TOSHIBA

Toshiba International Corporation

Quality, Environmental, Health Safety and Information Security Manual

Doc. No. 2M-421-001
Rev. 26 (06/27/24)

Title:	Written or revised by:	Revision No.:
Table of Contents and Cross Reference	Maribel Abella, Donald Fiddes, Muhammad Iman, Arturo Garcia	26
	Approved By:	Effective Date:
	Ken Takagi	6/27/24

Section No	Title	ISO 9001:2015 Reference	IATF 16949:2016 Reference	Ford CSR for IATF 16949:2016 Reference	ISO 14001:2015 Reference	ISO 45001: 2018 Reference	ISO 27001: 2022 Reference	UL CTDP ISO/IEC 17025:2017 Reference
1	Assistance CEO, VP and General Manager Statement							
2	QEHSIS Management Systems	1.0, 4.0, 7.5, 5.2, 6.2	1.0, 4.3.1, 4.4, 7.5, 5.2, 6.2	1.0, 4.3, 4.4, 7.5.2, 5.2, 6.2	1, 4.1, 4.2, 4.3, 5.2, 5.3, 6.2, 7.1, 7.2, 7.3,	1, 4.1, 4.2, 4.3, 4.4, 5.2	1.0, 4.0,5.2, 6.2,7.5	8
3	Planning for the QEHSIS Management Systems	6.1	6.0	6.0, 6.1.2.3	4.1, 4.2, 6.1, 6.2	4.1, 4.2, 4.4, 6.1, 6.2	6.0	N/A
4	Leadership	5.1, 7.1, 7.4	5.1, 7.1, 7.1.3.1, 7.4	5.1, 7.1, 7.1.3.1, 7.4	5.1, 5.2,5.3, 7.1, 7.4	5.1, 5.2, 5.3, 7.1, 7.4	5.0, 7.1	5
5	QEHSIS Organizational Roles, Responsibilities, and Authorities	5.3	5.3	5.3, 5.3.1	5.3, 7.4	5.3, 7.4	5.3	6
6	Management Review	9.3	9.3	9.3, 9.3.1.1, 9.3.2	9.3	9.3	9.3	8.9
7	Documented Information	7.5	7.5	7.5, 7.5.2	5.2, 6.1, 6.2.1,7.2, 7.4, 7.5, 8.1, 8.2, 9, 10.2	4.3, 5.2, 6.1,6.2, 7.2, 7.5, 8.2, 9.1, 9.2, 9.3, 10.2, 10.3	7.5	8.2, 8.3
8	Resources	7.1	7.1	7.1, 7.1.3.1	5.3, 7.1, 7.2, 7.3	7.1	7.1	6.2
9	Operation Planning and Control	8.1	8.2, 8.3	8.2, 8.2.1, 8.2.3.1.2, 8.2.3.1.3, 8.3, 8.3.1.1, 8.3.2.1, 8.3.2.2, 8.3.4	6.1.3, 8.1	8.1.4	8.1	N/A
10	Determination of Requirements for Products and Services	8.2	8.2	8.2	7.4	8.1.3, 8.1.4	N/A	N/A
11	Design and Development of Products and Services	8.3	8.2, 8.3	8.2, 8.2.1, 8.2.3.1.2, 8.2.3.1.3, 8.3, 8.3.1.1, 8.3.2.1, 8.3.2.2, 8.3.4	8.1	8.1.3, 8.1.4	N/A	N/A

Section No	Title	ISO 9001:2015 Reference	IATF 16949:2016 Reference	Ford CSR for IATF 16949:2016 Reference	ISO 14001:2015 Reference	ISO 45001: 2018 Reference	ISO 27001:2022 Reference	UL CTDP ISO/IEC 17025:2017 Reference
12	Control of Externally Provided Products and Services	8.4	8.4	8.4, 8.4.1.2, 8.4.1.3, 8.4.2.1, 8.4.2.2, 8.4.2.3, 8.4.2.4	8.1	8.1.4	NA	N/A
13	Production and Service Provision	8.5	8.5	8.5	6.1, 7.5.3, 8.1	8.1, 8.2	N/A	N/A
14	Monitoring and Measuring Resources	7.1.5	7.1.5, 7.1.5.1.1, 7.1.5.2, 7.1.5.3	7.1.5, 7.1.5.1.1, 7.1.5.2, 7.1.5.3.2	9.1	9.1	9.1	6.5
15	Performance Evaluation	9.1, 9.1.1, 9.1.3	9.1, 9.1.1.1, 9.1.1.2, 9.1.1.3, 9.1.2.1, 9.1.3.1	9.1, 9.1.1.1, 9.1.1.2, 9.1.1.3, 9.1.2, 9.1.2.1, 9.1.3.1, 9.2.2.3	8.1, 8.2, 9.1, 9.2, 9.3, 10	9.1, 10.3	9.0	N/A
16	Control of Non-conforming Process Outputs, Products and Services	8.7, 10.2	8.7.1.1, 8.7.1.3, 8.7.1.4, 8.7.1.5, 8.7.1.6, 8.7.1.7, 10.2, 10.2.3, 10.2.4, 10.2.5, 10.2.6	8.7.1.1, 8.7.1.3, 8.7.1.4, 8.7.1.5, 8.7.1.6, 8.7.1.7, 10.2,1, 10.2.2 10.2.3, 10.2.4, 10.2.5, 10.2.6	10.2	10.2	10.2	N/A
17	Analysis and Evaluation	9.0	9.1	9.1, 9.1.1.1, 9.1.2, 9.1.2.1	9.1.1	9.1.1	9.1	N/A
18	Improvement	10.0	10.3, 10.3.1	10.3,10.3.1	6.2, 9.1, 10	5.4, 6.1, 8.2, 9.1, 9.3, 10.3	10.0	8.6
19.1	Additional Environmental Management System Requirements	N/A	N/A	N/A	6.1.2, 6.1.3, 7.4.2, 7.4.3, 7.5.3, 8.1, 8.2, 9.1.1, 9.2.2, 10.2	N/A	N/A	N/A

Section No	Title	ISO 9001:2015 Reference	IATF 16949:2016 Reference	Ford CSR for IATF 16949:2016 Reference	ISO 14001:2015 Reference	ISO 45001: 2018 Reference	ISO 27001:2022 Reference	UL CTDP ISO/IEC 17025:2017 Reference
19.2	Additional Occupational Health and Safety Management System Requirements	N/A	N/A	N/A	N/A	4.3.1, 4.3.2, 4.4.3.1, 4.4.6, 4.4.7, 4.5.1, 4.5.3.1, 4.4.5, 4.4.1, 4.5.4	N/A	N/A
20.1	UL Client Test Data Acceptance Program - Technical Records	N/A	N/A	N/A	N/A	N/A	N/A	7.5
20.2	UL Client Test Data Acceptance Program - Externally Provided Products and Services	N/A	N/A	N/A	N/A	N/A	N/A	6.6
20.3	UL Client Test Data Acceptance Program - Nonconforming Work	N/A	N/A	N/A	N/A	N/A	N/A	7.10
20.4	UL Client Test Data Acceptance Program - Facilities and Environmental Conditions	N/A	N/A	N/A	N/A	N/A	N/A	6.3
20.5	UL Client Test Data Acceptance Program - Equipment	N/A	N/A	N/A	N/A	N/A	N/A	6.4
20.6	UL Client Test Data Acceptance Program - Handling of Test and Calibration Items	N/A	N/A	N/A	N/A	N/A	N/A	7.4
20.7	UL Client Test Data Acceptance Program - Reporting the results	N/A	N/A	N/A	N/A	N/A	N/A	7.8
21	Glossary (Terms and Definitions)	3	3	3	3	3	3	3
22	Record of Revisions	7.5.2	7.5.2	7.5.2	7.5.3	4.4.5	7.5.2	7.5

Toshiba International Corporation (TIC) is proud to design, manufacture, and provide sales and service of motors, adjustable speed drives, uninterruptible power supplies, and motor control and distribution equipment; and to provide sales and support of programmable logic controllers (PLCs), industrial plant systems, magnetic flow meters, transportation equipment.

TIC defines its mission as contributing to the development of customers and society, paying taxes, disbursing dividends to its shareholders, and providing employees with opportunities to exert their full capability.

TIC understands that quality should not only relate to the performance and function of products but also integrated into the operations process including quotation, booking of orders, design manufacturing, testing, shipment, delivery, acceptance and after-sale service.

TIC defines Quality Management as persistently pursuing the cycle of activities necessary to establish the manufacturing process of products, documenting the process, periodically checking it and improving it, if necessary, with financial investments.

TIC encourages every single employee to fully understand the definition of Quality Management and work to continuously improve the quality in daily operations in accordance with legal, customer and ISO compliance requirements.

The Chief Quality Executive of TIC has pledged to draw up the Quality Management Plan, to understand how the plan is being implemented in each department and to report to Top Management of TIC when necessary.

DocuSigned by:
Ken Takagi
72700D3032D24D2...
President & CEO

June 27, 2024
Date

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 VP and General Manager, I have responsibility for the Quality, Environmental, Health, Safety and Information Security Management Systems (QEHSIS), which is comprised of methods, documents, and people producing products for our customers. To support the QEHSIS Management Systems, we have compiled this QEHSIS Management Systems 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 9001:2015, IATF 16949:2016, Ford Customer Specific Requirements (CSR), ISO 14001:2015, ISO 45001:2018, ISO 27001:2022, and ISO/IEC 17025:2017 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, Health and Safety Policy. It is important everyone here at Toshiba International Corporation works 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 QEHSIS Management Systems Manual to ensure effective planning, operation, and control of the QEHSIS Management Systems. The QEHSIS Management Systems is planned to meet the requirements of the referenced standards. Changes to the QEHSIS Management Systems are planned to maintain its integrity.

As part of the QEHSIS Management Systems, 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, Occupational Health and Safety and Information Security, 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 QEHSIS Management Systems.

I will show my commitment to our QEHSIS Management Systems 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 QEHSIS Management Systems 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 QEHSIS Management Systems. To ensure we have a good process for communication, I have established appropriate methods, including those needed regarding effectiveness of the QEHSIS Management Systems.

DocuSigned by: David Chichanosky 842F0368B088438...	DocuSigned by: Greg Mack 3F3BB8F1E8804F25...	DocuSigned by: Nobunori Mashimura ECC83CB81373496...	DocuSigned by: Soichi Nakashima D1B948F2F26B47C...
Motors & Drives Division VP & General Manager	Power Electronics Division VP & General Manager	Automotive Systems Division VP & General Manager	Assistant CEO VP/Strategic Planning

1.0 PURPOSE:

This section establishes the Scope of and requirements for the integrated Quality Management Systems, Environmental Management Systems, Occupational Health, Safety Management Systems and Information Security (QEHSIS Management Systems) in order to demonstrate Toshiba International Corporation's (TICs) ability to consistently provide product and services meeting requirements of interested parties, 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, internal and external issues relevant to business purposes, and Occupational Health, Safety, and Information Security.

2.0 REFERENCE DOCUMENTS:

Standard(s) and Specification(s):

2.1 ISO 9001:2015, Clauses 4

2.2 ISO 14001:2015, Clause 4

2.3 ISO 45001: 2018, Clauses 4

2.4 IATF 16949:2016, Clause 4

2.5 ISO 27001:2022, Clause 4

2.6 ISO/IEC 17025: 2017, Clause 8

2.7 Ford Customer Specific Requirement for IATF 16949:2016 Clause 4 Quality Management System

QEHSIS Manual:

2.8 QEHSIS Manual, Section 5, QEHSIS Organizational Roles, Responsibilities, and Authorities

2.9 QEHSIS Manual, Section 6, Management Review

2.10 QEHSIS Manual, Section 8, Resources

2.11 QEHSIS Manual, Section 15, Performance Evaluation

2.12 QEHSIS Manual, Section 16, Control of Non-conforming Process Outputs, Products and Services

2.13 QEHSIS Manual, Section 17, Analysis and Evaluation

2.14 QEHSIS Manual, Section 18, Improvement

2.15 QEHSIS Manual, Section 19.1, Additional Environmental Management System Requirements

2.16 QEHSIS Manual, Section 19.2, Additional Occupational Health and Safety Management System Requirements

Applicable Procedure(s):

2.17 Strategy Deployment Procedure – Doc. No. 2P-551-002

2.18 Context of the Organization Procedure – Doc. No. 2P-400-001

2.19 Motors and Drives Division, and Power Electronics Division Strategy Maps

2.20 Environmental Health & Safety Context of the Organization Procedure

2.21 HEV Strategy Map 4PD-007 (HEV)

2.22 HEV Process Map and Interactions 4PD-001 (HEV)

2.23 Quality Planning 4PD-004 (HEV)

2.24 Context of the organization 4P-004 (HEV)

2.25 Strategy Deployment Procedure 4P-046 (HEV)

3.0 DEFINITIONS:

3.1 See QEHSIS Manual, Section 21, Glossary (Terms and Definitions) for definitions of italicized terms.

3.2 ISO – International Organization for Standardization

3.3 QEHSIS – Quality, Environmental, Health and Safety and Information Security

3.4 PLC – Programmable Logic Controller

3.5 CSR – Customer Specific Requirements

4.0 QEHSIS MANAGEMENT SYSTEMS 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 QEHSIS Management Systems in order to demonstrate its:

4.1.2.1 ability to consistently provide product and services meeting interested parties, ***Customer,*** and applicable Regulatory Requirements and other compliance obligations.

4.1.2.2 aim to enhance Customer Satisfaction through effective application of the QEHSIS Management Systems, including processes for Continual Improvement of the Management System and assurance of conformity of all products and processes, including service parts and those that are outsourced to the Customer and applicable Regulatory Requirements.

4.1.2.3 commitment to understanding the internal, external, environmental and information security issues relevant to activities, products and services, and reducing the impact on the Environment through pollution prevention activities on-site as well as cooperative initiatives with Local Organizations in order to ensure the enhancement of environmental performance, fulfilment of compliance obligations and achievement of the related objectives

4.1.3 The Scope of the QEHSIS Management Systems applies to sites owned or controlled by Toshiba International Corporation. These sites include:

4.1.3.1 13131 West Little York Road, Houston, Texas 77041

4.1.3.2 48679 Alpha Drive, Wixom MI 48393

4.1.3.3 2121 Nao Asahi-cho, Mie-gun Mie-ken 510-8521 Japan

4.1.3.4 16134 114 Ave NW Edmonton AB T5M 2Z5

4.1.3.5 Beltsville, MD

4.1.3.6 Okanella Warehouse:

4.1.3.6.1 10510 Okanella St. Houston, Texas 77041

4.1.3.6.2 10435 Okanella St. Houston, Texas 77041

4.1.3.6.3 10420 Okanella Rd, Houston, Texas 77041

4.2 Management System – General:

4.2.1 Toshiba International Corporation, has established, documented and implemented a QEHSIS Management System and continually improves its effectiveness, as well as manages processes in accordance with requirements of ISO 9001:2015, IATF 16949:2016, ISO 14001:2015, ISO 45001:2018, Standards, ISO 27001:2022 and ISO/IEC 17025:2017 UL CTDP, Ford CSR and other requirements Toshiba International Corporation subscribes.

4.2.2 This established QEHSIS Management Systems are maintained by:

The departments and/or Process Owners related to the Quality of the products to be supplied by TIC follow the requirements of applicable standards to establish, document, implement, and maintain the Quality Management Systems and improve its effectiveness continuously.

