed for each product as specified in the control plans. Results are readily available for customer review.

4.5.12 Ensuring product conformity to requirements is demonstrated by:

4.5.12.1 Customer Feedback;

4.5.12.2 Non-conformance analysis based on reject rates;

4.5.12.3 Customer specific product Audits as applicable;
4.5.12.4 Warranty Feedback;
4.5.12.5 Identification of opportunities for improvement through monthly Quality Meetings and associated analysis of non-conforming data.

5.0 RESPONSIBILITY:

5.1 Responsibility for monitoring, measurement, analysis and improvement does not reside with any specific Department or person within Toshiba International Corporation but with affected Department Managers, Supervisors or associated personnel.

5.2 All employees are responsible for ensuring Customer Satisfaction.

5.3 Management and Supervision are responsible for monitoring and measurement of processes.

6.0 RECORDS:

6.1 Required records are listed in the associated procedures. Records associated with Internal QEHS Management System Audits are defined (Reference 2.12 and 2.13).

6.2 All records are maintained (Reference 2.16).
1.0 **PURPOSE:**

This Section defines the QEHS Management System requirements for Control of Non-conforming Product and Material.

2.0 **REFERENCE DOCUMENTS:**

2.1 QEHS Manual, Section 7, Documentation Requirements
2.2 ISO 9001:2008/ISO/TS16949:2009, Clause 8.3, 8.3.1, 8.3.2, 8.3.3, and 8.3.4
2.3 ISO 14001:2004, Clause 4.5.2
2.4 OHSAS 18001:2007
2.5 Control of Non-conforming Product Procedure – Doc. No. 2P-830-001
2.6 Corrective/Preventive Action Procedure – Doc. No. 2P-850-001
2.7 Records Management Procedure – Doc. No. 2P-424-001
2.8 FMC CSR, Clause 4.44 and 4.45
2.9 Nonconformance Product Control Procedure – Doc. No. 4P-830

3.0 **DEFINITIONS:**

3.1 See QEHS Manual, Section 21, Glossary (Terms and Definitions) for definitions of italicized terms.
3.2 FMC CSR – Ford Motor Company Customer-Specific Requirements
3.3 ISO – International Organization for Standardization
3.4 OHSAS – Occupational Health and Safety Advisory Services
3.5 QEHS – Quality, Environmental, Health and Safety
3.6 TS – Technical Specification

4.0 **QEHS MANAGEMENT SYSTEM REQUIREMENTS:**

4.1 General:

4.1.1 Incoming raw materials, in-process materials, and finished product not conforming to requirements are identified in order to avoid their unintended use during production operations or distribution to the Customer. Controls and related responsibilities and authorities for handling and investigating non-conformances as well as for dealing with non-conforming product and material are defined in documented procedures (Reference 2.5, 2.6, 2.7, and FMC CRF 4.44).

4.1.2 Included with the above is taking of action to mitigate any impacts caused and for initiating and completing Corrective and Preventive Action.

4.1.1.1 This control provides for identification, documentation, evaluation, segregation (where practical), and disposition of non-conforming product and material, as well as for notification to functions concerned.

4.1.1.2 Non-conforming product or material is dealt with in one or more of the following ways (Reference 2.6):

4.1.1.2.1 taking action to eliminate the detected non-conformity;
### Control of Non-conforming Product and Material

| 4.1.1.2.2 | reworked to meet specifications; |
| 4.1.1.2.3 | authorizing its use, release or acceptance under Concession by a relevant authority and, where applicable, by the Customer; |
| 4.1.1.2.4 | regraded for alternate applications; |
| 4.1.1.2.5 | rejected as scrap to be moved off-site; |
| 4.1.1.2.6 | taking action to preclude its original intended use or application. |

**4.1.1.3** HEV Plant/FMC CSR: Any non-conforming product or process output is analyzed using the 8D methodology to ensure root cause correction and problem prevention; unless an alternate methodology is approved in writing by the STA.

**4.1.1.4** HEV Plant/FMC CSR: Ford approval is required before the use or implementation of a non-conforming or changed process. Such process change authorization is obtained through the Supplier Request for Engineering Approval (SREA) and PPAP process.

**4.1.1.5** When non-conforming product is corrected, it is re-verified to demonstrate conformity to requirements.

**4.1.1.6** HEV Plant/TS16949: Product with unidentified or suspect status are classified and treated as nonconforming product.

**4.1.1.7** HEV Plant/TS16949: Instructions for rework, including re-inspection requirements, are readily available to and utilized by the appropriate personnel.

**4.1.1.8** Records of the nature of non-conformities and any subsequent actions taken, including Concessions obtained, are maintained (Reference 2.8).

**4.1.1.9** When non-conforming product or material is corrected, it is subject to re-verification to demonstrate conformity to the requirements. When non-conforming product or material is detected after delivery or use has started, action is taken which is appropriate to the effects, or potential effects, of the non-conformity.

**4.1.1.10** HEV Plant/TS16949: Customers are informed promptly in the event that nonconforming product has been shipped.

**4.1.1.11** HEV Plant/TS16949: Customer concession or deviation permit is obtained prior to further processing whenever the product or manufacturing process is different from that which is currently approved. Record is maintained to show expiration date or quantity authorized. Compliance is ensured with the original or superseding specifications and requirements when the authorization expires. Material shipped on an authorization is properly identified on each shipping container.

### 5.0 RESPONSIBILITY:

**5.1** Responsibility and authority for disposition of non-conforming product or material as well as the responsibilities and methods for material review and authorization are defined (Reference 2.8).

### 6.0 RECORDS:

**6.1** The nature of non-conformities and any subsequent actions taken, including Concessions obtained, are documented and maintained (Reference 2.8).
1.0 **PURPOSE:**

This Section of the QEHS Management System Manual establishes requirements for Analysis of Data.

2.0 **REFERENCE DOCUMENTS:**

2.1 QEHS Manual, Section 10, Customer-Related Processes
2.2 QEHS Manual, Section 15, Monitoring, Measurement, Analysis, Improvement and Evaluation of Compliance
2.3 ISO 9001:2008/ISO/TS16949:2009, Clause 8.4, 8.4.1
2.4 ISO 14001:2004
2.5 OHSAS 18001:2007, Clause 4.5.3.2
2.6 Monitoring and Measurement of QEHS Performance Procedure – Doc. No. 2P-840-001
2.7 Records Management Procedure – Doc. No. 2P-424-001
2.8 Internal Audit Procedure – Doc. No. 2P-822-001
2.9 Internal Audit for Environmental Health and Safety Compliance Procedure
2.10 Management Review Procedure – Doc. No. 2P-560-002
2.11 Corrective/Preventive Action Procedure – Doc. No. 2P-850-001
2.12 Purchasing – Supplier Quality Evaluation Procedure – Doc. No. 2P-741-003
2.13 QMS Audit Procedure – Doc. No. 4P-8221
2.14 Manufacturing Process Audit Procedure – Doc. No. 4P-8222
2.15 Product Audit Procedure – Doc. No. 4P-8223

3.0 **DEFINITIONS:**

3.1 See QEHS Manual, Section 21, Glossary (Terms and Definitions) for definitions of italicized terms.
3.2 ISO – International Organization for Standardization
3.3 OHSAS – Occupational Health and Safety Advisory Services
3.4 QEHS – Quality, Environmental, Health and Safety
3.5 TS – Technical Specification

4.0 **QEHS MANAGEMENT SYSTEM REQUIREMENTS:**

4.1 Appropriate data is determined, collected, and analyzed to demonstrate the suitability and effectiveness of the QEHS Management System and to evaluate where Continual Improvement of QEHS Management System effectiveness can be made. Data generated as a result of monitoring and measurement or from other relevant sources are evaluated for opportunities of Continual Improvement of the QEHS Management System. The types of data include, but are not limited to:

4.1.1 Customer Satisfaction;
4.1.2 findings from Internal and External Audits (Reference 2.8 and 2.9);
4.1.3 In-process performance measurements;
4.1.4 results from Management Reviews (Reference 2.10);
4.1.5 Customer Feedback (Complaints);
4.1.6 conformance to product requirements (Reference 2.1);
4.1.7 characteristics and trends of processes and products including opportunities for Preventive and Corrective Action (Reference 2.11);
4.1.8 Supplier performance (Reference 2.13);
4.1.9 Environmental, and Occupational Health and Safety performance measurement and monitoring.