Each department and/or Process Owner shall implement the following and manage these processes (businesses):

4.2.2.1 identifying processes needed for application throughout the Organization;

Identify QMS processes and clarify the application to each department. The identified processes and the application to each department are shown Figure 1 QMS Processes and Applicable Departments

4.2.2.2 determining the sequence and interaction of these processes;

Reference the QMS Processes and Interactions

4.2.2.3 determining criteria and methods needed to ensure both operation and control of these processes are effective;

Clarify the criteria and method necessary for effective operation and management of identified QMS processes. These shall be clarified in sections of each process and related regulations, etc.

4.2.2.4 ensuring availability of resources and information necessary to support the operation and monitoring of these processes;

Clarify and make available the human resources, equipment and information necessary to support effective operation and monitoring of identified QMS processes.

4.2.2.5 monitoring, measuring and analyzing these processes.

4.2.2.6 implementing actions necessary to achieve planned results and Continual Improvement of these processes.

4.2.2.7 identify risks and opportunities that can affect conformity of products and services and the ability to enhance customer satisfaction

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, Safety and Information Security.

4.4 QEHSIS Policy:

4.4.1 QEHSIS Policy and Objectives are compatible with the context and strategic direction of the organization are formulated to comply with Legislative Requirements, and to consider information regarding Significant Environmental Impacts, Occupational Health and Safety and Information

Security which are in control of Toshiba International Corporation or which Toshiba International Corporation can be expected to have an influence.

4.4.1 **QEHSIS Policy:**

4.4.1.1 is communicated company-wide and all personnel **(employees and persons working on our behalf)** understand the Policy through training and/or orientation,

4.4.1.2 is posted throughout the organization.

4.4.1.3 provides a framework for establishing and reviewing the QEHSIS Management Systems and Environmental Objectives and Targets.

4.4.1.4 is annually reviewed during the QEHSIS Management Systems Management Review for continued relevance and suitability.

4.4.1.5 Defines and documents responsibilities, and interfaces of various functions within the organization.

4.4.1.6 Ensures equipment and facilities being suited for their intended purpose.

4.4.1.7 Ensures employees possess 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.

4.4.1.8 Ensures all activities are characterized by Quality, Environmental, Occupational Health and Safety and Information Security sensitivity as set forth in our QEHSIS Management Systems.

4.4.1.9 Ensures steps are taken to remedy any existing defects and deficiencies, either internally or externally; and to prevent reoccurrence.

4.4.1.10 Ensures QEHSIS Management Representatives are appointed.

4.4.1.11 Ensure our commitment to comply with relevant Legislation and Regulations.

4.4.1.12 Ensures availability of the QEHSIS Policy to interested parties.

4.5 QEHSIS Management Systems Objectives and Associated Targets:

4.5.1 It is the responsibility of Toshiba International Corporation, Senior Management to ensure QEHSIS 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, strategically aligned, and consistent with the QEHSIS Policy. In establishing these Objectives, the Legal Requirements, Significant Environmental Aspects, Occupational Health and Safety Risks and Hazards, Information Security, Technological Options, Laboratory Requirements and Financial, Operational, and Business Requirements as well as views of interested parties are considered.

4.5.2 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.

4.5.3 The overall general QEHSIS Objectives are:

4.5.3.1 obtain and maintain, ISO 9001:2015, IATF 16949: 2016, ISO 14001:2015, ISO 45001:2018, ISO/IEC 27001:2022 ISO/IEC 17025:2017 UL Client Test Data Program (CTDP).

4.5.3.2 serve and respond to needs of our Customers through Continual Improvement of processes.

4.5.3.3 establish and nurture a culture which is focused on Quality, the natural Environment, and the impact of work processes on Occupational Health and Safety and information Security.

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

4.5.3.5 to continually review and improve Systems and Procedures.

4.5.3.6 to operate consistent with Environmental, and Occupational Health and Safety and Information Security Legislation and Regulations.

4.5.3.7 to fulfill stated Objectives relative to selected Significant Environmental Aspects and associated Impacts.

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

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

4.6 Key Toshiba International Corporation Operation Objectives are:

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

4.6.2 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.

4.6.3 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.

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

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

4.6.6 Information Security – To protect and preserve the confidentiality, integrity and availability of identities, systems, networks, applications and data.

5.0 RESPONSIBILITY:

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

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

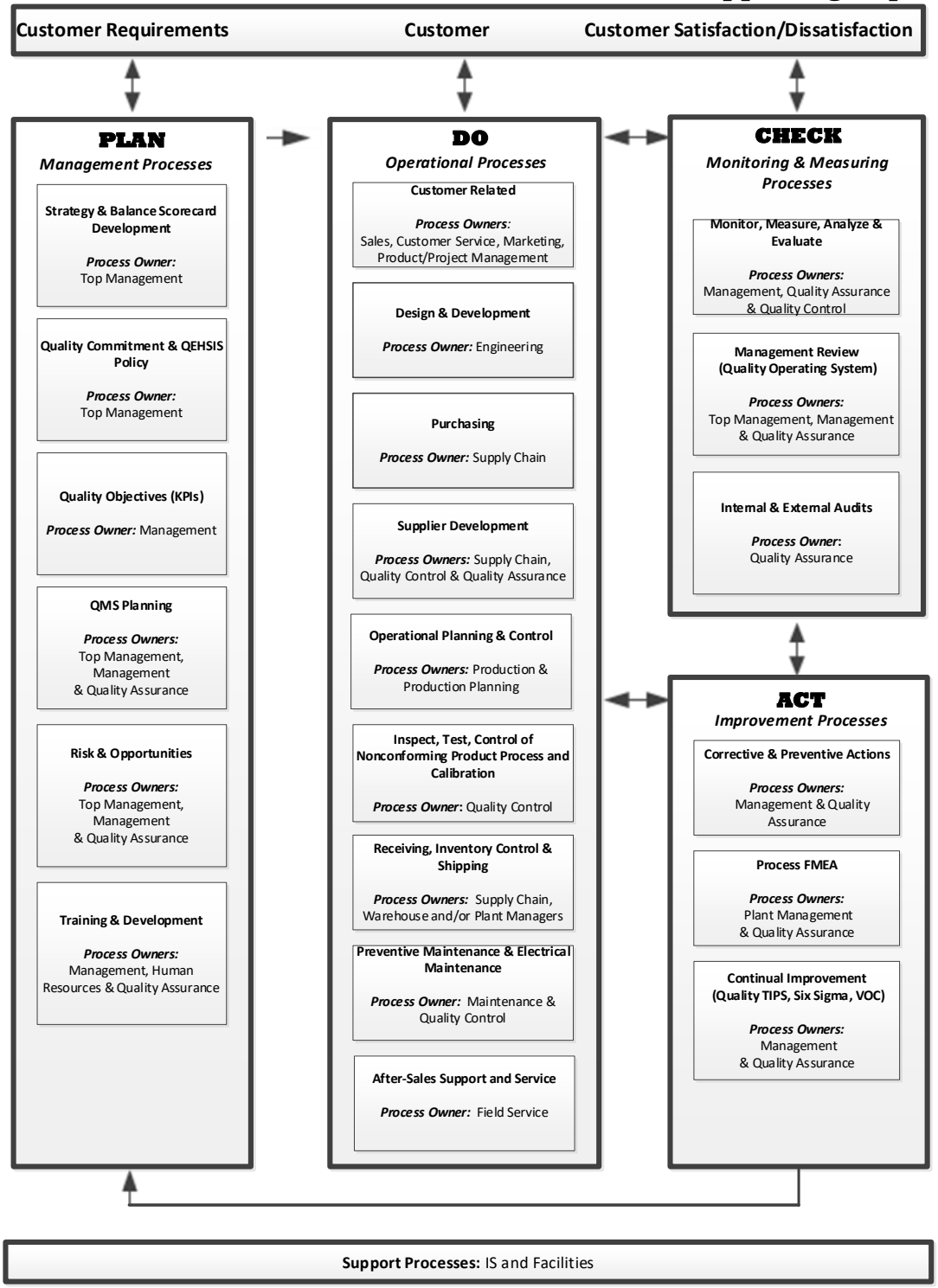
5.3 All employees are responsible for Product Quality, Environmental Aspects under their control, Information Security and Occupational Health and Safety.

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

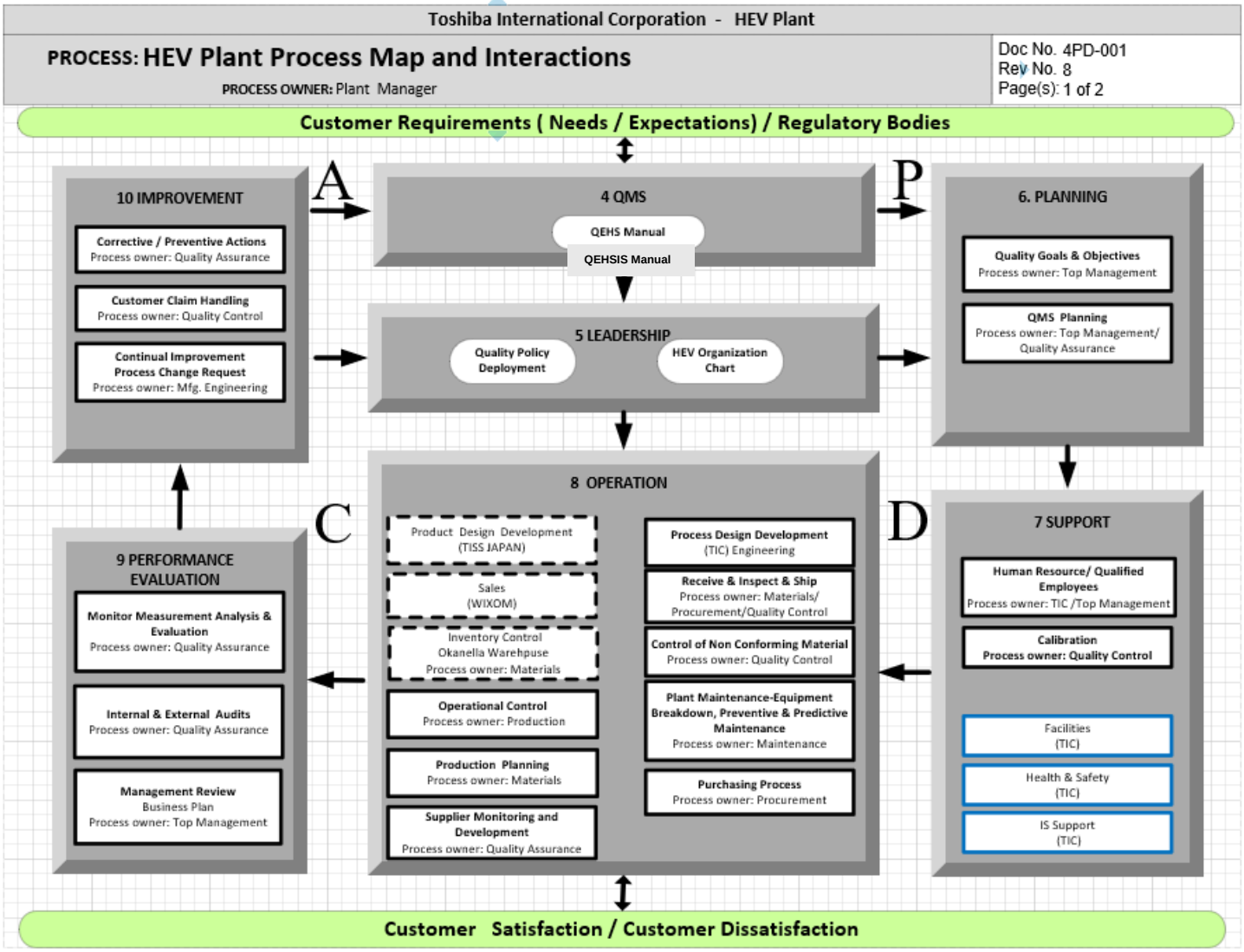
6.0 RECORDS:

6.1 None

QMS Processes and Interactions
for the Control, Motor and Power Electronics Plant and Supporting Departments



HEV Plant QMS Processes and Interactions



1.0 PURPOSE:

This Section establishes Planning for the QEHSIS Management Systems identifying how activities are coordinated to direct and control the QEHSIS Management Systems of Toshiba International Corporation (TIC).

2.0 REFERENCE DOCUMENTS:

Standard(s) and Specification(s):

2.1 ISO 9001:2015, Clause 6

2.2 ISO 14001:2015, Clauses 4 and 6

2.3 ISO 45001: 2018, Clause 6

2.4 ISO 27001:2022, Clause 4 and 6

2.5 IATF 16949:2016, Clause 6

2.6 Ford Customer Specific Requirements for IATF 16949:2016 (CSR), Clause 4 and Clause 6

QEHSIS Manual:

2.7 QEHSIS Manual, Section 2, QEHSIS Management Systems

2.8 QEHSIS Manual, Section 9, Operation planning and Control

Applicable Procedure(s):

2.9 Strategy Deployment Procedure –Doc. No. 2P-551-002

2.10 Organizational Knowledge Procedure – Doc. No. 2P-716-001

2.11 Monitoring and Measurement of QEHSIS Performance – Doc. No. 2P-840-001

2.12 Management Review Procedure – Doc. No. 2P-560-002

2.13 Design Control New Product Development Procedure – Doc. No. 2P-734-001

2.14 Context of the Organization Procedure – Doc. NO. 2P-400-001

2.15 Environmental Aspects Identification, Management and Performance Procedure

2.16 Hazard Assessment Procedure

2.17 Job Safety Analysis Procedure (JSA)

2.18 HEV Strategy Plan 4PD-007 (HEV)

2.19 HEV Process Map and Interactions 4PD-001 (HEV)

2.20 Quality Planning 4PD-004 (HEV)

2.21 Quality Goals & Objectives 4PD-003 (HEV)

2.22 Product Design Development 4PD-024 (HEV)

2.23 Process Design Development 4PD-008 (HEV)

2.24 Purchasing Process 4PD-014 (HEV)

2.25 Strategy Deployment Procedure 4P-046 (HEV)

3.0 DEFINITIONS:

3.1 See QEHSIS Manual, Section 21, Glossary (Terms and Definitions) for definitions of italicized terms.

3.2 EMS – Environmental Management Systems

3.3 ISO – International Organization for Standardization

3.4 OHSAS – Occupational Health and Safety Assessment Series

3.5 QEHSIS – Quality, Environmental, Health and Safety and Information Security

4.0 QEHSIS MANAGEMENT SYSTEMS REQUIREMENTS:

4.1 QEHSIS Management Systems Overall Planning:

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

4.1.1.1 Planning for the QEHSIS Management Systems is performed to meet specified requirements, as well as QEHSIS Objectives and Targets;

4.1.1.2 QEHSIS Management Systems 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;

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;

4.1.1.5 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;

4.1.1.6 Aspects related to Information Security are considered when identifying relevant internal and external issues and understanding stakeholder needs, including legal and contractual requirements, to enhance its information security management system's effectiveness. This also includes establishing, maintaining, and improving this system, determining its scope, assessing and treating risks, setting security objectives, and ensuring any system changes are systematically planned.

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

4.1.1.8 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 Quality Requirements:

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

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 Requirements:

4.3.1 Toshiba International Corporation recognizes development, implementation, maintenance, and continual improvement of an effective Occupational Health and Safety Management System are not possible without appropriate planning. Occupational Health and Safety minimal planning elements are listed below along with Hazard identification and Risk assessment methodology is proactive and includes:

4.3.1.1 Determination of internal and external issues relevant to the organizations purpose and ability to achieve objectives

4.3.1.2 Determination of the needs and expectations interested parties and which elements are or could be requirements

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

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

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

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

4.3.1.7 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 Systems (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, internal and external issues relevant to its purpose and needs and expectations of interested parties;

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.

4.5 Planning for Meeting Automotive Requirements:

4.5.1 Toshiba International Corporation recognizes development, implementation, and maintenance of an effective Automotive Quality Management Systems (QMS) are not possible without appropriate planning. At a minimum, such planning includes:

4.5.1.1 Internal and External issues relevant to the Organizations purpose, as well as the needs and expectations of Interested Parties, must be considered.

4.5.1.2 Risk Analysis should include at a minimum, lessons learned from product recalls, product audits, field returns and repairs, complaints, scrap, and rework.

4.5.1.3 The Organization shall establish a process to lessen the impact of negative effects of risks per IATF 16949:2016 – 6.1.2.2

4.5.1.4 Establishing a Contingency Plan to identify & evaluate internal & external risks to all manufacturing process & infrastructure equipment, continuity of supply, and periodically test the plan for effectiveness.

4.6 Planning for Meeting Information Requirements:

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

4.6.1.1 Determine external and internal issues that are relevant to its purpose and that affect its ability to achieve the intended outcome(s) of its information security management system.

4.6.1.2 Determine interested parties that are relevant to the information security management system and the relevant requirements of these interested parties.

4.6.1.3 Determine which of these requirements will be addressed through the information security management system. The requirements of interested parties can include legal and regulatory requirements and contractual obligations.

4.6.1.4 Determine the boundaries and applicability of the information security management system to establish its scope and shall consider the external and internal issues, the requirements and the interfaces and dependencies between activities performed by the organization, and those that are performed by other organizations.

4.6.1.5 Establish, implement, maintain and continually improve an information security management system, including the processes needed and their interactions, in accordance with the requirements of ISO 27001.

4.6.1.6 Determine the risks and opportunities that need to be addressed to ensure the information security management system can achieve its intended outcomes; prevent, or reduce, undesired effects and achieve continual improvement.

4.6.1.7 Plan actions to address risks and opportunities; and how to integrate and implement the actions into its information security management system processes; and evaluate the

effectiveness of these actions. Define and apply an information security risk assessment process.

4.6.1.8 Define and apply an information security risk treatment process.

4.6.1.9 Establish information security objectives at relevant functions and levels

4.6.1.10 Determines the need for changes to the information security management system, the changes shall be carried out in a planned manner.

5.0 RESPONSIBILITY:

5.1 Toshiba International Corporation Management, Design Engineering, Quality Assurance, Quality Control, Manufacturing Engineering, Information Security and Marketing are responsible for Planning for the QEHSIS Management Systems within their respective functions.

6.0 RECORDS:

6.1 Records associated with Planning are identified throughout the QEHSIS Management Systems and associated documentation.

1.0 PURPOSE:

This Section establishes Management's Responsibilities with regard to Continual Improvement of the QEHSIS Management Systems and enhancement of Customer Satisfaction.

2.0 REFERENCE DOCUMENTS:

Standard(s) and Specification(s):

2.1 ISO 9001:2015, Clause 5

2.2 IATF 16949:2016, Clause 5

2.3 Ford Customer Specific Requirements for IATF 16949:2016 (CSR), Clause 5

2.4 ISO 14001:2015, Clauses 5.1, 5.25.3, 7.1, 7.4

2.5 ISO 45001:2018, Clauses 5, 7

2.6 ISO/IEC 27001:2022, Clauses 5, 7

2.7 ISO/IEC 17025:2017, Clauses 5

QEHSIS Manual:

2.8 QEHSIS Manual, Section 2, QEHSIS Management Systems

2.9 QEHSIS Manual, Section 3, Planning for the QEHSIS Management Systems

2.10 QEHSIS Manual, Section 5, QEHSIS Organizational Roles, Responsibilities and Authorities

2.11 QEHSIS Manual, Section 6, Management Review

2.12 QEHSIS Manual, Section 8, Resources

2.13 QEHSIS Manual, Section 10, Determination of Requirements for Products and Services

Applicable Procedure(s):

2.14 Context of the Organization Procedure – Doc. No. 2P-400-001

2.15 Management Review Procedure – Doc. No. 2P-560-002

2.16 Competency, Awareness and Training Procedure – Doc. No. 2P-622-002

2.17 Skills Matrix Procedure – Doc. No. 2P-622-001

2.18 Monitoring and Measurement of QEHSIS Procedure – Doc. No. 2P-840-001

2.19 Corrective and Preventive Action Procedure – Doc. No. 2P-850-001

2.20 Design Control New Product Development Procedure – Doc. No. 2P-734-001

2.21 Internal and External Communication Procedure - Doc. No. 2P-510-001

2.22 Customer and Quality Representative Procedure – 4P-009 (HEV)

2.23 Confidentiality Procedure – Doc. No. 4P-017 (HEV)

2.24 Quality Planning 4PD-004 (HEV)

2.25 Quality Goals & Objective 4PD-003 (HEV)

2.26 Human Resources / Qualified Employees 4PD-005 (HEV)

2.27 Management Review 4PD-018 (HEV)

2.28 Continual Improvement 4PD-021 (HEV)

3.0 DEFINITIONS:

3.1 See QEHSIS Manual, Section 21, Glossary (Terms and Definitions) for definitions of italicized terms.

3.2 ISO – International Organization for Standardization

3.3 QEHSIS – Quality, Environmental, Health, Safety, and Information Security

3.4 IATF – International Automotive Task Force

3.5 APQP – Advance Product Quality Planning

4.0 QEHSIS MANAGEMENT SYSTEMS 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, Information Security 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 QEHSIS Management Systems by:

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

4.1.1.1.2 establishing a QEHSIS Policy and ensuring the Policy and objectives are understood by all employees;

4.1.1.1.3 ensuring the QEHSIS Policy and Objectives are established and reviewed for strategic alignment, continuing suitability and adequacy, and when necessary, the need for change;

4.1.1.1.4 conducting Management Reviews;

4.1.1.1.5 ensuring availability and support of relevant management roles and resources (human, specialized skills, technology, laboratory and financial) essential for implementation, control, and effectiveness of the QEHSIS Management System;

4.1.1.1.6 appointment of specific QEHSIS Management Representatives.

4.1.1.1.7 Define and implement corporate responsibility policies including at a minimum an anti-bribery policy, an employee code of conduct and an ethics escalation policy;

4.1.1.1.8 Taking overall responsibility of the QEHSIS Management Systems

4.1.1.1.9 ensuring the QEHSIS Management Systems are integrated into the business process and achieves intended outcomes;

4.1.1.1.10 Supporting establishment of health and safety committees, related processes for worker collaboration, and protecting workers from reprisals when reporting health and safety related items.

4.1.1.1.11 Promotes a culture that supports Quality, Health and Safety outcomes

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.

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

4.1.2.3 HEV Plant/IATF 16949: Management has designated process owners 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 customers.

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 QEHSIS Management Systems. 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;

4.1.3.1.2 Receiving, documenting, and responding to QEHSIS 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.

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 Information Security, Occupational Health and Safety. Employees are also represented in 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 communication to interested parties relative to the QEHSIS is communicated.

5.2 External communications to interested parties relative to Information Security, 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 QEHSIS Management System.

2.0 REFERENCE DOCUMENTS:

Standard(s) and Specification(s):

2.1 ISO 9001:2015, Clause 5

2.2 IATF 16949:2016, Clause 5

2.3 Ford Customer Specific Requirements for IATF 16949:2016 (CSR), Clause 5

2.4 ISO 14001:2015

2.5 ISO 45001:2018, Clauses 5.3

2.6 ISO/IEC 27001:2022 Clause 5.3

2.7 ISO/IEC 17025:2017, Clause 6

QEHSIS Manual:

2.8 QEHSIS Manual, Section 6, Management Review

Applicable Procedures:

2.9 Management Review Procedure – Doc. No. 2P-560-002

2.10 Monitoring and Measurement of QEHSIS Performance – Doc. No. 2P-840-001

2.11 Competency, Awareness and Training Procedure – Doc. No. 2P-622-002

2.12 Organizational Knowledge Procedure – Doc. No. 2P-716-001

2.13 Customer and Quality Representative Procedure – Doc. No. 4P-009 (HEV)

2.14 Quality Goals & Objectives 4PD-003 (HEV)

2.15 Human Resources / Qualified Employees 4PD-005 (HEV)

2.16 Management Review 4PD-018 (HEV)

2.17 Monitor, Measurement, Analysis & Evaluation 4PD-016 (HEV)

Applicable Form/Record(s):

2.18 Job Descriptions

2.19 Organization Charts

3.0 DEFINITIONS:

3.1 See QEHSIS 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 QEHSIS – Quality, Environmental, Health, Safety and Information Security

3.6 STA – Supplier Technical Assistance

3.7 IATF – International Automotive Task Force

3.8 VPP – Voluntary Protection Program

3.9 APQP – Advanced Product Quality Planning

4.0 QEHSIS 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, Safety and Information Security 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 QEHSIS Management System are as follows:

4.2.1 VP and General Managers are Responsible for:

4.2.1.1 the QEHSIS 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 QEHSIS Management System remains effective;

4.2.1.3 support of the QEHSIS Manual and Policy Statements

4.2.1.4 establishing QEHSIS Objectives and Targets for their respective Divisions

4.2.2 Business Directors 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.

4.2.2.2.1 For HEV Plant Business Unit Manager works with Plant Manager in determining Annual Goals and Objectives.

4.2.3 Plant Managers are Responsible for:

4.2.3.1 QEHSIS Management System implementation at the Plant Level;

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

4.2.3.3 complying with Toshiba International Corporation QEHSIS 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 Management Representatives are Responsible for:

4.2.4.1 Toshiba International Corporation Management has appointed five Management Representatives {(Quality Management System (1), Information Security (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:

4.2.4.1.1 ensuring processes needed for the QEHSIS Management System are established, implemented, and maintained in accordance with, ISO 9001:2015, IATF 16949:2016, FMC CSR, ISO 14001:2015, ISO 45001:2018, ISO/IEC 17025:2017 Standards, ISO/IEC 27001:2022, UL Client Test Data Program (CTDP), TGEA Requirements, and Voluntary Protection Program (VPP) Requirements;

4.2.4.1.2 reporting QEHSIS Management System Performance to Executive Management for review, including any recommendations for improvement;

4.2.4.1.3 ensuring promotion and awareness of Customer Requirements throughout the Organization;

4.2.4.1.4 facilitating, guiding, and providing input to QEHSIS Objectives and Targets for Toshiba International Corporation.

4.2.4.1.5 Responsible for the Document Control Administration

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

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

4.2.5.1 Additional responsibilities include:

4.2.5.1.1 Integration of division activities to create organizational clarity and focus in regard to Quality Assurance and Quality Control

4.2.5.1.2 enhanced quality management planning providing guidance, expertise and coordination on Quality matters;

4.2.6 The TIC Quality Assurance Manager is Responsible for Overall Maintenance of the Quality Management System at TIC and in the manufacturing plants, Control Plant, Motor Plant and Power Electronics Plant:

4.2.6.1 Additional responsibilities include:

4.2.6.1.1 maintaining Corporate Quality Management System Policy and Procedures;

4.2.6.1.2 facilitating Quality Management System Management Review Meetings;

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

4.2.6.1.4 coordinating Procedures, Work Instructions, and related documentation in a consistent, uniform, and clear manner;

4.2.6.1.5 providing guidance, expertise and coordination on Quality Management System matters;

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

4.2.6.1.7 coordinating Internal and External Audits;

4.2.6.1.8 Process support for supplier projects;

4.2.6.1.9 Manages customer relationships relative to customer needs, concerns, dissatisfactions, audits, and inspections. Investigates and resolves customer complaints regarding quality received by the Front Office and/or through the external VOC.

4.2.6.1.10 Development of Management Innovation

4.2.6.1.11 Designs and implements quality assurance training programs to key personnel in conjunction with managers.

4.2.6.1.12 The HEV Plant Quality Assurance Manager has the same responsibilities for the HEV Plant.

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

4.2.7.1 Additional responsibilities include:

4.2.7.1.1 maintaining Corporate Environmental Management System Policies and Procedures including compliance with TGEA Requirements;

4.2.7.1.2 conducting Environmental Management Systems and Occupational Health and Safety Management System Management Review Meetings;

4.2.7.1.3 providing Management and Employee Training and Development;

4.2.7.1.4 maintaining Corporate Occupational Health and Safety Management System Policies and Procedures;

4.2.7.1.5 coordinating Procedures, Work Instructions, and related documentation in a consistent, uniform, and clear manner;

4.2.7.1.6 providing guidance, expertise and coordination on Environmental and Occupational Health and Safety matters;

4.2.7.1.7 assuring proper Document Control, including the review and coordination of all Environmental Management System and all Occupational Health and Safety Management System document releases;

4.2.7.1.8 coordinating Internal and External Audits;

4.2.7.1.9 conducting Occupational Health and Safety related Training and maintaining Training Records.

4.2.7.1.10 Reporting on the performance of the EH&S Management Systems to Sr. Management.

4.2.8 The Information Security Manager is Responsible for Overall Information Security Management System, including Regulatory Compliance:

4.2.8.1 Additional responsibilities include:

4.2.8.1.1 Ensuring that the information security management system conforms to the Information Security requirements of ISO 27001:2022reporting on the performance of the information security management system to top management

4.2.9 Supply Chain Managers are Responsible for Procurement of Goods and Services, and:

4.2.9.1 monthly Supplier Delivery Performance Reporting and Review

4.2.9.2 following and enforcing rules contained in the Chemical Hazard Communication Program Procedure;

4.2.9.3 creation of action plans for poor performing suppliers

4.2.10 Document Control Administrators are Responsible for:

4.2.10.1 Effectively follow TIC's standard operating procedures in the control of documents by:

4.2.10.1.1 assisting in the creation of documents

4.2.10.1.2 ensuring documents have no errors in filenames

4.2.10.1.3 ensuring reference documents contained within are current before releasing into InfoSource

4.2.10.1.4 assigning document numbers using TIC's document nomenclature;

4.2.10.1.5 Ensuring documents meet formatting compliance

4.2.10.1.6 communicate new or revised documents to plant and/or department affected by the change, highlighting the changes that were made in the correspondence;

4.2.10.1.7 ensuring documents and data relevant to Quality, Environment, Health & Safety are available to locations where operations essential to the effective functioning of the Quality, Environment, Health & Safety Management System are performed;

4.2.10.1.8 ensuring documents and data under their control are current;

4.2.10.1.9 maintaining the Document, Knowledge & Record Management (DKRM) Matrix

4.2.10.1.10 performing annual audits of documents in order to ensure that all documents are controlled, approved and properly submitted to departments.