4.2 Compilation of the Analysis of Data is found in, but not limited to, the following:
   4.2.1 Internal and External Audit Reports;
   4.2.2 Reject Material Report (RMR);
   4.2.3 Management Review Minutes;
   4.2.4 Corrective and Preventive Action.

4.3 HEV Plant/TS16949: Trends in quality and operational performance are compared with progress toward objectives and lead to action to support the following:
   4.3.1 Development of priorities for prompt solutions to customer-related problems;
   4.3.2 Determination of key customer-related trends and correlation for status review, decision making and longer term planning;
   4.3.3 An information system for the timely reporting of product information arising from usage.

5.0 RESPONSIBILITY:

5.1 Responsibility for Analysis of Data does not reside with any specific Department or person within Toshiba International Corporation (TIC) but with affected Department Managers, Supervisors or associated Quality, Environmental, and/or Occupational Health and Safety personnel.

6.0 RECORDS:

6.1 A variety of records are generated as a result of analysis activities (See Subsection 4.0 above).
6.2 Records are identified in the Records Management Procedure (Reference 2.7).
1.0 **PURPOSE:**

This Section establishes requirements for ensuring Continual Improvement of QEHS Management System effectiveness.

2.0 **REFERENCE DOCUMENTS:**

2.1 QEHS Manual, Section 7, Documentation Requirements
2.2 ISO 9001:2008/ISO/TS16949:2009, Clause 8.5, 8.5.1.2 and 8.5.2.4
2.3 ISO 14001:2004, Clause 4.3.3
2.4 OHSAS 18001:2007, Clause 4.3.3
2.5 Corrective Action Procedure – 2P-852
2.6 Internal Audit for Environmental, Health and Safety Compliance Procedure
2.7 Internal Audit Procedure – 2P-822
2.8 Preventive Action Procedure – 2P-853
2.9 Records Management Procedure – 2P-424
2.10 QMS Audit Procedure – 4P-8221
2.11 Manufacturing Process Audit Procedure – 4P-8222
2.12 Product Audit Procedure – 4P-8223
2.13 Continual Improvement Procedure – 4P-851
2.14 Innovation and Continual Improvement Procedure– 2P-851
2.15 ISO/IEC 17025:2005, Clause 4.11.1, 4.11.2, 4.11.3, 4.11.4
2.16 Validation Test QC Procedure - 9P-736-001

3.0 **DEFINITIONS:**

3.1 See QEHS Manual, Section 21, Glossary (Terms and Definitions) for definitions of italicized terms.
3.2 ISO – International Organization for Standardization
3.3 OHSAS – Occupational Health and Safety Advisory Services
3.4 QEHS – Quality, Environmental, Health and Safety
3.5 TS – Technical Specification
3.6 CTDP – Client Test Data Program

4.0 **QEHS MANAGEMENT SYSTEM REQUIREMENTS:**

4.1 Continual Improvement:

4.1.1 Effectiveness of the QEHS Management System is continually improved through the use of the QEHS Policy, Objectives, Audit Results, Analysis of Data, Corrective and Preventive Actions, and Management Review.

4.1.2 HEV Plant/TS16949: Continual improvement is implemented once manufacturing processes are capable and stable or product characteristics are predictable and meet customer requirements.
4.1.3 HEV Plant/TS16949: Manufacturing process improvement shall continually focus upon control and reduction of variation in products characteristics and manufacturing process parameters.

4.2 Corrective Action:

4.2.1 Corrective and Preventive Action Sections of the QEHS Management System Manual describe the Toshiba International Corporation (TIC) System for implementing action plans aimed at eliminating instances and causes of non-conformances and potential non-conformance’s (Reference 2.5).

4.2.2 Action, which is appropriate to the magnitude of the problem and commensurate with the risks encountered, is taken to eliminate the cause of non-conformances in order to prevent recurrence. The root cause of the problem is identified and an action plan is developed to correct the problem and eliminate any recurrence.

4.2.3 Specifics are outlined in the procedure which defines the requirements, responsibilities, and authority for (Reference 2.5):
   4.2.3.1 reviewing non-conformances (including Customer Complaints, accidents and incidents);
   4.2.3.2 handling and investigation of accidents, incidents and non-conformances, determination of their causes, and implementation of appropriate action(s) needed to eliminate their causes;
   4.2.3.3 taking action to mitigate any consequences arising from accidents, incidents or non-conformances, and the application of controls to ensure non-conformances do not recur;
   4.2.3.4 confirming effectiveness of Corrective Action taken;

4.2.4 Corrective Action may come from one or more of the following:
   4.2.4.1 Internal Audits (Reference 2.6 and 2.7);
   4.2.4.2 External Audits;
   4.2.4.3 recurring Customer Feedback (Complaints);
   4.2.4.4 Preventive Action opportunities (information identifying potential non-conformities);
   4.2.4.5 Corrective Action opportunities;
   4.2.4.6 major product non-conformities;
   4.2.4.7 supplier Rejected Material Report;
   4.2.4.8 usage of Waivers and Deviations.

4.2.5 HEV Plant/TS16949: All parts rejected by the customer’s manufacturing plants, engineering facilities and dealerships shall be analyzed. Cycle time of this process will be minimized. Records of these analyses shall be kept and made available upon request. Once the analysis is performed, corrective action will be initiated to prevent recurrence.

4.2.6 The nature of non-conformities and any subsequent actions taken, including Concessions obtained, are documented and maintained, and recorded on the Corrective Action Request Form (Reference 2.5).

4.2.7 Any changes to documented procedures resulting from Corrective Action is implemented and recorded, following the Corrective Action Procedure (Reference 2.5).

4.2.8 PEP Validation Lab/CTDP system: The laboratory shall monitor the results to ensure that the corrective actions taken have been effective.
4.3 Preventive Action:

4.3.1 Action, which is appropriate to the effects of the potential problem, is taken to eliminate the causes of potential non-conformities in order to prevent their occurrence.

4.3.2 The Preventive Action Procedure details the specifics and defines the requirements for (Reference 2.8):

4.3.2.1 determining potential non-conformities and their causes through the use of appropriate sources of information, such as processes and work operations which affect the QEHS Management System, product, Concessions, Audit Results, records, and Customer Complaints to detect, analyze, and eliminate potential causes of non-conformances;

4.3.2.2 evaluating the need for action to prevent occurrence of non-conformities;

4.3.2.3 determining and implementing action needed and the application of controls to ensure it is effective;

4.3.2.4 records of results of action taken {Reference 2.5 (See 6.0 below)};

4.3.2.5 reviewing Preventive Action taken and confirmation relevant information on actions taken is effective and is submitted for Management Review.

4.4 Objectives:

4.4.1 Toshiba International Corporation will implement and document Objectives for Environmental, and Occupational Health and Safety at relevant functions within the Organization.

4.4.2 The Objectives will be measurable and practical within the Scope of the QEHS Policy and will include compliance with Legal requirements and other requirements to which Toshiba International Corporation subscribes.

5.0 RESPONSIBILITY:

5.1 Any Toshiba International Corporation employee may initiate Corrective or Preventive Action.

5.2 The Quality Systems Manager or designee is responsible for logging and tracking Corrective and Preventive Action Requests.

5.3 The Management Representatives for Quality, and Environmental and Occupational Health and Safety or Designees are responsible for administration of any Corrective Actions issued against their respective Management Systems.

5.4 Persons assigned to respond to Corrective Action Requests are responsible for ensuring causes of problems and adverse trends are thoroughly investigated and effective Corrective or Preventive Actions are taken without undue delay.

5.5 Management and Supervision are responsible for facilitating and overseeing the Corrective and Preventive Action in their respective work areas.

5.6 The Management Representatives or Designees are responsible for the Corrective and Preventive Action closeout after verification of the effectiveness of actions taken.

5.7 The Customer Representative is responsible for ensuring that customer requirements are addressed through the use of the business planning process and the APQP process.

6.0 RECORDS:

6.1 Records associated with Corrective and Preventive Action is contained in the Corrective and Preventive Action Procedure (Reference 2.5, 2.8 and 2.9).
1.0 **PURPOSE:**

This Section addresses all of ISO 14001:2004 requirements not previously addressed in other Sections of this QEHS Management System Manual.

2.0 **REFERENCE DOCUMENTS:**

2.1 QEHS Manual, Section 7, Documentation Requirements
2.2 ISO 9001:2008
2.3 ISO 14001:2004, Clauses 4.3.1, 4.3.2, 4.4.3, 4.4.2, 4.4.6, 4.4.7, 4.5.1, 4.5.4 and 4.5.2
2.4 OHSAS 18001:2007
2.5 Calibration, Control of Inspection, Measuring and Test Equipment Procedure – Doc. No. 2P-760-001
2.6 Competency, Awareness and Training Procedure – Doc. No. 2P-622-002
2.7 Corrective/Preventive Action Procedure – Doc. No. 2P-850-001
2.8 Document and Data Control Procedure – Doc. No. 2P-423-001
2.9 Toshiba Group Environmental Audit Requirements
2.10 Emergency Preparedness and Response Procedure
2.11 Environmental Aspects Identification, Management and Performance Procedure
2.12 Internal and External Communication Procedure – Doc. No. 2P-553-001
2.13 Internal Audit for Environmental, Health and Safety Compliance Procedure
2.14 Laws and Regulations Procedure – Doc. No. 2P-560-003
2.15 Monitoring and Measuring of QEHS Performance Procedure – Doc. No. 2P-840-001
2.16 Procedures for Significant Environmental Aspects
2.17 Records Management Procedure – Doc. No. 2P-424-001

3.0 **DEFINITIONS:**

3.1 See QEHS Manual, Section 21, Glossary (Terms and Definitions) for definitions of italicized terms.
3.2 ISO – International Organization for Standardization
3.3 OHSAS – Occupational Health and Safety Advisory Services
3.4 QEHS – Quality, Environmental, Health and Safety
3.5 TGEA- Toshiba Group Environmental Audit

4.0 **QEHS MANAGEMENT SYSTEM REQUIREMENTS:**

4.1 **Environmental Aspects:**

4.1.1 Environmental Aspects are considered throughout implementation and maintenance of the Environmental Management System.
4.1.2 A procedure has been established and is periodically updated, to identify Environmental Aspects of activities, products, and services (Reference 2.11).

4.1.3 This procedure includes the method for determining those Aspects which have or can have Significant Environment Impacts. The procedure identifies Aspects related to planned or new developments, or new or modified activities, products, and services.

4.1.4 Aspects related to any Significant Impacts are considered in establishing Environmental Objectives.

4.2 **Legal and Other Requirements:**

4.2.1 A procedure has been established and maintained to identify and provide direction to access Governmental Statutes and Other Requirements which Toshiba International Corporation (TIC) is regulated with regard to Environmental Aspects of its activities, products, or services (Reference 2.14).

4.2.2 The procedure also provides how Legal and Other Requirements apply to the Organization’s Environmental Aspects.

4.2.3 Management Representatives communicate these requirements to all affected personnel. Toshiba International Corporation operates in accordance with these requirements.

4.3 **Consultation and Communication (Internal and External):**

4.3.1 A procedure has been established and maintained to describe Internal Communication between various levels and functions at Toshiba International Corporation (Reference 2.12).

4.3.2 The procedure also details methods for receiving, documenting and responding to relevant communication from external interested parties.

4.3.3 Employees are:

4.3.3.1 involved in development and review of policies and procedures to manage risks;

4.3.3.2 consulted when there are any changes affecting Occupational Health and Safety;

4.3.3.3 informed of their Environmental Representative(s) and specified Management Appointee.

4.4 **Operational Control:**

4.4.1 Toshiba International Corporation has identified operations and activities associated with its Significant Environmental Aspects in line with its Policy, Objectives and Targets. Toshiba International Corporation plans these activities, including maintenance, to ensure they are performed under specified conditions by:

4.4.1.1 establishing and maintaining documented procedures to cover situations where their absence could lead to deviations from the Environmental Policy, Objectives and Targets;

4.4.1.2 stipulating operating criteria in the procedures;

4.4.1.3 establishing and maintaining procedures related to identifiable Significant Environmental Aspects of goods and services used by Toshiba International Corporation and communicating relevant procedures and requirements to suppliers and contractors.

4.5 **Emergency Preparedness and Response:**

4.5.1 A procedure has been established and maintained to identify a potential for and response to accidents, incidents, and emergency situations, and for preventing and mitigating the likely illness, injury and Environmental Impacts associated with them (Reference 2.10).

4.5.2 The Emergency Preparedness Procedure and associated plans are reviewed and revised, where necessary, and in particular, after the occurrence of accidents, incidents, or emergency situations.
The Emergency Preparedness Procedure and associated plans are periodically tested where practicable.

4.6 Performance Measuring and Monitoring:

4.6.1 Toshiba International Corporation has established and maintains documented procedures to monitor and measure, on a regular basis, key characteristics of its operations and activities having a Significant Impact on the Environment. This includes recording information to track performance, relevant operational controls, and conformance with Toshiba International Corporation Environmental Objectives and Targets.

4.6.2 Monitoring equipment is calibrated and maintained, and records kept according to Toshiba International Corporation Records Management Procedure and the Calibration, Control of Inspection, Measuring and Test Equipment Procedure.

4.6.3 The procedures provide for:

   4.6.3.1 both qualitative and quantitative measures, appropriate needs of Toshiba International Corporation;
   4.6.3.2 proactive measures of performance monitoring compliance with QEHS Objectives are met;
   4.6.3.3 reactive performance measures monitoring accidents, ill health, incidents (including near-misses) and other historical evidence of deficient QEHS Management System performance;
   4.6.3.4 recording monitoring and measurement data and results sufficient to facilitate subsequent Corrective and Preventive Action analysis.

4.6.4 Toshiba International Corporation has established and maintains a documented procedure for periodically evaluating compliance with relevant Environmental Legislation, Regulations, and Other Requirements Toshiba International Corporation subscribes.

4.7 Environmental System Audits:

4.7.1 Toshiba International Corporation has established and maintains a documented procedure for Environmental Management System Audits to ensure the QEHS Management System (Reference 2.13):

   4.7.1.1 conforms to planned arrangements for Environmental Management including the requirements of the ISO 14001 Standard;
   4.7.1.2 has been properly implemented and maintained;
   4.7.1.3 provides information regarding Audits Results, past and present, to Management.

4.7.2 Audits are periodically performed by Toshiba Japan as part of the TGEA Program.

4.8 Accidents, Incidents, Non-conformances, and Corrective and Preventive Action:

4.8.1 Toshiba International Corporation has established and maintains procedures for defining responsibility and authority for handling and investigating Environmental accidents, incidents, and non-conformances; taking action to mitigate any impacts caused and initiating and completing Corrective and Preventive Action, and confirmation of effectiveness of actions taken (Reference 2.7).

4.8.2 Toshiba International Corporation implements and records any changes in documented procedures resulting from Corrective and Preventive Action.
4.9 Document and Data Control:

4.9.1 Toshiba International Corporation has established and maintains a procedure for controlling documents and data required by ISO 9001 and ISO 14001 (Reference 2.8).

5.0 RESPONSIBILITY:

5.1 Management Representatives are responsible for Emergency Preparedness and Response.

5.2 Management Representatives, in conjunction with Management, are responsible for communicating Environmental requirements to all affected personnel.

5.3 Management is responsible for determination of Aspects and their significance.

6.0 RECORDS:

6.1 Records associated with requirements of this QEHS Management System Manual Section are stated in associated procedures and are maintained (Reference 2.1 and 2.18).
1.0 PURPOSE:
This Section addresses all Occupational Health and Safety requirements not previously addressed in other Sections of this QEHS Management System Manual.