4.2.11 Quality Control Managers are Responsible for:

4.2.11.1 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;

4.2.11.2 conducting monthly Plant Quality Operating System Meetings based on the Plant's Quality Performance;

4.2.11.3 ensuring that Cost of Quality data is analyzed and distributed every month to improve product quality

4.2.11.4 Following regulatory compliance rules

4.2.12 Material Control is Responsible for:

4.2.12.1 storage of Toshiba International Corporation product and materials in a way to prevent damage and deterioration, in compliance with documented procedures,

4.2.12.2 packaging and shipping of finished product; in compliance with documented procedures,

4.2.12.3 following and enforcing rules contained in the Chemical Hazard Communication Program Procedure.

4.2.13 Production Managers are Responsible for:

4.2.13.1 production, scheduling, prioritizing, and controlling processes to meet Customer Requirements;

4.2.13.2 following and enforcing rules contained in the Chemical Hazard Communication Program Procedure;

4.2.13.3 following Regulatory Compliance rules and Recycling efforts.

4.2.14 Inspectors are Responsible for:

4.2.14.1 Receiving, In-process, and Final Inspections of products in accordance with pre-determined Inspection Checklists, Procedures, etc.

4.2.14.2 Following regulatory compliance rules.

4.2.15 Maintenance Manager is Responsible for:

4.2.15.1 maintenance of machinery, equipment, and tooling used for product production and facilities use, including Preventive and Predictive Maintenance;

4.2.15.2 maintaining equipment used to monitor Environmental Aspects;

4.2.15.3 following and enforcing rules contained in the Chemical Hazard Communication Program Procedure;

4.2.15.4 Motor Plant - Responsible for storage of chemicals to meet Regulatory Compliance.

4.2.16 Facilities Manager is Responsible for:

4.2.16.1 maintaining equipment used to monitor Environmental Aspects;

4.2.16.2 following and enforcing rules contained in the Chemical Hazard Communication Program Procedure;

4.2.16.3 Contracting suppliers related to Environmental Regulatory Compliance.

4.2.17 Field Service Manager is Responsible for:

4.2.17.1 post-delivery support of products.

4.2.17.2 Prepare reports for and work with other department managers to improve product design;

4.2.17.3 Establish service training programs for both Toshiba employees and customers.

4.2.18 Research and Development Managers are Responsible for:

4.2.18.1 coordinating the Product Design;

4.2.18.2 following and enforcing rules contained in the Chemical Hazard Communication Program Procedure.

4.2.18.3 ISO/IEC 17025 –Test Lab: managing technical operations, resources needed and verifying work of quality of the testing and/or calibration activities.

4.2.19 Human Resources is Responsible for:

4.2.19.1 Delivery coordination of Environmental Training activities.

4.2.19.2 Monitor/oversee curriculum development, delivery and tracking of all Human Resources Training initiatives

4.2.20 General:

4.2.20.1 All personnel are responsible for Product Quality under their control and for following applicable Environmental, and Occupational Health and Safety Rules and Regulations.

4.2.20.2 Additional Organizational responsibilities are shown in the Toshiba International Corporation Organization Chart and in individual functional Job Descriptions

4.2.20.3 All personnel are responsible for following QEHSIS 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 QEHSIS 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.

5.5 HEV Plant/ IATF16949: FMC STA shall be notified within 10 working days of any changes to senior management responsible for Quality or company ownership.

5.6 HEV Plant/ IATF16949: Dynamic Manufacturing Inc. shall be notified of any pending major changes including but not limited to the following: changes in (ERP/MRP), ownership, management or management structure, union contract negotiations and/or strike. This must be submitted to the Supply Chain Customer Service (SCCS) department at Dynamic.

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 QEHSIS Management Systems to ensure its continuing suitability, adequacy and effectiveness.

2.0 REFERENCE DOCUMENTS:

Standard(s) and Specification(s):

2.1 ISO 9001:2015, Clause 9.3

2.2 IATF 16949:2016, Clause 9.3

2.3 Ford Customer Specific Requirements for IATF 16949:2016 (CSR), Clause 9.3

2.4 ISO 14001:2015, Clause 9.3

2.5 ISO 45001:2018, Clause 9.3

2.6 ISO/IEC 27001:2022 Clause 9.3

2.7 ISO/IEC 17025:2017

QEHSIS Manual:

2.8 QEHSIS Manual, Section 3, Planning for the QEHSIS Management Systems

2.9 QEHSIS Manual, Section 7, Documented Information

2.10 QEHSIS Manual, Section 15, Performance Evaluation

2.11 QEHSIS Manual, Section 16, Control of Non-conforming Process Outputs Products and Services

2.12 QEHSIS Manual, Section 18, Improvement

Applicable Procedure(s):

2.13 Corrective and Preventive Action Procedure – Doc. No. 2P-850-001

2.14 Internal and External Audit Procedure – Doc. No. 2P-822-001

2.15 Management Review Procedure – Doc. No. 2P-560-002

2.16 Internal and External Communications Procedure Doc. No. 2P-510-001

2.17 Records Management Procedure – Doc. No. 2P-424-001

2.18 Control of Non-conforming Material or Product Procedure – Doc. No. 2P-830-001

2.19 Supplier Quality Evaluation Procedure – Doc. No. 2P-741-003

2.20 Monitoring and Measurement of QEHSIS Performance – Doc. No. 2P-840-001

2.21 Internal Audit for Environmental, Health and Safety Compliance Procedure

2.22 Internal and External Audit Procedure – Doc. No. 4P-039 (HEV)

2.23 Records Management Procedure – Doc. No. 4P-008 (HEV)

2.24 Corrective and Preventive Action Procedure 4P-003 (HEV)

2.25 HEV Process Map and Interactions 4PD-001 (HEV)

2.26 Management Review 4PD-018 (HEV)

2.27 Internal and External Audits 4PD-017 (HEV)

2.28 Corrective and Preventive Actions 4PD-019 (HEV)

2.29 Control of Non-conforming Material 4PD-010 (HEV)

2.30 Supplier Development 4PD-013 (HEV)

3.0 DEFINITIONS:

3.1 See QEHSIS 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 QEHSIS – Quality, Environmental, Health, Safety, and Information Security

3.5 TS – Technical Specification

3.6 IEC – International Electrotechnical Commission

4.0 QEHSIS MANAGEMENT SYSTEMS REQUIREMENTS:

4.1 Management Review – General:

4.1.1 Management reviews the QEHSIS Management Systems at least once per fiscal year to ensure its continuing suitability, adequacy and effectiveness. This review includes assessing opportunities for improvement and the need for changes to the QEHSIS Management Systems, including the Policy, Objectives and Targets. Records from these Reviews are maintained.

4.1.2 HEV Plant: The frequency of management review(s) shall be increased based on the risk of compliance with customer requirements resulting from internal or external changes impacting the QMS and performance related issues.

4.1.3 The Management Review process ensures necessary information is collected to allow Management to perform this evaluation of QEHSIS Management Systems effectiveness and includes both Review Inputs and Outputs.

4.1.4 Plant management 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 the strategic direction of the organization and information on the Cost of Poor Quality and:

4.2.1.1 Follow-up actions from Previous Management Reviews.

4.2.1.2 Changes in the external and internal issues that are relevant to the Quality and environmental management system.

4.2.1.3 Customer Satisfaction and Feedback from relevant interested parties.

4.2.1.4 Monitoring and measuring process performance and product conformity to requirements.

4.2.1.5 Status of Nonconformities, Corrective and Preventive Actions, including trend information.

4.2.1.6 Audit Results.

4.2.1.7 Performance of external providers.

4.2.1.8 Adequacy of resources.

4.2.1.9 changes affecting the QEHSIS Management Systems, including changes to the Policy, Objectives, requirements of interested parties, significant environmental aspects, risks and opportunities, Procedure or other elements of the QEHSIS Management Systems.

4.2.1.10 recommendations for improvement.

4.2.1.11 Legal and Regulatory Requirements relevant to the QEHSIS Management Systems.

4.2.1.12 Changes in the external and internal issues that are relevant to the Quality and environmental management system.

4.2.1.13 The extent of which QEHSIS objectives have been met, resources, and continual improvement opportunities.

4.2.1.14 Communication from external parties, including complaints regarding Environmental matters.

4.2.1.15 HEV Plant/FMC CSR: Management Review Input must also include the Q1 Manufacturing Site Assessment results, cost of poor quality, product performance, assessments of manufacturing feasibility made for changes to existing operations and for new product, customer satisfaction, review of performance against maintenance objectives, warranty performance, customer score cards, identification of potential field failures identified through risk analysis (FMEA), actual field failures and the impact on safety or the environment

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 QEHSIS Management Systems and its processes;

4.3.1.2 improvement of product related to Customer Requirements;

4.3.1.3 continued suitability of the QEHSIS Policies and Objectives;

4.3.1.4 possible need for changes to the QEHSIS Policies, Objectives and other elements of the QEHSIS Management Systems;

4.3.1.5 Resource needs;

4.3.1.6 actions for objectives that have not been achieved, if needed

4.3.1.7 Management Review Records.

4.3.1.8 Any related QEHSIS implications for the strategic direction and opportunities to better integrate the management systems with other business processes if needed.

4.3.1.9 HEV Plant/IATF: Top management shall document and implement an action plan when customer performance targets are not met.

5.0 RESPONSIBILITY:

5.1 Individual responsibilities associated with Management Review are stated in the Management Review Procedure. Overall responsibility for Management Review resides with Management. Ensuring 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 QEHSIS Management Systems Manual and includes minutes and associated data.

1.0 PURPOSE:

This Section establishes Documented Information of the QEHSIS Management System.

2.0 REFERENCE DOCUMENTS:

Standard(s) and Specification(s):

2.1 ISO 9001:2015, Clause 7.5

2.2 IATF 16949:2016, Clause 7.5

2.3 Ford Customer Specific Requirements for IATF 16949:2016 (CSR), Clauses 4.4, 4.31, 4.33, 7.5

2.4 ISO 14001:2015, Clause 7.5

2.5 ISO 45001:2018, Clause 7.5

2.6 ISO/IEC 27001:2022

2.7 ISO/IEC 17025:2017

QEHSIS Manual:

2.8 QEHSIS Manual, Section 2, QEHSIS Management System

2.9 QEHSIS Manual, Section 3, Planning for the QEHSIS Management System

2.10 QEHSIS Manual, Section 9, Operation Planning and Control

Applicable Procedure(s):

2.11 Document and Data Control Procedure – Doc. No. 2P-423-001

2.12 Records Management Procedure – Doc. No. 2P-424-001

2.13 Document and Data Control Procedure – Doc. No. 4P-007 (HEV)

2.14 Record Management Procedure – Doc. No. 4P-008 (HEV)

2.15 RDE Lab Validation and Test Procedure - Doc. No. 14P-830-002

2.16 HEV Process Map and Interactions 4PD-001 (HEV)

2.17 Quality Planning 4PD-004 (HEV)

2.18 Process Design Development 4PD-008 (HEV)

3.0 DEFINITIONS:

3.1 See QEHSIS 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 Standardizations

3.4 QEHSIS – Quality, Environmental, Health, Safety, and Information Security

3.5 STA – Supplier Technical Assistance

3.6 IATF – International Automotive Task Force

3.7 FMEA – Failure Mode and Effects Analysis

3.8 DAP – Data Acceptance Program

3.9 CTDP – Client Test Data Program

3.10 IEC – International Electro-technical Commission

4.0 QEHSIS MANAGEMENT SYSTEMS REQUIREMENTS:

4.1 Documented Information– General:

4.1.1 Toshiba International Corporation (TIC) has established and maintains documented procedures to control documents and data relating to requirements of the QEHSIS Management Systems.

4.1.2 QEHSIS Management Systems documentation includes:

4.1.2.1 documented statements of a QEHSIS Policy and QEHSIS Objectives;

4.1.2.2 this QEHSIS Manual (See Subsection 4.2 below);

4.1.2.3 documented procedures referenced within each Section of this QEHSIS Manual and as required by ISO 9001:2015, IATF 16949:2016, FMC CSR, ISO 14001:2015, ISO 45001:2018, ISO 27001:2022 and ISO/IEC 17025:2017 UL CTDP Standards;

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 process elements of the QEHSIS Management Systems and their interaction;

4.1.2.6 records required by ISO 9001:2015, IATF 16949:2016, FMC CSR, ISO 14001:2004, ISO 45001:2018, ISO 27001:2022 and ISO/IEC 17025:2017 UL CTDP Standards and requirements.

4.1.3 Documentation may be in the form of hardcopy or electronic media.

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 QEHSIS Manual:

4.2.1 This QEHSIS Manual provides an overall description of the QEHSIS Management Systems Scope. It also includes the QEHSIS Policy, QEHSIS Objectives, documented procedures (Referenced within this QEHSIS Manual) and a description of interactions between processes of the QEHSIS Management Systems. This QEHSIS Manual also is used to instruct and guide all Toshiba International Corporation personnel and to inform Interested Parties and Customers of controls implemented to assure Product Quality, Environmental Compliance, and Occupational Health and Safety.

4.2.2 This established and maintained QEHSIS Manual includes:

4.2.2.1 requirements of the QEHSIS Management Systems (See Subsection 4.0 within each Section of this QEHSIS Manual) as it applies to product and services. No exclusions are claimed under ISO 9001:2015.

4.2.2.2 inclusion or reference to documented procedures established for the QEHSIS Management Systems (Reference Subsection 2.0 within each Section of this QEHSIS Manual);

4.2.2.3 a description of interactions between processes of the QEHSIS Management Systems (Reference Section 02 of this QEHSIS Manual).

4.2.2.4 the applicable clauses of ISO/IEC 17025:2017 standard to meet UL Client Test Data Program (CTDP) in the PE Lab.

4.3 Control of Documents:

4.3.1 Documents required by the QEHSIS Management Systems are controlled as defined in the Document and Data Control Procedure, which defines the controls needed for:

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 QEHSIS Policies, Objectives and Targets. Current operating criteria are stipulated in the associated procedures.

4.3.3 HEV/ IATF 16949: 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.

4.3.4 HEV/ IATF 16949: shall maintain a record of the date on which each change is implemented in production. The implementation includes updated documents.

4.3.5 HEV/ IATF 16949: 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.

4.3.6 PE Lab/CTDP system - Test and calibration methods and method validation:

4.3.6.1 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.

4.3.6.2 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.

4.3.6.3 As of Jan. 1, 2009, other supporting documentation is 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.

4.3.7 PE Lab/CTDP system - Selection of methods:

4.3.7.1 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 QEHSIS Management Systems. Records are maintained to be legible, readily identifiable and retrievable. Controls are needed for identification, storage, protection, retrieval, retention time and disposition of records.

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.

4.4.4 Customer requirements do not supersede any regulatory requirements. (HEV Reference FMC CSR 7.5.3.2.1)

4.4.5 HEV/ IATF 16949: 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.

4.4.6 HEV/ IATF 16949: 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.

4.4.7 HEV/ IATF 16949: Specific records requirements specified by FMC (CSR 7.5.3.2.1) will be included in the Records Management Procedure.

4.4.8 PE 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.

4.4.8.1 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.

4.4.8.2 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.

4.4.8.3 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 appropriate documents are available for use in their areas. These documents shall be periodically reviewed, and obsolete documents shall be removed. It is the responsibility of Department Managers to ensure required documented records from their functional areas are also created and maintained as specified.

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

5.3 Document Control Administrators are responsible for controlling and maintaining Master Lists of hardcopies and electronic QEHSIS documents.

6.0 RECORDS:

6.1 QEHSIS Management Systems Records are identified in each Section of this QEHSIS 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 QEHSIS Management Systems.

2.0 REFERENCE DOCUMENTS:

Standard(s) and Specification(s):

2.1 ISO 9001:2015, Clause 7.1

2.2 IATF 16949:2016, Clause 7.1

2.3 Ford Customer Specific Requirements for IATF 16949:2016 (CSR), Clauses 7.1

2.4 ISO 14001:2015, Clause 7.1

2.5 ISO 45001:2018, Clause 7.1

2.6 ISO/IEC 27001:2022, Clause 7.1

2.7 ISO/IEC 17025:2017, Clause 6.2

QEHSIS Manual:

2.8 QEHSIS Manual, Section 7, Documented Information

Applicable Procedure(s):

2.9 Competency, Awareness and Training Procedure – Doc. No. 2P-622-002

2.10 Records Management Procedure – Doc. No. 2P-424-001

2.11 Skill Matrix Procedure –Doc. No. 2P-622-001

2.12 Organizational Knowledge Procedure – Doc. No. 2P-716-001

2.13 Context of the Organization Procedure – Doc. No. 2P-400-001

2.14 Management Review Procedure – Doc. No. 2P-560-002

2.15 Strategy Deployment Procedure – Doc. No. 2P-551-002

2.16 Record Management Procedure – Doc. No. 4P-008 (HEV)

2.17 Employee Training Procedure – Doc. No. 4P-010 (HEV)

2.18 Operator/Group Leader Training Procedure – Doc. No. 4P-011 (HEV)

2.19 Facility Maintenance Procedure – Doc. No. 4P-012 (HEV)

2.20 Contingency Response Procedure – Doc. No. 4P-016 (HEV)

2.21 Quality Planning 4PD-004 (HEV)

2.22 Quality Goals & Objectives 4PD-003 (HEV)

2.23 Human Resources / Qualified Employees 4PD-005 (HEV)

2.24 Management Review 4PD-018 (HEV)

2.25 Continual Improvement 4PD-021 (HEV)

3.0 DEFINITIONS:

3.1 See QEHSIS Manual, Section 21, Glossary (Terms and Definitions) for definitions of italicized terms.

3.2 ISO – International Organization for Standardization

3.3 QEHSIS – Quality, Environmental, Health, Safety, and Information Security

3.4 DAP – Data Acceptance Program

3.5 CTDP – Client Test Data Program

4.0 QEHSIS MANAGEMENT SYSTEMS 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 QEHSIS Management Systems and continually improve its effectiveness, and to enhance Customer Satisfaction by meeting Customer Requirements and requirements of Interested Parties.

4.1.2 Any employee may identify requirements for additional resources (equipment, services, and personnel). Management is responsible for evaluating 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 QEHSIS Management Systems 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 QEHSIS Management Systems 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 PE 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, information security 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 and Interested Parties Requirements, requirements of the QEHSIS Management Systems, 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 Assurance Manager is responsible for the Quality Management Systems-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 and Environmental related Training.

5.6 The Information Security Manager is responsible for Information Security 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 QEHSIS Manual.

1.0 PURPOSE:

Toshiba management shall plan, implement and control the processes needed to meet the requirements for the provision of products and services, and to implement the actions to address the risks and opportunities.

2.0 REFERENCE DOCUMENTS:

Standard(s) and Specification(s):

2.1 ISO 9001:2015, Clause 8.2,8.3

2.2 IATF 16949:2016, Clause 8.2,8.3

2.3 Ford Customer Specific Requirements for IATF 16949:2016 (CSR), Clauses 4.14, 4.15, 8.2, 8.3

2.4 ISO 14001:2015, Clauses 6.1.3, 8.1

2.5 ISO 45001:2018, Clause 8.1.4

2.6 ISO/IEC 27001:2022 Clause 6

QEHSIS Manual:

2.7 QEHSIS Manual, Section 2, QEHSIS Management System

2.8 QEHSIS Manual, Section 3, Planning for the QEHSIS Management System

2.9 QEHSIS Manual, Section 7, Documented Information

2.10 QEHSIS Manual, Section 8, Resources

2.11 QEHSIS Manual, Section 10, Determination of Requirements for Products and Services

2.12 QEHSIS Manual, Section 11, Design and Development of Products and Services

2.13 QEHSIS Manual, Section 12, Control of Externally Provided Products and Services

2.14 QEHSIS Manual, Section 13, Production and Service Provision

2.15 QEHSIS Manual, Section 14, Monitoring and Measuring Resources

2.16 QEHSIS Manual, Section 15, Performance Evaluation

Applicable Procedure(s):

2.17 Records Management Procedure – Doc. No. 2P-424-001

2.18 Design Control New Product Development Procedure – Doc. No. 2P-734-001

2.19 Design Control of Modified and/or Custom Product Procedure – Doc. No. 2P-830-002

2.20 Supplier Quality Evaluation Procedure – Doc. No. 2P-741-003

2.21 Calibration Control of Inspection Measuring and Test Equipment Procedure – Doc. No. 2P-760-001

2.22 Monitoring and Measurement of QEHSIS Performance – Doc. No. 2P-840-001

2.23 Incoming Receipt of Product and Material Procedure – Doc. No. 2P-743-001

2.24 Product Identification and Traceability Procedure- Doc. No. 2P-753-002

2.25 Inspection and Test Status Procedure – Doc. No. 2P-753-001

2.26 Customer Supplied Product Procedure – Doc. No. 2P-754-001

2.27 Management Review Procedure – Doc. No. 2P-560-002

2.28 Foreign Material Exclusion Procedure – Doc. No. 2P-751-001

2.29 Handling, Storage, Preservation and Shipment Procedure – Doc. No. 2P-755-001

2.30 Environmental Aspects Identification, Management and Performance Procedure

2.31 Hazard Assessment Procedure

2.32 Records Management Procedure – Doc. No. 4P-008 (HEV)

2.33 Product Design Development Procedure 4P-001 (HEV)

2.34 Process Design Development Procedure 4P-002 (HEV)

2.35 HEV Process Map and Interactions 4PD-001 (HEV)

2.36 Quality Planning 4PD-004 (HEV)

2.37 Sales Process Diagram 4PD-002 (HEV)

2.38 Process Design Development 4PD-008 (HEV)

2.39 Purchasing Process 4PD-014 (HEV)

2.40 Receive & Inspect & Ship 4PD-009 (HEV)

2.41 PFMEA 4PD-020 (HEV)

2.42 Operational Control 4PD-012 (HEV)

2.43 Monitor, Measurement Analysis & Evaluation 4PD-016 (HEV)

2.44 Calibration 4PD-006 (HEV)

2.45 Supplier Monitoring & Development 4PD-013 (HEV)

2.46 Preventive and Predictive Maintenance Process 4PD-011 (HEV)

2.47 Production Planning 4PD-026 (HEV)

2.48 Management of Change Procedure Doc. No. 2P-630-002

3.0 DEFINITIONS:

3.1 See QEHSIS 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 QEHSIS – Quality, Environmental, Health, Safety, and Information Security

3.6 IATF – International Automotive Task Force

4.0 QEHSIS MANAGEMENT SYSTEM REQUIREMENTS:

4.1 Operation Planning and Control:

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 and controlled. Planning of is consistent with requirements of other processes of the QEHSIS Management System

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 and controlled to ensure they are performed under specified conditions.

4.1.4 Planning and Control is in the form of documented procedures to cover situations where their absence could lead to deviations from the QEHSIS 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 Operation Planning and Control, Management determines the following as appropriate:

4.1.6.1 QEHSIS Objectives and product requirements

4.1.6.2 the need to establish processes, documents, and provide resources specific to the product;

4.1.6.3 required Determination of Requirements for Products and Services, Verification, Validation, Monitoring, Inspection and Test activities specific to the product and criteria for product acceptance;

4.1.6.4 establishment of Performance Evaluation processes;

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;

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 QEHSIS Policy, Objectives and Targets. 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 of Operation Planning and Control processes and resulting product meet requirements.

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

4.1.8 HEV/ IATF 16949: Customer requirements and references to its technical specifications shall be included in the planning of product realization design and develop planning shall include all affected

stakeholders within the organization and as appropriate its supply chain, some areas for using such as multidisciplinary approach include but are not limited to APQP, DFMEA, PFMEA, Control Plan

4.1.9 HEV/ IATF 16949: Acceptance criteria shall be defined and approved by the customer. For attribute data sampling, acceptance-level shall be zero defects. (Reference FMC CSR Table A)

4.1.10 HEV/ IATF 16949: Toshiba International Corporation ensures the confidentiality of customer-contracted products and projects under development, and related product information.

4.1.11 HEV/ IATF 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 Operation Planning and Control 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 Operation Planning and Control are defined in associated procedures, check sheets, production schedules, control plans (as applicable), and those maintained electronically on the Toshiba International Corporation Network.

1.0 PURPOSE:

This Section is to determine, review, and communicate product and service requirements.

2.0 REFERENCE DOCUMENTS:

Standard(s) and Specification(s):

2.1 ISO 9001:2015 Clause 8.2.1, 9.1.2

2.2 IATF 16949:2016 Clause 8.2.1, 9.1.2

2.3 Ford Customer Specific Requirements for IATF 16949:2016 (CSR) Clause 8.2.1, 9.1.2

2.4 ISO 14001:2015Clause 7.4

2.5 ISO 45001:2018 Clause 8.1.4

QEHSIS Manual:

2.6 QEHSIS Manual, Section 7, Documented Information

Applicable Procedure(s):

2.7 Change Request Procedure – Doc. No. 2P-723-001

2.8 Engineering Change Order Procedure – Doc. No. 2P-737-001

2.9 Internal and External Communication Procedure 2P-510-001

2.10 Pricing Approval for Quotations – Doc. No. 2P-722-001

2.11 Records Management Procedure – Doc. No. 2P-424-001

2.12 Design Control New Product Development Procedure – Doc. No. 2P-734-001

2.13 Design Control Modified and/or Custom Product Procedure – Doc. No. 2P-830-002

2.14 Customer Supplied Product Procedure – Doc. No. 2P-754-001

2.15 Corrective and Preventive Action Procedure – Doc. No. 2P-850-001

2.16 Internal and External Audit Procedure – Doc. No. 2P-822-001

2.17 Control of Nonconforming Material or Product Procedure – Doc. No. 2P-830-001

2.18 Record Management Procedure – Doc. No. 4P-008 (HEV)

2.19 Customer Claim Handling Procedure – Doc. No. 4P-032 (HEV)

2.20 Customer and Quality Representative Procedure 4P-009 (HEV)

2.21 Product Design Development Procedure 4P-001 (HEV)

2.22 Process Design Development Procedure 4P-002 (HEV)

2.23 RMA Process and Handling Procedure – Doc. No. 108P-830-001

2.24 HEV Process Map and Interactions 4PD-001 (HEV)

2.25 Quality Planning 4PD-004 (HEV)

2.26 Sales Process Diagram 4PD-002 (HEV)

2.27 Process Design Development 4PD-008 (HEV)

2.28 Purchasing Process 4PD-014 (HEV)

2.29 Supplier Monitoring & Development 4PD-013 (HEV)

2.30 Internal and External Audits 4PD-017 (HEV)

2.31 Corrective and Preventive Actions 4PD-019 (HEV)

2.32 Control of non-conforming Material 4PD-010 (HEV)

3.0 DEFINITIONS:

3.1 See QEHSIS 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 QEHSIS – Quality, Environmental, Health, Safety, and Information Security

3.6 IATF – International Automotive Task Force

3.7 PPAP – Production Part Approval Process

3.8 APQP – Advanced Product Quality Planning

4.0 QEHSIS MANAGEMENT SYSTEMS REQUIREMENTS:

4.1 Procedures detailing methods for reviewing proposals and contracts have been established to ensure the capability to meet all the Customer's specified requirements are implemented.

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 Operation Planning and Control with Inputs relative to scheduling, material and labor costing, and resource requirements from appropriate Manufacturing or Engineering functions responsible for Operation Planning and Control. The product related requirements are finalized at the contract stage and communicated throughout the Operation Planning and Control, 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.

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 Operation Planning and Control.

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;

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.

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 suppliers 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 7.5.2).

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.

4.1.4.1.3 HEV Plant: The Organization shall monitor performance and customer satisfaction metric as defined per Q1.

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 Operation Planning and Control 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 QEHSIS Manual.

1.0 PURPOSE:

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

2.0 REFERENCE DOCUMENTS:

Standard(s) and Specification(s):

2.1 ISO 9001:2015, Clause 8.3

2.2 IATF 16949:2016 Clause 8.3

2.3 Ford Customer Specific Requirements for IATF 16949:2016, Clauses 8.3

2.4 ISO 14001:2015 Clause 8.1

2.5 ISO 45001:2018 Clause 8.1.4

Corporate Documents:

2.6 Product Safety Manual – Doc. No. DOD1000

QEHSIS Manual:

2.7 QEHSIS Manual, Section 7, Documented Information

2.8 QEHSIS Manual, Section 10, Determination of Requirements for Products and Services

Applicable Procedure(s):

2.9 Design Control of Modified and or Custom Product Procedure – Doc. No. 2P-830-002

2.10 Design Control New Product Development Procedure – Doc. No. 2P-734-001

2.11 Change Request Procedure – Doc. No. 2P-723-001

2.12 Engineering Change Order Procedure – Doc. No. 2P-737-001

2.13 Records Management Procedure – Doc. No. 2P-424-001

2.14 Configuration Management Procedure – Doc. No. 2P-714-001

2.15 Product Identification and Traceability Procedure – Doc. No. 2P-753-002

2.16 Inspection and Test Plan (ITP) Procedure – Doc. No. 2P-722-002

2.17 Reliability Availability Maintainability Safety (RAMS) Procedure – Doc. No. 2P-731-002

2.18 Record Management Procedure – Doc. No. 4P-424-001 (HEV)

2.19 Product Design Development Procedure 4P-001 (HEV)

2.20 Process Design Development Procedure 4P-002 (HEV)

2.21 QC Notice / Change Notice Procedure – Doc. No. 4P-019 (HEV)

2.22 FMEA Procedure – Doc. No. 4P-021 (HEV)

2.23 Special Characteristics Procedure – Doc. No. 4P-023 (HEV)

2.24 Control Plan Procedure– Doc. No. 4P-030 (HEV)

2.25 Product Identification and Traceability Procedure 4P-033 (HEV)

2.26 HEV Process Map and Interactions 4PD-001 (HEV)

2.27 Quality Planning 4PD-004 (HEV)

2.28 Sales Process Diagram 4PD-002 (HEV)

3.0 DEFINITIONS:

3.1 See QEHSIS 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 QEHSIS – Quality, Environmental, Health, Safety, and Information Security

3.7 SDS – System Design Specification

3.8 IATF – International Automotive Task Force

3.9 VDS – Vehicle Design Specification

3.10 FMEA – Failure Mode and Effects Analysis

4.0 QEHSIS MANAGEMENT SYSTEM REQUIREMENTS:

4.1 Design and Development Planning:

4.1.1 In determining the stages and controls for design and development, the following shall be considered:

a. The nature, duration and complexity of the design and development activities;

b. The required process stages, including applicable design and development reviews;

c. The required design and development verification and validation activities;

d. The responsibilities and authorities involved in the design and development process;

e. The internal and external resources need for the design and development of products and services;

f. The need to control interfaces between persons involved in the design and development process;

g. The need for involvement of customers and users in the design and development process;

h. The requirements for subsequent provision of products and services;

i. The level of control expected for the design and development process by customers and other relevant interested parties;

j. The documented information needed to demonstrate that design and development requirements have been met

k. HEV/ IATF 16949: Multidisciplinary Approach

Operation Planning and Control shall be prepared using multidisciplinary approach (involving design, manufacturing, engineering, quality, production, etc.), including:

- All affected stakeholders within the organization and as appropriated its supply chain.