2.0 REFERENCE DOCUMENTS:
2.1 QEHS Manual, Section 7, Documentation Requirements
2.2 OHSAS 18001:2007, Clauses 4.5.3 and 4.5.3.2
2.3 Accident/Incident Reporting Procedure
2.4 Competency, Awareness and Training Procedure – Doc. No. 2P-622-002
2.5 Corrective/Preventive Action Procedure – Doc. No. 2P-850-001
2.6 Document and Data Control Procedure – Doc. No. 2P-423-001
2.7 Emergency Preparedness and Response Procedure
2.8 Environmental, Health and Safety Targets, Goals, and Objectives
2.9 Hazard Assessment Procedure
2.10 Internal and External Communication Procedure – Doc. No. 2P-553-001
2.11 Internal Audit for Environmental, Health and Safety Compliance Procedure
2.12 Job Safety Analysis Procedure (JSA)
2.13 Laws and Regulations Procedure – Doc. No. 2P-560-003
2.14 Monitoring and Measuring of QEHS Performance Procedure – Doc. No. 2P-840-001
2.15 Records Management Procedure – Doc. No. 2P-424-001

3.0 DEFINITIONS:
3.1 See QEHS Manual, Section 21, Glossary (Terms and Definitions) for definitions of italicized terms.
3.2 ISO – International Organization for Standardization
3.3 OHSAS – Occupational Health and Safety Advisory Services
3.4 QEHS – Quality, Environmental, Health and Safety

4.0 QEHS MANAGEMENT SYSTEM REQUIREMENTS:
4.1 Hazard identification, risk assessment and determining controls:
  4.1.1 A procedure has been established and maintained to identify hazards, perform risk assessment, and determine control methods to mitigate the hazards at Toshiba International Corporation. (Reference 2.9)
  4.1.2 This procedure is designed to be proactive in identifying hazards of both routine and non-routine activities prior to the introduction of changes.
  4.1.3 The risks and determination of controls are taken into account when establishing, implementing and maintaining our Occupational Health & Safety management system.
4.2 Legal and Other Requirements:

4.2.1 A procedure has been established and maintained to identify and have access to Governmental Statutes and other requirements which Toshiba International Corporation (TIC) is subject; and are applicable to Environmental Aspects and Occupational Health and Safety activities, products, or services (Reference 2.7 and 2.13).

4.2.2 Management Representatives communicate these requirements to all affected personnel. Toshiba International Corporation operates in accordance with these requirements.

4.3 Consultation and Communication (Internal and External):

4.3.1 A procedure has been established and maintained to describe internal communication between various levels and functions at Toshiba International Corporation. The procedure also details methods for receiving, documenting, responding to relevant communication from external interested parties, consultation with contractors, and other affected persons working under the control of Toshiba International Corporation (Reference 2.10).

4.3.2 These persons can be included by:

4.3.2.1 involvement in development and review of Policies and Procedures to manage risks;
4.3.2.2 participate in accident and incident investigations, near miss reporting, hazard and risk assessment;
4.3.2.3 consultation when there are any changes affecting Occupational Health and Safety;
4.3.2.4 informed of their Occupational Health and Safety Representative(s) and specified Management Appointee.

4.4 Operational Control:

4.4.1 Toshiba International Corporation has identified operations and activities associated with its Significant Environmental, and Occupational Health and Safety Aspects in line with its Policy, Objectives and Targets. Toshiba International Corporation plans these activities, including maintenance, to ensure they are performed under specified conditions.

4.4.2 These processes are considered Change Management and include, but not limited to:

4.4.2.1 establishing and maintaining documented procedures to cover situations where their absence could lead to deviations from QEHS Policy, Objectives and Targets (Reference 2.14);
4.4.2.2 stipulating operating criteria in the procedures;
4.4.2.3 establishing and maintaining procedures related to identifiable Significant Environmental, and Occupational Health and Safety Aspects of goods and services used by Toshiba International Corporation and communicating relevant procedures and requirements to suppliers and contractors;
4.4.2.4 Establishing and maintaining procedures for the Design of workplace, process, installations, machinery, operating procedures, and work organizations, including their adaptation to human capabilities, in order to eliminate or reduce Occupational Health and Safety Risks at their source, or present deviation to Occupational Health and Safety Policy or Organization Objectives.
4.5 Emergency Preparedness and Response:

4.5.1 A procedure has been established and maintained to identify potential for and response to accidents, incidents, and emergency situations; and for preventing and mitigating the likely illness, injury and Environmental Impact associated with them.

4.5.2 The Emergency Preparedness Procedure and associated plans are reviewed and revised, where necessary, and in particular, after the occurrence of accidents, incidents or emergency situations. The Emergency Preparedness Procedure and associated plans are periodically tested where practicable.

4.5.3 When evaluating and assessing Emergency Response actions, Toshiba International Corporation will take into account needs of all interested and affected parties, neighbors, as well as Emergency Response agencies and service providers.

4.6 Performance Measuring and Monitoring:

4.6.1 Toshiba International Corporation has established and maintains documented procedures to monitor and measure, on a regular basis, key characteristics of its operations and activities having a Significant Occupational Health and Safety Impact. This includes recording information to track performance, relevant operational controls, and conformance with Toshiba International Corporation’s Environmental, Health and Safety Goals, Objectives and

4.6.2 Monitoring equipment is calibrated and maintained, and records kept according to Toshiba International Corporation Records Management Procedure and Calibration, Control of Inspection, Measuring and Test Equipment Procedure.

4.6.3 The procedures provide for:

4.6.3.1 both qualitative and quantitative measures, appropriate needs of Toshiba International Corporation;

4.6.3.2 proactive performance measures monitoring compliance with Environmental, and Occupational Health and Safety Goals, Objectives and Targets are met;

4.6.3.3 reactive performance measures of monitoring accidents, ill health, incidents (including near-misses) and other historical evidence of deficient QEHS Management System performance;

4.6.3.4 recording monitoring and measurement data and results sufficient to facilitate subsequent Corrective and Preventive Action analysis;

4.6.3.5 Evaluation of “Other Requirements” and Systems which the Organization subscribes.

4.6.4 Toshiba International Corporation has established and maintains a documented procedure for periodically evaluating compliance with relevant Environmental, Health and Safety Legislation and Regulation.

4.7 Accidents, Incidents, Non-conformances, and Corrective and Preventive Action:

4.7.1 Toshiba International Corporation has established and maintains procedures for defining responsibility and authority for handling and investigating accidents, incidents and non-conformance, taking action to mitigate any impacts caused, initiating and completing Corrective and Preventive Action, and confirmation of effectiveness of actions taken having any Occupational Health and Safety consequences. Toshiba International Corporation implements and records any changes in documented procedures and Management System documentation to reflect such changes resulting from Corrective or Preventive Action.
4.8  Document and Data Control:

4.8.1 Toshiba International Corporation has established and maintains a procedure for controlling documents and data.

5.0  RESPONSIBILITY:

5.1 Management Representatives are responsible for Emergency Preparedness and Response.

5.2 Management Representatives, in conjunction with Management, are responsible for communicating Occupational Health and Safety requirements to all affected personnel.

6.0  RECORDS:

6.1 Records associated with requirements of this QEHS Management System Manual Section are stated in associated procedures and are maintained (Reference 2.1 and 2.16).
1.0 **PURPOSE:**

This section establishes the requirements for the identification, collection, indexing, access, filing, storage, maintenance and disposal of quality and technical records.

2.0 **REFERENCE DOCUMENTS:**

2.1 ISO 17025:2005 Clause 4.13

2.2 PEP Records Management Procedure – Doc. No. 9P-424-001

2.3 00-OP-C0025 Data Recording, Reporting and Related Requirements

2.4 Validation Test QC Procedure – Doc. No. 9P-736-001

3.0 **DEFINITIONS:**

3.1 CTDP – Client Test Data Program

4.0 **CTDP MANAGEMENT SYSTEM REQUIREMENTS:**

4.1 Quality Records

4.1.1 Quality records shall include reports from internal audits and management reviews as well as records of corrective and preventive actions.

4.1.2 All records shall be legible and shall be stored and retained in such a way that they are readily retrievable in facilities that provide a suitable environment to prevent damage or deterioration and to prevent loss.

4.1.3 Applies to electronic records as well as hard copy records.

4.1.4 Retention times of records shall be established. 5 year period after product withdrawal for DAP participants.

4.1.5 All records shall be held secure and in confidence.

4.1.6 The laboratory shall have procedures to protect and back-up records stored electronically and to prevent unauthorized access to or amendment of these records.

4.2 Technical records

4.2.1 The laboratory must comply with UL's Data Recording and Reporting requirements.

4.2.2 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.

4.2.3 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.
4.2.4 The records shall include the identity of personnel responsible for the sampling, performance of each test and/or calibration and checking of results.

4.2.5 Observations, data and calculations shall be recorded at the time they are made and shall be identifiable to the specific task.

4.2.6 When mistakes occur in records, each mistake shall be crossed out, not erased, made illegible or deleted, and the correct value entered alongside. All such alterations to records shall be signed or initialed by the person making the correction.

4.2.7 In the case of records stored electronically, equivalent measures shall be taken to avoid loss or change of original data.

5.0 RESPONSIBILITY:

5.1 The QC Manager or designee is responsible for the effective implementation of this requirement.

5.2 The lab personnel are responsible for following the requirements set forth in this document.

6.0 RECORDS:

6.1 Validation records shall be maintained in accordance with the Power Electronics Plant Records Management Procedure.
1.0 PURPOSE:

This section establishes the requirements for verifying that purchased material conforms to the specified purchasing requirements.

2.0 REFERENCE DOCUMENTS:

2.1 ISO 17025:2005 Clause 4.6
2.2 Laboratory Consumables for UL testing – Doc. No. 9P-743
2.3 Inspection Checksheet for Laboratory Consumables – Doc. No. 9F-743
2.4 Approved Supplier List for UL Consumables – Doc. No. 9F-741-001
2.5 Supplier Evaluation of UL Critical Consumables – Doc. No. 9F-741
2.6 Validation Test QC Procedure – Doc. No. 9P-736-001

3.0 DEFINITIONS:

3.1 CTDP – Client Test Data Program

4.0 CTDP MANAGEMENT SYSTEM REQUIREMENTS:

4.1 The laboratory shall have a policy and procedure(s) for the selection and purchasing of services and supplies it uses that affect the quality of the tests and/or calibrations. Procedures shall exist for the purchase, reception and storage of reagents and laboratory consumable materials relevant for the tests and calibrations.

4.2 The laboratory shall ensure that purchased supplies and reagents and consumable materials that affect the quality of tests and/or calibrations are not used until they have been inspected or otherwise verified as complying with standard specification or requirements defined in the methods for the tests and/or calibrations concerned. Records of actions taken to check compliance shall be maintained.

4.3 Purchasing documents for items affecting the quality of laboratory output shall contain data describing the services and supplies ordered. These purchasing documents shall be reviewed and approved for technical content prior to release.

4.4 The laboratory shall evaluate suppliers of critical consumables, supplies and services that affect the quality of testing and calibration, and shall maintain records of these evaluations and list those approved.

5.0 RESPONSIBILITY:

5.1 The QC Manager is responsible for annual evaluation of suppliers of critical consumables.

5.2 The QC Data Specialist is responsible for ordering critical consumables and inspecting purchased product.

6.0 RECORDS:

6.1 Supplier evaluations and inspection records of laboratory consumables shall be maintained.
1.0 **PURPOSE:**

This section of the quality manual defines the requirements for the control of testing and calibration that is found to be nonconforming.

2.0 **REFERENCE DOCUMENTS:**

2.1 ISO 17025:2005 Clause 4.9

2.2 Validation Discrepancy Report Form – Doc. No. 9F-83

2.3 PEP Calibration Assessment Form – Doc. No. 9F-760-002

2.4 Corrective - Preventive Action Request Form – QT9 QMS

2.5 Validation Test QC Procedure – Doc. No. 9P-736-001

3.0 **DEFINITIONS:**

3.1 CTDP – Client Test Data Program

4.0 **CTDP MANAGEMENT SYSTEM REQUIREMENTS:**

4.1 The laboratory shall have a policy and procedures that shall be implemented when any aspect of its testing and/or calibration work, or the results of this work, do not conform to its own procedures or the agreed requirements of the customer.

4.2 The laboratory must have a process to recall test data generated with equipment that is received at calibration out of tolerance.

4.3 The responsibilities and authorities for the management of nonconforming work are designated and actions (including halting of work and withholding of test reports and calibration certificates, as necessary) are defined and taken when nonconforming work is identified.

4.4 An evaluation of the significance of the nonconforming work is made.

4.5 Correction is taken immediately, together with any decision about the acceptability of the nonconforming work.

4.6 Where necessary, the customer is notified and work is recalled.

4.7 The responsibility for authorizing the resumption of work is defined.

4.8 Where the evaluation indicates that the nonconforming work could recur or that there is doubt about the compliance of the laboratory's operations with its own policies and procedures, the corrective action procedures given in section 18 shall be promptly followed.

5.0 **RESPONSIBILITY:**

5.1 The QC Manager or designee is responsible for the effective implementation of this requirement.
5.2 Lab personnel are responsible for documenting non-conformances.

6.0 **RECORDS:**

6.1 Validation Discrepancy Reports shall be maintained.
1.0 **PURPOSE:**
Management determines, provides and maintains the infrastructure needed to achieve environmental conformity and product conformity to customer requirements.

2.0 **REFERENCE DOCUMENTS:**
2.1 ISO 17025:2005 Clause 5.3
2.2 Accommodations and Environmental Conditions - Doc. No. 9P-64
2.3 Validation Test QC Procedure – Doc. No. 9P-736-001

3.0 **DEFINITIONS:**
3.1 CTDP – Client Test Data Program

4.0 **CTDP MANAGEMENT SYSTEM REQUIREMENTS:**
4.1 The laboratory must have appropriate environment for testing and/or calibrations.
4.2 Laboratory facilities for testing and/or calibration, including but not limited to energy sources, lighting and environmental conditions, shall be such as to facilitate correct performance of the tests and/or calibrations.
4.3 The laboratory shall ensure that the environmental conditions do not invalidate the results or adversely affect the required quality of any measurement.
4.4 Particular care shall be taken when sampling and tests and/or calibrations are undertaken at sites other than a permanent Laboratory facility.
4.5 The technical requirements for accommodation and environmental conditions that can affect the results of tests and calibrations shall be documented.
4.6 The laboratory shall monitor, control and record environmental conditions as required by the relevant specifications, methods and procedures or where they influence the quality of the results.
4.7 Due attention shall be paid, for example, to biological sterility, dust, electromagnetic disturbances, radiation, humidity, electrical supply, temperature, and sound and vibration levels, as appropriate to the technical activities concerned.
4.8 Tests and calibrations shall be stopped when the environmental conditions jeopardize the results of the tests and/or calibrations.
4.9 There shall be effective separation between neighboring areas in which there are incompatible activities.
4.10 Measures shall be taken to prevent cross contamination.
4.11 Access to and use of areas affecting the quality of the tests and/or calibrations shall be controlled.

4.12 The laboratory shall determine the extent of control based on its particular circumstances.

4.13 Measures shall be taken to ensure good housekeeping in the laboratory. Special procedures shall be prepared where necessary.

5.0 RESPONSIBILITY:

5.1 The QC Manager or designee is responsible for the effective implementation of this requirement.

5.2 The lab personnel are responsible for following the requirements set forth in this document.

6.0 RECORDS:

6.1 Records demonstrating monitoring and control of laboratory conditions specified by the testing requirements are to be acquired throughout the testing process for proof of compliance.
1.0 PURPOSE:
This section establishes the requirements for ensuring that the laboratory is furnished with all items of sampling, measurement and test equipment required for the correct performance of the tests and/or calibrations.