- Project management including product and manufacturing process design activities.
- Development/finalization and monitoring of special characteristics
- Development and review of process flow
- Development and review of FMEAs including actions to reduce potential risks
- Development and review of control plans, plans including incoming inspection and standard work instructions.
- Design FMEA by design responsible organization required Ford engineering approval in writing, as well as revisions to these documents after initial acceptance.
- Manufacturing Feasibility assessments shall include capacity planning following FMC CSR 7.1.3.1

4.2 Design and Development Inputs:

4.2.1 In determining the requirements essential for the specific types of products and services to be designed and developed. The following shall be considered:

a. Functional and performance requirements;

b. Information derived from previous similar design and development activities;

c. Statutory and regulatory requirements;

d. Standards or codes of practice that the organization has committed to implement;

e. Potential consequences of failure due to the nature of the products and services.

f. Environmental Aspects and their life cycle stages, and Occupational Health and Safety Risks associated with the resulting product or service.

g. HEV/ IATF 16949: Conformity to customer requirements for designation, documentation and control of special characteristics, identification, traceability, packing assessment of risk.

4.2.2 Input shall be adequate for design and development purposes, complete and unambiguous.

4.2.3 Conflicting design and development inputs shall be resolved.

4.2.4 Documented information on design and development inputs shall be retained.

4.3 Design and Development Controls

4.3.1 To apply controls to the design and development process to ensure that:

a. The results to be achieved are defined;

b. Reviews are conducted to evaluate the ability of the results of design and development to meet requirements;

c. Verification activities are conducted to ensure that the design and development outputs meet the input requirements;

d. Validation activities are conducted to ensure that the resulting products and services meet the requirements for the specified application or intended use;

e. Any necessary actions are taken on problems determined during the reviews, or verification and validation activities;

f. Documented information of these activities is retained.

4.3.2 Design and development reviews, verification and validation have distinct purposes. They can be conducted separately or in any combination, as is suitable for the products and services.

4.3.3 HEV Plant/FMC CSR; The organization shall perform Design Verification (DV) to show conformance to the appropriate Ford Engineering requirements.

4.3.4 HEV Plant/FMC CSR; The organization is responsible for the quality of the parts it produces and for any subcontracted services, including sub-tier suppliers specified by Ford Motor Company without a Multi-Party Agreement.

4.4 Design and Development Outputs:

4.4.1 The Design and Development Outputs shall:

a. Meet the Input requirements;

b. Are adequate for the subsequent processes for provision of products and services;

c. include or reference monitoring and measuring requirements, as appropriate, and acceptance criteria;

d. specify the characteristics of the products and service that are essential for their intended purpose and their safe and proper provision.

e. Documented information on design and development outputs shall be retained

4.4.2 HEV Plant/IATF 16949; The product design output shall be expressed in terms that can be verified and validated against product design input requirements.

4.4.3 HEV Plant/IATF 16949; The organization shall document the manufacturing process design output in a manner that enables verification against the manufacturing process design inputs.

4.5 Control of Design and Development Changes:

4.5.1 To identify, review and control changes made during, or subsequent to, the design and development of products and services, to the extent necessary to ensure that there is no adverse impact on conformity to requirements.

4.5.2 Documented Information shall be retained on:

a. Design and development changes;

b. The results of reviews;

c. The authorization of the changes;

d. The actions taken to prevent adverse impacts.

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.

1.0 PURPOSE:

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

2.0 REFERENCE DOCUMENTS:

Standard(s) and Specification(s):

2.1 ISO 9001:2015 Clause 8.2

2.2 ISO 14001:2015 Clause 8.1

2.3 ISO 45001:2018 Clause 8.1.4

2.4 IATF 16949:2016 Clause 8.2

Corporate Documents:

2.5 Capital Appropriation Procedure – Doc. No. CQA03.40

QEHSIS Manual:

2.6 QEHSIS Manual, Section 7, Documented Information

Applicable Procedures:

2.7 Purchase 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 Internal and External Communication Procedure - Doc. No. 2P-510-001

2.13 Incoming Receipt of Product and Material Procedure – Doc. No. 2P-743-001

2.14 Context of the Organizational Procedure - Doc. No. 2P-400-001

2.15 Supplier Standards Manual – Doc. No. 104M-741-001

2.16 Procurement Guideline – Supplier Relations – Controls and Processes – Doc. No. 2P-711-001

2.17 Procurement Quality Standard – Doc. No. 4P-025 (HEV)

2.18 Receiving Procedure – Doc. No. 4P-034 (HEV)

2.19 Supplier Monitoring and Development Procedure – Doc. No. 4P-027 (HEV)

2.20 Purchasing Procedure – Doc. No. 108P-740-001 (M&D)

2.21 ODM-Purchasing Development – Doc. No. 108S-740-005 (M&D)

2.22 Record Management Procedure – Doc. No. 4P-008 (HEV)

2.23 Sales Process Diagram 4PD-002 (HEV)

2.24 Purchasing Process 4PD-014 (HEV)

2.25 Process Design Development 4PD-008 (HEV)

2.26 Internal and External Audits 4PD-017 (HEV)

2.27 Control of Special Processes Procedure - Doc. No. 2P-752-001

3.0 DEFINITIONS:

3.1 See QEHSIS 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 QEHSIS – Quality, Environmental, Health, Safety, and Information Security

3.5 TS – Technical Specification

3.6 FMEA – Failure Mode and Effects Analysis

4.0 QEHSIS MANAGEMENT SYSTEMS REQUIREMENTS:

4.1 Toshiba International Corporation (TIC) has established and maintains documented procedures which define controls for purchasing of production related products and materials, outsourced processes and services.

4.1.1 Purchasing Process:

4.1.1.1 The Purchasing process ensures purchased material, processes, and services conform to specified purchasing requirements. The type and extent of control applied to the supplier and the purchased material, process, and service is dependent upon its effect on subsequent Operation Planning and Control 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. Criteria for selection, evaluation, and re-evaluation of suppliers are established.

4.1.1.3 Environmental Health and Safety requirements for suppliers are listed in the TIC Supplier Standards Manual.

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

4.1.1.5 HEV/ IATF 16949: Purchasing process shall include recycling, environmental impact and characteristics identified based on product and manufacturing knowledge.

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, and services where applicable.

4.1.2.2 Purchasing documents, in conjunction with Engineering documents, contain technical requirements, accept/reject criteria, and QEHSIS 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 Vendor List. They are also responsible for maintaining the Approved Vendor 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.

6.2 Records of acceptable suppliers have been established and are maintained.

1.0 PURPOSE:

This Section establishes requirements for Production and Service 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:

Standard(s) and Specification(s):

2.1 ISO 9001:2015, Clause 8.5

2.2 IATF 16949:2016, Clause 8.5

2.3 Ford Customer Specific Requirements for IATF 16949:2016, Clause 8.5

2.4 ISO 14001:2015 Clause 8.1

2.5 ISO 45001:2018 Clause 8.1

Corporate Documents:

2.6 Capital Appropriation Procedure – Doc. No. CQA03.40

2.7 Production Cycle – Doc. No. CQA02.60

QEHSIS Manual:

2.8 QEHSIS Manual, Section 7, Documented Information

2.9 QEHSIS Manual, Section 8, Resources

2.10 QEHSIS Manual, Section 10, Determination of Requirements for Products and Services

2.11 QEHSIS Manual, Section 14, Monitoring and Measuring Resources

2.12 QEHSIS Manual, Section 15, Performance Evaluation

Applicable Procedure(s):

2.13 Product Identification and Traceability Procedure – Doc. No. 2P-753-002

2.14 Records Management Procedure – Doc. No. 2P-424-001

2.15 Incoming receipt of product and Material Procedure - Doc. No. 2P-743-001

2.16 Handling Storage Preservation Shipment Procedure - Doc. No. 2P-755-001

2.17 Monitoring and Measurement of QEHSIS Performance – Doc. No. 2P-840-001

2.18 Calibration Control of Inspection Measuring and Test Equipment Procedure – Doc. No. 2P-760-001

2.19 Inventory Control procedure – Doc. No. 4P-036 (HEV)

2.20 Verification of Job Set ups – Doc. No. 4P-031 (HEV)

2.21 Offsite Material Replenishment Procedure – Doc. No. 4P-035 (HEV)

2.22 Facility Maintenance Procedure – Doc. No. 4P-012 (HEV)

2.23 Product Identification and Traceability Procedure – Doc. No. 4P-033 (HEV)

2.24 Control Plan Procedure 4P-030 (HEV)

2.25 Monitoring and Measurement of Processes 4P-040 (HEV)

2.26 Product Release 4P-041 (HEV)

2.27 HEV Process Map and Interactions 4PD-001 (HEV)

2.28 Quality Planning 4PD-004 (HEV)

2.29 Sales Process Diagram 4PD-002 (HEV)

2.30 Process Design Development 4PD-008 (HEV)

2.31 Purchasing Process 4PD-014 (HEV)

2.32 Receive & Inspect & Ship 4PD-009 (HEV)

2.33 PFMEA 4PD-020 (HEV)

2.34 Operational Control 4PD-012 (HEV)

2.35 Calibration 4PD-006 (HEV)

2.36 Supplier Monitoring & Development 4PD-013 (HEV)

2.37 Preventive and Predictive Maintenance Process 4PD-011 (HEV)

2.38 Monitor, Measurement Analysis & Evaluation 4PD-016 (HEV)

2.39 Production Planning 4PD-026 (HEV)

3.0 DEFINITIONS:

3.1 See QEHSIS 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 QEHSIS – Quality, Environmental, Health, Safety, and Information Security

3.7 IATF – International Automotive Task Force

3.8 CTDP – Client Test Data Program

4.0 QEHSIS MANAGEMENT SYSTEMS REQUIREMENTS:

4.1 Control of Production and Service Provision:

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

4.1.1.1 availability of information describing characteristics of the product or service;

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;

4.1.1.3 use of suitable equipment and working Environment;

4.1.1.4 availability and use of Monitoring and Measuring Devices;

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;

4.1.1.7 criteria for workmanship are available in a clear practical manner (e.g. representative samples, written standards, or illustrations);

4.1.1.8 release, delivery, and post-delivery activities;

4.1.1.9 suitable equipment maintenance to ensure continued process capability

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;

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 QEHSIS Policy, Objectives and associated Targets.

4.1.1.13 HEV Plant/ IATF 16949: 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/ IATF 16949: 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/ IATF 16949: 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;

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 a timely review of planned maintenance activities and a documented action plan, included in the Management Review process, to address any backlog.
- HEV Plant/ IATF 16949: 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 workstation. 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.

4.2.9 HEV Plant /IATF 16949. Documentation for set up personnel must be maintained, perform first-off last-off part variation and comparison where applicable

4.2.10 HEV Plant / IATF 16949. Verification after planned or unplanned shutdown: necessary actions shall be implemented to ensure product compliance with requirements.

4.2.11 HEV Plant / IATF 16949: Standardized operator instructions shall be legible and presented in the language(s) understood by the personnel responsible for following them. They shall be communicated and understood by the employees performing the task; these instructions shall be accessible for use at the designated work area(s). These instructions shall be derived from sources such as the quality plan, the control plan and the product realization process.

4.2.12 HEV Plant / FMC CSR: The organization shall ensure that work instructions contain reaction plans for non-conformances showing the specific required steps.

4.3 **Identification and Traceability:**

4.3.1 Toshiba International Corporation (TIC) maintains Systems and Procedures for identifying products, material, and services by suitable means. 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. This identification is recorded.

4.3.3 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

4.4 **Customer or External Provider Property:**

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

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

4.4.3 HEV Plant/ IATF16949: 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 products in stock at planned intervals in order to detect deterioration, as well as use an inventory management system to optimize inventory turnover time and assure stock rotation. Obsolete products are controlled in a similar manner to nonconforming products. Organizations shall comply with preservation, packaging, shipping, and labeling requirements as provided by their customers.

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 along with their risks and opportunities. Toshiba International Corporation plans these activities, including maintenance or outsourced processes, to ensure they are performed under specified conditions by:

4.6.1.1 establishing and maintaining documented procedures to cover potential emergencies or situations where their absence could lead to deviations from the QEHSIS 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, contractors or other interested parties.

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 HEV Plant: Materials Manager is responsible for shipping.

5.5 Production Engineering is responsible for Validation of Processes. The responsibility for the control of Customer Supplier Product is identified in the procedure.

5.6 Manufacturing Engineering is responsible for Validation of production processes.

5.7 Quality Control is responsible for monitoring and measurement, identification, and traceability.

5.8 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.

1.0 PURPOSE:

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

2.0 REFERENCE DOCUMENTS:

Standard(s) and Specification(s):

2.1 ISO 9001:2015, Clause 7.1.5, 9.1.3

2.2 IATF 16949:2016, Clause7.1.5, 9.1.3

2.3 Ford Customer Specific Requirements for IATF 16949:2016, Clause 4.35, 4.36, 7.1.5,9.1.3

2.4 ISO 14001:2015 Clause 9.1

2.5 ISO 45001:2018 Clause 9.1

2.6 ISO/IEC 17025:2017, Clause 9.1

QEHSIS Manual:

2.7 QEHSIS Manual, Section 7, Documented Information

2.8 QEHSIS Manual, Section 10, Determination of Requirements for Products and Services

Applicable Procedures:

2.9 Calibration, Control of Inspection, Measuring and Test Equipment Procedure – Doc. No. 2P-760-001

2.10 Control of Non-conforming Material or Product Procedure – Doc. No. 2P-830-001

2.11 Corrective and Preventive Action Procedure – Doc. No. 2P-850-001

2.12 RDE Lab Validation and Test Procedure - Doc. No. 14P-830-002

2.13 Monitoring and Measurement of QEHSIS Performance Procedure – Doc. No. 2P-840-001

2.14 Records Management Procedure – Doc. No. 2P-424-001

2.15 Record Management Procedure – Doc. No. 4P-008(HEV)

2.16 Tools & Jigs Control Procedure – Doc. No. 4P-014 (HEV)

2.17 Calibration Control of IM&TE Procedure – Doc. No. 4P-044 (HEV)

2.18 Measurement System Analysis Procedure – Doc. No. 4P-038 (HEV)

2.19 Control of Non-conforming Material 4PD-010 (HEV)

2.20 Corrective and Preventive Actions 4PD-019 (HEV)

2.21 Monitor, Measurement Analysis & Evaluation 4PD-016 (HEV)

2.22 Internal and External Audits 4PD-017 (HEV)

3.0 DEFINITIONS:

3.1 See QEHSIS 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 QEHSIS – Quality, Environmental, Health, Safety, and Information Security

3.5 IATF – International Automotive Task Force

3.6 CTDP – Client Test Data Program

4.0 QEHSIS MANAGEMENT SYSTEMS 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.

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.

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 is 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/ IATF 16949: 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 the customer reference manuals on MSA.

4.7 HEV Plant/ IATF 16949: The customer is to be notified if a suspect product or material has been shipped due to inaccurate monitoring and measuring devices. Initial communication shall be followed with detailed documentation of the event.