2.0 REFERENCE DOCUMENTS:
2.1 ISO 17025:2005 Clause 5.5
2.2 Calibration, control of inspection, measuring & test equipment procedure – Doc. No. 2P-760-001
2.3 Validation Test QC Procedure – Doc. No. 9P-736-001
2.4 PEP Validation Lab Equipment Check Out Sheet – Doc. No. 9F-753-001
2.5 UL Test Equipment Accuracy Table – Doc. No. 9S-76

3.0 DEFINITIONS:
3.1 CTDP – Client Test Data Program

4.0 CTDP MANAGEMENT SYSTEM REQUIREMENTS:
4.1 In those cases where the laboratory needs to use equipment outside its permanent control, it shall ensure that the requirements of this International Standard are met.

4.2 Equipment and its software used for testing, calibration and sampling shall be capable of achieving the accuracy required and shall comply with specifications relevant to the tests and/or calibrations concerned.

4.3 Calibration programs shall be established for key quantities or values of the instruments where these properties have a significant effect on the results.

4.4 Before being placed into service, equipment (including that used for sampling) shall be calibrated or checked to establish that it meets the laboratory's specification requirements and complies with the relevant standard specifications. It shall be checked and/or calibrated before use.

4.5 Equipment shall be operated by authorized personnel.

4.6 Up-to-date instructions on the use and maintenance of equipment (including any relevant manuals provided by the manufacturer of the equipment) shall be readily available for use by the appropriate laboratory personnel.

4.7 Each item of equipment and its software used for testing and calibration and significant to the result shall, when practicable, be uniquely identified.

4.8 Records shall be maintained of each item of equipment and its software significant to the tests and/or calibrations performed. The records shall include at least the following:
4.8.1 The identity of the item of equipment and its software; Current Requirement.

4.8.2 The manufacturer's name, type identification, and serial number or other unique identification.

4.8.3 Checks that equipment complies with the specification (see 4.2).

4.8.4 The current location, where appropriate.

4.8.5 The manufacturer's instructions, if available or reference to their location.

4.8.6 Dates, results and copies of reports and certificates of all calibrations, adjustments, acceptance criteria, and the due date of next calibration.

4.8.7 The maintenance plan, where appropriate, and maintenance carried out to date.

4.8.8 Any damage, malfunction, modification or repair to the equipment.

4.9 The laboratory shall have procedures for safe handling, transport, storage, use and planned maintenance of measuring equipment to ensure proper functioning and in order to prevent contamination or deterioration.

4.10 Equipment that has been subjected to overloading or mishandling, gives suspect results, or has been shown to be defective or outside specified limits, shall be taken out of service. It shall be isolated to prevent its use or clearly labeled or marked as being out of service until it has been repaired and shown by calibration or test to perform correctly.

4.11 The laboratory shall examine the effect of the defect or departure from specified limits on previous tests and/or calibrations and shall institute the “Control of nonconforming work” procedure (see section 3).

4.12 Whenever practicable, all equipment under the control of the laboratory and requiring calibration shall be labeled, coded or otherwise identified to indicate the status of calibration, including the date when last calibrated and the date or expiration criteria when recalibration is due.

4.13 When, for whatever reason, equipment goes outside the direct control of the laboratory, the laboratory shall ensure that the function and calibration status of the equipment are checked and shown to be satisfactory before the equipment is returned to service.

4.14 When intermediate checks are needed to maintain confidence in the calibration status of the equipment, these checks shall be carried out according to a defined procedure.

4.15 Where calibrations give rise to a set of correction factors, the laboratory shall have procedures to ensure that copies (e.g. in computer software) are correctly updated.

4.16 Test and calibration equipment, including both hardware and software, shall be safeguarded from adjustments which would invalidate the test and/or calibration results.

5.0 RESPONSIBILITY:

5.1 The QC Manager or designee is responsible for the effective implementation of this requirement.
5.2 The QC Manager or designee is responsible for ensuring the calibrated test items meet the accuracy as defined in the UL Test Equipment Accuracy Table.

5.3 Lab personnel are responsible for maintaining the PEP Validation Lab Equipment Check Out Sheet.

6.0 RECORDS:

6.1 Equipment accuracy table and calibration records shall be maintained.
1.0 PURPOSE:
This section establishes the requirements for ensuring that the laboratory handles test and calibration items under controlled conditions.

2.0 REFERENCE DOCUMENTS:
2.1 ISO 17025:2005 Clause 5.8
2.2 Calibration, control of inspection, measuring & test equipment procedure – Doc. No. 2P-760-001
2.3 Validation Test QC Procedure – Doc. No. 9P-736-001

3.0 DEFINITIONS:
3.1 CTDP – Client Test Data Program

4.0 CTDP MANAGEMENT SYSTEM REQUIREMENTS:
4.1 The laboratory shall have procedures for the transportation, receipt, handling, protection, storage, retention and/or disposal of test and/or calibration items, including all provisions necessary to protect the integrity of the test or calibration item, and to protect the interests of the laboratory and the customer.

4.2 The laboratory shall have a system for identifying test and/or calibration items. The identification shall be retained throughout the life of the item in the laboratory. The system shall be designed and operated so as to ensure that items cannot be confused physically or when referred to in records or other documents. The system shall, if appropriate, accommodate a sub-division of groups of items and the transfer of terms within and from the laboratory.

4.3 Upon receipt of the test or calibration item, abnormalities or departures from normal or specified conditions, as described in the test or calibration method, shall be recorded.

4.4 When there is doubt as to the suitability of an item for test or calibration, or when an item does not conform to the description provided, or the test or calibration required is not specified in sufficient detail, the laboratory shall consult the customer for further instructions before proceeding and shall record the discussion.

4.5 The laboratory shall have procedures and appropriate facilities for avoiding deterioration, loss or damage, to the test or calibration item during storage, handling and preparation.

4.6 Handling instructions provided with the item shall be followed.

4.7 When items have to be stored or conditioned under specified environmental conditions, these conditions shall be maintained, monitored and recorded.

4.8 Where a test or calibration item or a portion of an item is to be held secure, the laboratory shall have arrangements for storage and security that protect the condition and integrity of the secured items or portions concerned.
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<td>5.1 The QC Manager or designee is responsible for the effective implementation of this requirement.</td>
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<td>6.0 RECORDS:</td>
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1.0 **PURPOSE:**

This section establishes the requirements for ensuring that the laboratory handles test and calibration items under controlled conditions.

2.0 **REFERENCE DOCUMENTS:**

2.1 ISO 17025:2005 Clause 5.10
2.2 00-OP-C0025 UL DAP Reporting
2.3 ULS-01778-YEDU-DataSheet
2.4 00-OP-C0032 Calibration Certificates
2.5 Validation Test QC Procedure 9P-436-001

3.0 **DEFINITIONS:**

3.1 CTDP – Client Test Data Program

4.0 **CTDP MANAGEMENT SYSTEM REQUIREMENTS:**

4.1 General

4.1.1 The results of each test, calibration, or series of tests or calibrations carried out by the laboratory shall be reported accurately, clearly, unambiguously and objectively, and in accordance with any specific instructions in the test or calibration methods.

4.1.2 The results shall be reported, usually in a test report or a calibration certificate, and shall include all the information requested by the customer and necessary for the interpretation of the test or calibration results and all information required by the method used. This information is normally that required by 4.2, and 4.3 or 4.4.

4.1.3 In the case of tests or calibrations performed for internal customers, or in the case of a written agreement with the customer, the results may be reported in a simplified way.

4.1.4 Any information listed in 4.2 to 4.4, which is not reported to the customer, shall be readily available in the laboratory which carried out the tests and/or calibrations.

4.2 Test reports and calibration certificates

4.2.1 Each test report or calibration certificate shall include at least the following information, unless the laboratory has valid reasons for not doing so:

4.2.1.1 A title (e.g. “Test Report” or “Calibration Certificate"

4.2.1.2 The name and address of the laboratory, and the location where the tests and/or calibrations were carried out, if different from the address of the laboratory.

4.2.1.3 Unique identification of the test report or calibration certificate (such as the serial number), and on each page an identification in order to ensure that the page is
4.2.1.4 The name and address of the customer.

4.2.1.5 Identification of the method used.

4.2.1.6 A description of, the condition of, and unambiguous identification of the item(s) tested or calibrated.

4.2.1.7 The date of receipt of the test or calibration item(s) where this is critical to the validity and application of the results, and the date(s) of performance of the test or calibration.

4.2.1.8 Reference to the sampling plan and procedures used by the laboratory or other bodies where these are relevant to the validity or application of the results.

4.2.1.9 The test or calibration results with, where appropriate, the units of measurement.

4.2.1.10 The name(s), function(s) and signature(s) or equivalent identification of person(s) authorizing the test report or calibration certificate.

4.3 Test reports

4.3.1 In addition to the requirements listed in 4.2, test reports shall, where necessary for the interpretation of the test results, include the following:

4.3.1.1 Deviations from, additions to, or exclusions from the test method, and information on specific test conditions, such as environmental conditions.

4.3.1.2 Where relevant, a statement of compliance/noncompliance with requirements and/or specifications.

4.3.1.3 Where applicable, a statement on the estimated uncertainty of measurement; information on uncertainty is needed in test reports when it is relevant to the validity or application of the test results, when a customer’s instruction so requires, or when the uncertainty affects compliance to a specification limit.

4.3.1.4 Where appropriate and needed, opinions and interpretations (see 4.5).

4.3.1.5 Additional information which may be required by specific methods, customers or groups of customers.

4.3.2 In addition to the requirements listed in 4.2 and 4.3.1, test reports containing the results of sampling shall include the following, where necessary for the interpretation of test results:

4.3.2.1 The date of sampling.

4.3.2.2 Unambiguous identification of the substance, material or product sampled (including the name of the manufacturer, the model or type of designation and serial numbers as appropriate).
4.3.2.3 The location of sampling, including any diagrams, sketches or photographs.

4.3.2.4 A reference to the sampling plan and procedures used.

4.3.2.5 Details of any environmental conditions during sampling that may affect the interpretation of the test results.

4.3.2.6 Any standard or other specification for the sampling method or procedure, and deviations, additions to or exclusions from the specification concerned.

4.4 Calibration certificates

4.4.1 In addition to the requirements listed in 4.2, calibration certificates shall include the following, where necessary for the interpretation of calibration results:

4.4.1.1 The conditions (e.g. environmental) under which the calibrations were made that have an influence on the measurement results.

4.4.1.2 The uncertainty of measurement and/or a statement of compliance with an identified metrological specification or clauses thereof.

4.4.1.3 Evidence that the measurements are traceable.

4.4.2 The calibration certificate shall relate only to quantities and the results of functional tests. If a statement of compliance with a specification is made, this shall identify which clauses of the specification are met or not met.

4.4.2.1 When a statement of compliance with a specification is made omitting the measurement results and associated uncertainties, the laboratory shall record those results and maintain them for possible future reference.

4.4.2.2 When statements of compliance are made, the uncertainty of measurement shall be taken into account.

4.4.3 When an instrument for calibration has been adjusted or repaired, the calibration results before and after adjustment or repair, if available, shall be reported.

4.4.4 A calibration certificate (or calibration label) shall not contain any recommendation on the calibration interval except where this has been agreed with the customer. This requirement may be superseded by legal regulations.

4.5 Opinions and interpretations

4.5.1 When opinions and interpretations are included, the laboratory shall document the basis upon which the opinions and interpretations have been made. Opinions and interpretations shall be clearly marked as such in a test report.

4.5.1.1 Opinions and interpretations should not be confused with inspections and product certifications.
4.5.1.2 Opinions and interpretations included in a test report may comprise, but not be limited to, the following:

4.5.1.2.1 An opinion on the statement of compliance/noncompliance of the results with requirements.

4.5.1.2.2 Fulfillment of contractual requirements.

4.5.1.2.3 Recommendations on how to use the results

4.5.1.2.4 Guidance to be used for improvements.

4.5.1.3 In many cases it might be appropriate to communicate the opinions and interpretations by direct dialogue with the customer. Such dialogue should be written down.

4.6 Testing and calibration results obtained from subcontractors

4.6.1 When the test report contains results of test performed by subcontractors, these results shall be clearly identified. The subcontractor shall report the results in writing or electronically.

4.6.2 When a calibration has been subcontracted, the laboratory performing the work shall issue the calibration certificate to the contracting laboratory.

4.7 Electronic transmission of results

4.7.1 In the case of transmission of test or calibration results by telephone, facsimile other electronic or electromagnetic means, the requirements of this international standard shall be met (see also Section 1, 4.4)

4.8 Format of reports and certificates

4.8.1 The format shall be designed to accommodate each type of test or calibration carried out and to minimize the possibility of misunderstanding or misuse.

4.8.1.1 Attention should be given to the lay-out of the test report or calibration certificate, especially with regard to the presentation of the test or calibration data and ease of assimilation by the reader.

4.8.1.2 The headings should be standardized as far as possible.

4.9 Amendments to the test reports and calibration certificates

4.9.1 Material amendments to a test report or calibration certificate after issue shall be made only in the form of a further document, or date transfer, which includes the following statement or an equivalent form of wording:

“Supplement to Test Report [or Calibration Certificate], serial number… [or otherwise identified]”,

4.9.2 Such amendments shall meet all the requirements of this International Standard.

4.9.3 When it is necessary to issue a complete new test report or calibration certificate, this shall be uniquely identified and shall contain a reference to the original that it replaces.
5.0 RESPONSIBILITY:

5.1 The QC Manager or designee is responsible for the effective implementation of this requirement.

5.2 Lab personnel are responsible for adhering to the requirements as set forth in this document.

6.0 RECORDS:

6.1 Validation reports and calibration records shall be maintained.
TERMS AND DEFINITIONS
(Note: Italicized terms are also defined in this Section)

**Applicable Laws and Regulations** – Legal requirements promulgated by Country, State or Local Government Authorities applying to Organizational Environmental Aspects and Occupational Health and Safety activities, products or services.

**Assign** – To transfer responsibility for action, with mutual consent, to an individual or group (i.e. team or committee).

**Audit** – Systematic, independent, and documented process for obtaining and evaluating evidence objectively to determine the extent of which criteria is fulfilled.

**Audit Criteria** – Set of policies, procedures, or requirements used as reference.

**Audit Conclusion** – Outcome of an Audit provided by an Audit Team after consideration of Audit objectives and all Audit findings.

**Audit Evidence** – Records, statement of facts, or other information which is relevant to audit criteria and verifiable.

**Audit Finding** – Results of the collected audit evidence evaluation against audit criteria. **Note:** Audit findings can indicate either conformity or non-conformity with audit criteria, or opportunities for improvement.

**Audit Program** – Set of one or more audits planned for a specific time frame and directed towards a specific purpose. **Note:** One auditor of the Audit Team is generally appointed as Lead Auditor.

**Audit Team** – One or more auditors conducting an audit.

**Auditee** – An Organization being audited.

**Auditor** – Person with the competence to conduct an audit.

**Capability** – Ability of an Organization, System, or Product Realization Process fulfilling requirements for a product.

**Characteristic** – Distinguishing feature.

**Competence** – Demonstrated ability to apply knowledge and skills.

**Concession** – Permission to use or release a product not conforming to specified requirements.

**Conformity** – Fulfillment of a requirement.

**Continual Improvement** – Recurring activity to increase the ability to fulfill requirements.

**Correction** – Action taken to eliminate a detected non-conformity.

**Corrective Action** – Action to eliminate the root cause(s) of a detected non-conformance, non-conforming product, or other undesirable situation. **Note:** There is a distinction between Correction and Corrective Action.