4.8 HEV Plant/IATF 16949: 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.
- Customer requirements if any

4.9 HEV Plant/ IATF 16949: 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), there shall be evidence that the external laboratory is acceptable to the customer.

4.10 HEV Plant/ IATF 16949: 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 4.8 above have been met.

4.11 PE 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 PE 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 Environmental Health & Safety 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 2.9).

6.2 HEV/ IATF 16949: 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 Performance Evaluation of the QEHSIS Management System and associated processes.

2.0 REFERENCE DOCUMENTS:

Standard(s) and Specification(s):

2.1 ISO 9001:2015, Clause 9.1

2.2 ISO 14001:2015 Clauses 9.1, 10

2.3 ISO 45001:2018 Clauses 9.1, 10.3

2.4 ISO 27001:2022 Clauses 9 and 10

2.5 IATF 16949:2016, Clause 9.1

2.6 Ford Customer Specific Requirements for IATF 16949:2016, Clause 9.1

QEHSIS Manual:

2.7 QEHSIS Manual, Section 6, Management Review

2.8 QEHSIS Manual, Section 7, Documented Information

2.9 QEHSIS Manual, Section 9, Operation Planning and Control

2.10 QEHSIS Manual, Section 18, Improvement

Applicable Procedure(s):

2.11 Management Review Procedure – Doc. No. 2P-560-002

2.12 Corrective and Preventive Action Procedure – Doc. No.2P-850-001

2.13 Incoming Receipt of Product and Material Procedure – Doc. No. 2P-743-001

2.14 Internal External Audit Procedure – Doc. No. 2P-822-001

2.15 Monitoring and Measurement of QEHSIS Performance Procedure – Doc. No. 2P-840-001

2.16 Strategy Deployment Procedure – Doc. No. 2P-551-002

2.17 Records Management Procedure – Doc. No. 2P-424-001

2.18 Emergency Preparedness and Response Procedure

2.19 Environmental Aspects Identification, Management and Performance Procedure

2.20 Internal Audit for Environmental and Safety Compliance Procedure

2.21 Internal and External Audit Procedure – Doc. No. 4P-039 (HEV)

2.22 Monitoring and Measurement of Processes Procedure – Doc. No. 4P-040 (HEV)

2.23 Product Release Procedure – Doc. No. 4P-041 (HEV)

2.24 FMEA Procedure - Doc No 4P-021 (HEV)

2.25 Records Management Procedure – Doc. No. 4P-008 (HEV)

2.26 Corrective and Preventive Action Procedure 4P-003 (HEV)

2.27 HEV Process Map and Interactions 4PD-001 (HEV)

2.28 Monitor, Measurement Analysis & Evaluation 4PD-016 (HEV)

2.29 Internal and External Audits 4PD-017 (HEV)

2.30 Continual Improvement 4PD-021 (HEV)

2.31 Receive & Inspect & Ship 4PD-009 (HEV)

3.0 DEFINITIONS:

3.1 See QEHSIS 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

3.5 QEHSIS – Quality, Environmental, Health, Safety, and Information Security

3.6 STA – Supplier Technical Assistance

3.7 IATF – International Automotive Task Force

4.0 QEHSIS MANAGEMENT SYSTEMS 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/ IATF 16949: Appropriate statistical tools for each process shall be determined during advance quality planning and included in the APQP, DFMEA, PFMEA and Control Plan.

4.1.3 HEV/ IATF 16949: Basic statistical concepts, such as variation, control (stability), process capability and over-adjustment shall be understood and utilized by the employees involved in the collection, analysis, and management of statistical data.

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

4.1.5 Performance Evaluation processes are needed to demonstrate product conformity and ensure QEHSIS Management System conformity. This includes determination of applicable methods, including statistical techniques, as applicable, and the extent of their use.

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

4.2 Customer Satisfaction:

4.2.1 As one of the QEHSIS 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;

4.2.1.9 Customer Survey;

4.3 Internal Audit:

4.3.1 Internal Audits are conducted at planned intervals to determine whether the QEHSIS Management Systems are effective.

4.3.2 Conforms to planned arrangements, requirements of ISO 9001:2015/IATF 16949:2016, Ford CSR for IATF, ISO 14001:2015, ISO 45001:2018, ISO 27001:2022, and ISO/IEC 17025:2017 UL CTDP Standards, requirements established within this QEHSIS Manual (Reference 2.0);

4.3.2.1 is properly and effectively implemented and maintained.

4.3.3 Information regarding the results of QEHSIS Management System Audits is provided to Sr. Management for review.

4.3.4 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. Selection of Auditors and conducting Audits ensure objectivity and impartiality of the Audit process. Auditors shall not Audit their own work, or any other area where there may be a conflict of interest.

4.3.5 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

4.3.6 HEV/ IATF 16949 Internal Audits shall cover the entire quality management system including quality management system audits, manufacturing process audits and product audits. Audit programs shall be prioritized based on risk.

4.4 Monitoring and Measurement of QEHSIS Processes:

4.4.1 Suitable methods for monitoring and, where applicable, measurement of the QEHSIS Management System processes is 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. Recorded information is included to track performance, relevant operational controls, and conformance with the QEHSIS 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 and requirements from interested parties.

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 including

external environmental conditions with potential impact to Toshiba International Corporation. These procedures are periodically tested.

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.

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

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

4.4.2.2 proactive measures of performance to monitor compliance with QEHSIS requirements, operational criteria, and applicable Legislation and Regulatory requirements;

4.4.2.3 reactive measures of performance to monitor accidents, ill health, incidents (including near-misses) and other historical evidence of deficient OH&S performance;

4.4.2.4 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 Operation Planning and Control process in accordance with planned arrangements (Reference 2.8).

4.5.2 Evidence of conformity with acceptance criteria is maintained {Reference 2.8 (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 2.8).

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.

4.5.6 Records of Inspections and Tests performed are maintained as stated in these referenced procedures.

4.5.7 HEV Plant/ IATF16949: 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. A corrective action plan shall be developed and implemented by the organization indicating specific actions, 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.

4.5.8 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 are notified immediately, and test failures 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.

4.5.9 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.

4.5.10 HEV Plant/ IATF16949: 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/ IATF16949: 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:

4.5.2.1 Customer Feedback;

4.5.2.2 Non-conformance analysis based on reject rates;

4.5.2.3 Customer specific product Audits as applicable;

4.5.2.4 Warranty Feedback;

4.5.2.5 Identification of opportunities for improvement through monthly Quality Meetings and associated analysis of non-conforming data.

5.0 RESPONSIBILITY:

5.1 Responsibility for Performance Evaluation 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 QEHSIS Management System Audits are defined.

6.2 All records are maintained.

1.0 PURPOSE:

This Section defines the QEHSIS Management System requirements for Control of Non-conforming Process Outputs, Products and Services.

2.0 REFERENCE DOCUMENTS:

Standard(s) and Specification(s):

2.1 ISO 9001:2015, Clause 8.7

2.2 ISO 14001:2015 Clause 10.2

2.3 ISO 45001:2018 Clause 10.2

2.4 IATF 16949:2016, Clause 8.7

2.5 Ford Customer Specific Requirements for IATF 16949:2016, Clause 8.7

2.6 ISO/IEC 27001:2022 Clause 10.2

QEHSIS Manual:

2.7 QEHSIS Manual, Section 7, Documented Information

Applicable Procedures:

2.8 Control of Non-conforming Material or Product Procedure – Doc. No. 2P-830-001

2.9 Corrective/Preventive Action Procedure – Doc. No. 2P-850-001

2.10 Records Management Procedure – Doc. No. 2P-424-001

2.11 Monitoring and Measurement of QEHSIS Performance – Doc. No. 2P-840-001

2.12 Internal External Audit Procedure – Doc. No. 2P-822-001

2.13 Control of Non-conforming Material 4PD-010 (HEV)

2.14 Control of Nonconforming Material Procedure – Doc. No. 4P-042 (HEV)

2.15 QC Notice/ Change Notice Procedure – Doc. No. 4P-019 (HEV)

2.16 FMEA Procedure – Doc. No. 4P-021 (HEV)

2.17 Control Plan Procedure– Doc. No. 4P-030 (HEV)

2.18 Corrective and Preventive Action Procedure 4P-003 (HEV)

2.19 HEV Process Map and Interactions 4PD-001 (HEV)

2.20 Monitor, Measurement Analysis & Evaluation 4PD-016 (HEV)

2.21 Internal and External Audits 4PD-017 (HEV)

2.22 Continual Improvement 4PD-021 (HEV)

2.23 Receive & Inspect & Ship 4PD-009 (HEV)

2.24 Corrective and Preventive Actions 4PD-019 (HEV)

3.0 DEFINITIONS:

3.1 See QEHSIS 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

3.5 QEHSIS – Quality, Environmental, Health, Safety, and Information Security

3.6 IATF – International Automotive Task Force

4.0 QEHSIS MANAGEMENT SYSTEMS REQUIREMENTS:

4.1 General:

4.1.1 Incoming raw materials, in-process materials, and finished products 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 products and material, are defined in documented procedures.

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.

4.1.2.1 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.

4.1.2.2 Non-conforming product or material is dealt with in one or more of the following ways:

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

4.1.2.3 Records of the nature of non-conformities and any subsequent actions taken, including Concessions obtained, are maintained.

4.1.2.4 When a non-conforming product or material is corrected, it is subject to re-verification to demonstrate conformity to the requirements.

4.1.2.5 When a 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.

4.2 HEV Plant/FMC CSR General:

4.2.1 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. The appropriate documentation (e.g., PFMEA, Control Plan) shall be reviewed and updated when necessary.

4.2.2 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.

4.2.3 Products with unidentified or suspected status are classified and treated as nonconforming products.

4.2.4 Instructions for rework, including re-inspection requirements, are readily available to and utilized by the appropriate personnel.

4.2.5 Customers are informed promptly in the event that a nonconforming product has been shipped.

4.2.6 A 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 RESPONSIBILITY:

Responsibility and authority for disposition of non-conforming products, material, and services as well as the responsibilities and methods for material review and authorization are defined.

6 RECORDS:

The nature of non-conformities and any subsequent actions taken, including Concessions obtained, are documented and maintained.

1.0 PURPOSE:

This Section of the QEHSIS Management System Manual establishes requirements for Analysis and Evaluation.

2.0 REFERENCE DOCUMENTS:

Standard(s) and Specification(s):

2.1 ISO 9001:2015, Clause 9

2.2 ISO 14001:2015 Clause 9.1.1

2.3 ISO 45001:2018 Clause 9.1.1

2.4 IATF 16949:2016, Clause 9

2.5 Ford Customer Specific Requirements for IATF 16949:2016, Clause 9

QEHSIS Manual:

2.6 QEHSIS Manual, Section 10, Determination of Requirements for Products and Services

2.7 QEHSIS Manual, Section 15, Performance Evaluation

Applicable Procedure(s):

2.8 Monitoring and Measurement of QEHSIS Performance Procedure – Doc. No. 2P-840-001

2.9 Internal Audit for Environmental Health and Safety Compliance Procedure

2.10 Records Management Procedure – Doc. No. 2P-424-001

2.11 Internal External Audit Procedure – Doc. No. 2P-822-001

2.12 Management Review Procedure – Doc. No. 2P-560-002

2.13 Corrective and Preventive Action Procedure – Doc. No. 2P-850-001

2.14 Supplier Quality Evaluation Procedure – Doc. No.2P-741-003

2.15 Management of Change Procedure – Doc. No. 2P-630-002

2.16 Internal and External Audit Procedure – Doc. No. 4P-039 (HEV)

2.17 Monitoring and Measurement of Process Procedure – Doc. No. 4P-040 (HEV)

2.18 Record Management Procedure – Doc. No. 4P-008 (HEV)

2.19 Corrective and Preventive Action Procedure 4P-003 (HEV)

2.20 HEV Process Map and Interactions 4PD-001 (HEV)

2.21 Monitor, Measurement Analysis & Evaluation 4PD-016 (HEV)

2.22 Internal and External Audits 4PD-017 (HEV)

2.23 Continual Improvement 4PD-021 (HEV)

2.24 Receive & Inspect & Ship 4PD-009 (HEV)

2.25 Management Review 4PD-018 (HEV)

3.0 DEFINITIONS:

3.1 See QEHSIS Manual, Section 21, Glossary (Terms and Definitions) for definitions of italicized terms.

3.2 ISO – International Organization for Standardization

3.3 QEHSIS – Quality, Environmental, Health, Safety, and Information Security

3.4 IATF – International Automotive Task Force

4.0 QEHSIS MANAGEMENT SYSTEMS REQUIREMENTS:

4.1 Appropriate data is determined, collected, and analyzed to demonstrate the suitability and effectiveness of the QEHSIS Management System and to evaluate where Continual Improvement of QEHSIS 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 QEHSIS Management System, where needed. The types of data include, but are not limited to:

4.1.1 Customer Satisfaction;

4.1.2 findings from Internal and External Audits;

4.1.3 In-process performance measurements;

4.1.4 Customer Feedback (Complaints);

4.1.5 conformance to product and service requirements;

4.1.6 characteristics and trends of processes and products including opportunities for Preventive and Corrective Action;

4.1.7 performance of external providers;

4.1.8 if planning has been implemented effectively;

4.1.9 the effectiveness of actions taken to address risks and opportunities;

4.1.10 Environmental, and Occupational Health and Safety performance measurement and monitoring.

4.2 Compilation of the Analysis and Evaluation 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;

4.2.5 Plant's Process Failure, Modes, Effects Analysis (PFMEA)

4.3 HEV Plant/ IATF 16949: 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.

4.3.4 Organization shall maintain ongoing process capability at Ppk > 1.33

5.0 RESPONSIBILITY:

5.1 Responsibility for Analysis and Evaluation 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. Records are identified in the Records Management Procedure.

1.0 PURPOSE:

This Section establishes requirements for ensuring Continual Improvement of QEHSIS Management System suitability, adequacy and effectiveness.

2.0 REFERENCE DOCUMENTS:

Standard(s) and Specification(s):

2.1 ISO 9001:2015 Clause 10

2.2 ISO 14001:2015 Clause 10

2.3 ISO 45001:2018 Clause 10

2.4 ISO/IEC 17025 Standard

2.5 IATF 16949:2016 Clause 10

2.6 Ford Customer Specific Requirements for IATF 16949:2016, Clause 10

2.7 ISO/IEC 27001:2022 Clause 10

QEHSIS Manual:

2.8 QEHSIS Manual, Section 7, Documented Information

Applicable Procedure(s):

2.9 Corrective and Preventive Action Procedure – Doc. No. 2P-850-001

2.10 Internal and External Audit Procedure – Doc. No. 2P-822-001

2.11 Records Management Procedure – Doc. No. 2P-424-001

2.12 Context of the Organization Procedure – Doc. No. 2P-400-001

2.13 Management of Change Procedure – Doc. No. 2P-630-002

2.14 Strategy Deployment Procedure – Doc. No. 2P-551-002

2.15 Control of Nonconforming Material or Product Procedure – Doc. No. 2P-830-001

2.16 RDE Lab Validation and Test Procedure - Doc. No. 14P-830-002

2.17 Internal Audit for Environmental, Health and Safety Compliance Procedure

2.18 Internal and External Audit Procedure – Doc. No. 4P-039 (HEV)

2.19 FMEA Procedure – Doc. No. 4P-021 (HEV)

2.20 Multidisciplinary Team Approach Procedure– Doc. No. 4P-022 (HEV)

2.21 Record Management Procedure – Doc. No. 4P-008 (HEV)

2.22 Corrective and Preventive Action Procedure 4P-003 (HEV)

2.23 HEV Process Map and Interactions 4PD-001 (HEV)

2.24 Monitor, Measurement Analysis & Evaluation 4PD-016 (HEV)

2.25 Internal and External Audits 4PD-017 (HEV)

2.26 Continual Improvement 4PD-021 (HEV)

3.0 DEFINITIONS:

3.1 See QEHSIS Manual, Section 21, Glossary (Terms and Definitions) for definitions of italicized terms.

3.2 ISO – International Organization for Standardization

3.3 QEHSIS – Quality, Environmental, Health, Safety, and Information Security

3.4 IATF – International Automotive Task Force

3.5 CTDP – Client Test Data Program

4.0 QEHSIS MANAGEMENT SYSTEM REQUIREMENTS:

4.1 Continual Improvement:

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

4.1.2 Improve products and services to meet requirements as well as to address the future needs and expectations;

4.1.3 HEV Plant/ IATF 16949: Continual improvement is implemented once manufacturing processes are capable and stable, or product characteristics are predictable and meet customer requirements.