This document shall be considered “For Reference Only” when printed as a hardcopy. Revision status must be verified prior to use.
Glossary (Terms and Definitions)

Corrective Action System (CAS) – System identifying, analyzing, and implementing improvements and Corrective Action in products, services or work processes.

Corrective and Preventive Action Report (CPAR) – A documented request to improve a Procedure, Work Instruction, or initiate an internal investigation into the cause of a non-conformance for the purpose of applying Corrective or Preventive Action.

Customer – Person or Organization receiving a product or service.

Customer Satisfaction – Customer’s perception regarding the degree Customer Requirements have been fulfilled.

Defect – Failure to meet a specification or requirement related to an intended or specified use. This term should not be used whenever the term “non-conformance” will suffice. **Note:** Use of the term “defect” is not intended in any other manner and is not intended to convey a judgment that product has a defective design or is in a defective condition.

Design and Development – Set of processes transforming requirements into specified characteristics or into a product, process, or system specification.

Deviation – Permission to depart from originally specified requirements of a product prior to realization.

Document – Information and its supporting medium.

Effectiveness – Extent to which planned activities are realized, and planned results are achieved.

Environment – Surroundings in which an Organization operates including air, water, land, natural resources, flora, fauna, humans, and their interrelation.

Environmental Aspect – Element of an Organization’s activities, products, or services interacting with the Environment.

Environmental Impact – Any change to the Environment, whether adverse or beneficial, wholly or partially resulting from an Organization’s activities, products, or services.

Environmental Management Program – Plan identifying responsibilities and timeframes for achieving Objectives and Targets.

Environmental Objective – Overall Environmental Goal, arising from the Environmental Policy, an organization establishes itself to achieve, and which is quantified where practicable.

Environmental Performance – Measurable results of the Environmental Management System, related to an Organization’s control of its Environmental Aspects, and based on its Environmental Policy, Objectives, and Targets.

Environmental Target – Detailed performance requirement, quantified where practicable, applicable to the Organization or parts thereof, and arising from the Environmental Objectives and must be established and attained in order to achieve those Objectives.

Follow-up Audit – A special audit performed to verify Corrective Action has been implemented as scheduled and the action was effective in preventing or minimizing recurrence.

Independence – Freedom from bias and external influence; provides for objectivity and impartiality.

Infrastructure – System of facilities, equipment, and services needed for the operation of an Organization.
Inspection – Conformity evaluation by observation and judgment accompanied, as appropriate, by measurement, testing or gauging.

Inspection Record – Document stating results (data) concerning Inspection activities.

Interested Party – Individual or group concerned with or affected by the Environmental performance of an Organization and the Environmental Impacts of the Organization’s activities, products, or services.

Lead Auditor – The individual who manages the Audit Team during an audit.

Management – Toshiba International Corporation’s Managers and Supervisors.

Management, Senior – Toshiba International Corporation’s Staff Level.

Management Innovation – Toshiba International Corporation based continual improvement activities founded on Six Sigma Methodology.

Management System – System to establish Policy and Objectives, and achieve those Objectives.

Measurement Control System – Set of interrelated or interacting elements necessary to achieve metrological confirmation and continual control of measurement processes.

Measurement Process – Set of operations to determine the value of a quantity.

Metrological Confirmation – Set of operations required to ensure measuring equipment conforms to requirements for its intended use. Note: Generally includes calibration or verification, any necessary adjustment or repair, and subsequent recalibration comparison with metrological requirements for the intended use of the equipment; as well as any required sealing and labeling.

Measuring Equipment – Measuring instrument, software, measurement standard, reference material, auxiliary apparatus or combination thereof necessary to realize a measurement process.

Metrological Characteristic – Distinguishing feature which can influence measurement results.

Metrological Function – Function with Organizational responsibility for defining and implementing a measurement control system.

Non-conformance – Failure to substantially conform to specified requirements.

Objective Evidence – Data supporting the existence or verity of something.

Observation – A concern or weakness detected in an element of a Management System, but is not a non-conformance; a condition that may become a non-conformance if not addressed; an opportunity for improvement.

Opening Meeting – An introductory meeting between the auditor(s) and the Auditee’s Representative, at which time an overview of the Audit Plan is presented.

Opportunity for Improvement – An input into the Corrective Action System not initiated by a non-conformance, but is nevertheless an opportunity for improving QEHS Management System Procedures or Work Instructions.

Organization – Group of people and facilities with an arrangement of responsibilities, authorities and relationships.

Organizational Structure – Arrangement of responsibilities, authorities and relationships between people.
Pre-award Survey – An activity conducted prior to a contract award, and used to evaluate the overall Quality capability of a prospective supplier or contractor.

Preventive Action – Action to reduce and/or eliminate the cause of potential non-conformances, non-conforming product, or other undesirable situations from occurring. Note: Preventive Action is taken to prevent occurrence, whereas Corrective Action is taken to prevent recurrence.

Procedure – Specified way to perform an activity or process.

Process – Set of interrelated or interacting activities which transform Inputs into Outputs. Note 1: Process Inputs are generally Outputs from other processes. Note 2: Processes in an Organization are generally planned and performed under controlled conditions to add value. Note 3: A process where conformity of the resulting product cannot be readily or economically verified is frequently referred to as a “special process”.

Product – The Output of any process.

Project – Unique process, consisting of a set of coordinated and controlled activities with start and finish dates, undertaken to achieve an objective conforming to specific requirements, including the constraints of time, cost and resources.

Quality – Degree to which a set of inherent characteristics fulfils requirements.

Quality Assurance – Part of Quality Management focused on providing confidence Quality Requirements will be fulfilled.

Quality Control – Part of Quality Management focused on fulfilling Quality Requirements.

Quality Improvement – Part of Quality Management focused on increasing the ability to fulfill Quality Requirements.

Quality Management System (QMS) – A Management System to direct and control an Organization with regard to Quality.


Quality Objective – Something sought, or aimed for, related to Quality. Note 1: Quality Objectives are generally based on the Organization’s Quality Policy. Note 2: Quality Objectives are generally specified for relevant Levels and Functions within the Organization.

Quality Plan – Document specifying which procedures and associated resources shall be applied by whom and when to a specific project, product, process or contract.

Quality Planning – Part of Quality Management focused on establishing Quality Objectives and specifying necessary operational processes and related resources to fulfill the Quality Objectives.

Quality Policy – The overall intentions and direction of an Organization related to Quality as formally expressed by Top Management.

Record – Document stating results achieved or providing evidence of activities performed.

Release – Permission to proceed to the next stage of a process.

Requirement – Need or expectation stated, generally implied or obligatory.
Resources – People, time, money, buildings, equipment, and support activities, as necessary, that may be applied to a specific project, product, process, and/or contract in order to fulfill requirements.

Review – Activity undertaken to determine the suitability, adequacy, and effectiveness of subject matter to achieve established objectives.

Root Cause – A fundamental deficiency resulting in a non-conformance that must be eliminated through Corrective Action to prevent recurrence of the same or similar non-conformance.

Root Cause Analysis – Investigation to determine the fundamental deficiency resulting in a non-conformance.

Service – The result of at least one activity necessarily performed at the interface between the supplier and the customer and is generally intangible. Provision of a service can involve:
- Activity performed on a customer-supplied tangible product;
- Activity performed on a customer-supplied intangible product;
- Delivery of an intangible product;
- Creation of ambience for the customer.

Specification – Document stating requirements.

Supplier – A person or Organization providing a product.

Suspect Material – Material that may not meet specifications.

System – Set of interrelated or interacting elements.

Test – Determination of one or more characteristics according to a procedure.

Top Management – A person or group of people who direct and control an Organization at the highest level.

Traceability – Ability to trace the history, application, or location of which is under consideration.

Validation – Confirmation, through provision of objective evidence, requirements for a specific intended use or application have been fulfilled.

Verification – Confirmation, through provision of objective evidence, specified requirements have been fulfilled.

Work Environment – Set of conditions under which work is performed. Note: Conditions include physical, social, psychological, and Environmental factors (temperature, recognition schemes, ergonomics, and atmospheric composition).
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