4.1.4 HEV Plant/ IATF 16949: Manufacturing process improvement shall continually focus upon control and reduction of variation in products characteristics and manufacturing process parameters.

4.1.5 HEV Plant/ IATF 16949: The organization shall have a documented process for continual improvement. The organization shall include in the process the following:

1. Identification of the methodology used, objectives, measurement, effectiveness, and documented information;
2. A manufacturing process improvement action plan with emphasis on the reduction of process variation and waste;
3. And Risk analysis (such as FMEA).

4.2 Corrective Action:

4.2.1 Corrective and Preventive Action Sections of the QEHSIS 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, to correct, prevent or reduce undesired effects.

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:

4.2.3.1 reviewing and analyzing non-conformances (including Customer Complaints, accidents and incidents);

4.2.3.2 handling and investigation of non-conformances, accidents, and incidents, determination of their causes and if similar nonconformities exist or could potential occur, and implementation of appropriate action(s) needed to contain and 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;

4.2.3.5 updating risks and opportunities determined during planning, if necessary;

4.2.3.6 changing the Quality Management System, if necessary.

4.2.4 Corrective Action may come from one or more of the following:

4.2.4.1 Internal Audits;

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 Product non-conformities;

4.2.4.7 supplier Rejected Material Report;

4.2.4.8 usage of Waivers and Deviations.

4.2.5 The nature of non-conformities and any subsequent actions taken, including Concessions obtained, are documented and maintained, and may result in a Corrective Action Request.

4.2.6 Any changes to documented procedures resulting from Corrective Action is implemented and recorded, following the Corrective Action Procedure.

4.2.7 Reviewing Corrective Action performance is presented in Management Reviews.

4.2.8 HEV Plant/ IATF 16949: All parts rejected by the customer's manufacturing plants, engineering facilities and dealerships shall be analyzed. The organization should analyze any non-conformance using the 8D methodology following Ford CSR Guidelines, and test results are to be included in the monthly QOS performance report.

4.2.9 PE 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 Corrective and Preventive Action Procedure details the specifics and defines the requirements for:

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 QEHSIS 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;

4.4 Objectives:

4.4.1 Toshiba International Corporation will implement and document Objectives for Quality, Environmental, and Occupational Health and Safety at relevant functions within the Organization to improve the performance and effectiveness of the QEHSIS Management System.

4.4.2 The Objectives will be measurable and practical within the Scope of the QEHSIS 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 a Corrective or Preventive Action Request.

5.2 Management responsible 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.

5.3 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.

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

5.5 Management responsible for Quality, and Environmental and Occupational Health and Safety or Designees are responsible for the Corrective and Preventive Action closeout after verification of the effectiveness of actions taken.

5.6 HEV Plant/ IATF 16949: 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 are contained in the Corrective and Preventive Action Procedure.

1.0 PURPOSE:

This Section addresses all of ISO 14001:2015 requirements not previously addressed in other Sections of this QEHSIS Management System Manual.

2.0 REFERENCE DOCUMENTS:

Standard(s) and Specification(s):

2.1 ISO 9001:2015

2.2 ISO 14001:2015

2.3 ISO 45001:2018

QEHSIS Manual:

2.4 QEHSIS Manual, Section 7, Documented Information

Applicable Procedure(s):

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 Monitoring and Measuring of QEHSIS Performance Procedure – Doc. No. 2P-840-001

2.15 Procedures for Significant Environmental Aspects

2.16 Records Management Procedure – Doc. No. 2P-424-001

2.17 Environmental Health & Safety Targets Goals & Objectives Procedure

2.18 EH&S Compliance Listing

3.0 DEFINITIONS:

3.1 See QEHSIS Manual, Section 21, Glossary (Terms and Definitions) for definitions of italicized terms.

3.2 ISO – International Organization for Standardization

3.3 QEHSIS – Quality, Environmental, Health, Safety, and Information Security

3.4 TGEA- Toshiba Group Environmental Audit

4.0 QEHSIS MANAGEMENT SYSTEMS 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.

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, considering the life cycle stages

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 including those from interested parties which Toshiba International Corporation (TIC) is regulated with regard to Environmental Aspects of its activities, products, or services.

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 and External 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 are controlled and aligned with its Policy, Objectives, Targets and Environmental Management System. Toshiba International Corporation, plans and controls these activities, including maintenance, to ensure they are performed under specified conditions by:

4.4.1.1 establishing and maintaining documented procedures to cover both internal and controlled outsourced situations where their absence could lead to deviations from the Environmental Management System requirements;

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 activities, goods and services used by Toshiba International Corporation and communicating relevant procedures and requirements to suppliers and contractors.

4.4.1.4 Establishing appropriate controls to ensure that environmental requirements are met for product or service development that take into account the life cycle.

4.4.1.5 Considering needed information related to potential significant environmental impacts of products and services from transportation through disposal

4.4.1.6 Determining appropriate environmental requirements for the procurement of products and services

4.4.1.7 Communicating relevant environmental requirements to external providers

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.

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 and Environmental Performance. This includes recording information to track performance, relevant operational controls, and conformance with Toshiba International Corporation Environmental, Objectives and Targets and EH&S Management System.

4.6.1.1 Toshiba International Corporation shall list criteria that need to be monitored and measured in the Environmental Health & Safety Targets & Objectives Procedure and through the EH&S Compliance Listing.

a. The EH&S Management System effectiveness, compliance and requirements of interested parties shall be evaluated during Internal Audits, Management Review, and communicated internally, and externally as defined in the Internal & External Communications Procedure and EH&S Compliance Listing.

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 for the needs of Toshiba International Corporation;

4.6.3.2 proactive measures of performance monitoring compliance with QEHSIS Objectives are met;

4.6.3.3 reactive performance measures monitoring accidents, ill health, incidents (including near-misses) and other historical evidence of deficient QEHSIS 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 QEHSIS 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 Sr. 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.

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.

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 QEHSIS Management System Manual Section are stated in associated procedures and are maintained.

1.0 PURPOSE:

This Section addresses all Occupational Health and Safety requirements not previously addressed in other Sections of this QEHSIS Management System Manual.

2.0 REFERENCE DOCUMENTS:

Standard(s) and Specification(s):

2.1 ISO 45001: 2018 Clauses 5.4, 6.1, 8.2, 9.1

QEHSIS Manual:

2.2 QEHSIS Manual, Section 7, Documented Information

Applicable Procedure(s):

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

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 Measurement of QEHSIS Performance Procedure – Doc. No. 2P-840-001

2.15 Records Management Procedure – Doc. No. 2P-424-001

3.0 DEFINITIONS:

3.1 See QEHSIS Manual, Section 21, Glossary (Terms and Definitions) for definitions of italicized terms.

3.2 ISO – International Organization for Standardization

3.3 QEHSIS – Quality, Environmental, Health. Safety, and Information Security

4.0 QEHSIS 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.

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 with the collaboration of workers and relevant interested parties.

4.1.3 The risks and determination of controls are taken into account when establishing, implementing and maintaining our Occupational Health & Safety management system. A hierarchy of controls where elimination, substitution, engineering, administrative and then protective equipment shall be utilized.

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 including those from interested parties which Toshiba International Corporation (TIC) is subject; and are applicable to Environmental Aspects and Occupational Health and Safety activities, products, or services.

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.

4.3.2 These persons shall 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 (needs and expectations of interested parties, roles and responsibilities, legal and other requirements, objectives, controls for outsourcing, audit programs, monitored elements and continual improvement

4.3.2.4 informed of their Occupational Health and Safety Representative(s) and specified Management Appointee.

4.3.3 Emphasizing consultation from non-managerial workers on the items in 4.3.2 and their participation in identifying hazards and opportunities, assessing risks and control measures, elements of training, avenues of participation, correlating communication needs,

4.3.4 Obstacles or barriers to participation shall be removed or minimized.

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 QEHSIS 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 the 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 QEHSIS 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:

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 QEHSIS Management System Manual Section are stated in associated procedures and are maintained.

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:

Standard(s) and Specification(s):

2.1 ISO 17025:2017 Clause 7.5

2.2 00-OP-C0025 Data Recording, Reporting and Related Requirements

Applicable Procedure(s):

2.3 RDE Lab Validation and Test Procedure - Doc. No. 14P-830-002

2.4 Lab DKRM

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 Lab 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.

5.3 Test Procedure Doc. No. UXC0055

6.0 RECORDS:

6.1 Validation records shall be maintained in accordance with the Document-Knowledge-Record-Management - Doc. No. 14F-830-001.

1.0 PURPOSE:

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

2.0 REFERENCE DOCUMENTS:

Standard(s) and Specification(s):

2.1 ISO 17025:2017 Clause 6.6

Applicable Procedure(s):

2.2 RDE Lab Validation and Test Procedure - Doc. No. 14P-830-002

2.3 Lab DKRM

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 Lab Manager is responsible for the annual evaluation of suppliers of critical consumables.

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:

Standard(s) and Specification(s):

2.1 ISO 17025:2017 Clause 7.10

Applicable Procedure(s):

2.1 RDE Lab Validation and Test Procedure - Doc. No. 14P-830-002

2.2 Lab DKRM

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 regarding 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 Lab 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:

Standard(s) and Specification(s):

2.1 ISO 17025:2017 Clause 6.3

Applicable Procedure(s):

2.1 RDE Lab Validation and Test Procedure - Doc. No. 14P-830-002

2.2 Lab DKRM

3.0 DEFINITIONS:

3.1 CTDP – Client Test Data Program

4.0 CTDP MANAGEMENT SYSTEM REQUIREMENTS:

4.1 The laboratory must have an appropriate environment for testing and/or calibration.

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 Lab 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:

Standard(s) and Specification(s):

2.1 ISO 17025:2017 Clause 6.4

Applicable Procedure(s):

2.2 Calibration, control of Inspection, Measuring & Test Equipment Procedure - Doc. No. 2P-760-001

2.3 RDE Lab Validation and Test Procedure - Doc. No. 14P-830-002

2.4 Lab DKRM

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 calibration gives 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 Lab Manager or designee is responsible for the effective implementation of this requirement.

5.2 The Lab Manager or designee is responsible for ensuring the calibrated test items meet the accuracy as defined in the UL Test Equipment Accuracy Table.

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:

Standard(s) and Specification(s):

2.1 ISO 17025:2017 Clause 7.4

Applicable Procedure(s):

2.2 Calibration, Control of Inspection, Measuring & Test Equipment Procedure – Doc. No. 2P-760-001

2.3 RDE Lab Validation and Test Procedure - Doc. No. 14P-830-002

2.4 Lab DKRM

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.

5.0 RESPONSIBILITY:

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

6.0 RECORDS:

6.1 None.

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:

Standard(s) and Specification(s):

2.1 ISO 17025:2017 Clause 7.8

2.2 00-OP-C0025 UL DAP Reporting

2.3 ULS-01778-YEDU-DataSheet

2.4 00-OP-C0032 Calibration Certificates

QEHSIS Manual:

2.5 QEHSIS Manual, Section 20-1, Technical Records

Applicable Procedure:

2.0 RDE Lab Validation and Test Procedure - Doc. No. 14P-830-002

2.1 Lab DKRM

3.0 DEFINITIONS:

3.1 CTDP – Client Test Data Program

3.2 QEHSIS – Quality, Environmental, Health, Safety, and Information Security

4.0 CTDP MANAGEMENT SYSTEMS REQUIREMENTS:

4.1 General

4.1.1 The results shall be reviewed and authorized prior to release.

4.1.2 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.

4.1.3 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 required by 4.2, and 4.3 or 4.4.

4.1.4 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.

4.1.5 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 recognized as a part of the test report or calibration certificate, and a clear identification of the end of the test report or calibration certificate,

4.2.1.4 The name and contact information of the customer,

4.2.1.5 Identification of the method used,

4.2.1.6 A description, unambiguous identification, and when necessary, the condition of the items tested or calibration,

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

4.2.1.8 The date(s) of performance of the test or calibration,

4.2.1.9 The date of issue of the report,

4.2.1.10 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.

4.2.1.11 A statement to the effect that the results relate only to the items tested, calibrated or sampled,

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

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

4.2.1.14 Clear identification when results are from external providers.

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, the measurement uncertainty presented in the same unit as that of the measurement or in a term relative to the measurement (e.g. percent) when:

4.3.1.3.1 when it is relevant to the validity or application of the test results,

4.3.1.3.2 when a customer's instruction so requires, or

4.3.1.3.3 when the measurement uncertainty affects conformity to a specification limit.

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

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

4.3.2 In addition to the requirements listed in 4.2 and 4.3, 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 Unique identification of the item, 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 sampling methods 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.

4.3.2.7 Information required to evaluate measurement uncertainty for subsequent testing

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 have an influence on the measurement results.

4.4.1.2 The measurement uncertainty of the measurement result presented in the same unit as that of the measurement or in a term relative to the measurement (e.g. percent)

4.4.1.3 A statement identifying how measurements are traceable.

4.4.1.4 The results before and after any adjustment or repair, if available.

4.4.1.5 Where appropriate, opinions and interpretations.

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 Reporting Statements of Conformity

4.5.1 When a statement of conformity to a specification or standard is provided, the laboratory shall document the decision rule employed, taking into account the level of risk (such as false accept and false reject and statistical assumptions) associated with the decision rule employed, and apply the decision rule.

4.5.2 The laboratory shall report on the statement of conformity, such that the statement clearly identifies:

4.5.2.1 to which results the statement of conformity applies;

4.5.2.2 which specifications, standards or parts thereof are met or not met;

4.5.2.3 the decision rule applied (unless it is inherent in the requested specification or standard).

4.6 Reporting Opinions and interpretations

4.6.1 When opinions and interpretations are expressed, the laboratory shall ensure that only personnel authorized for the expression of opinions and interpretations release the respective statement. 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.

4.6.1.1 Opinions and interpretations should not be confused with inspections and product certifications.

4.6.1.2 Opinions and interpretations included in a test report may comprise, but not be limited to, the following:

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

4.6.1.2.2 Fulfillment of contractual requirements.

4.6.1.2.3 Recommendations on how to use the results

4.6.1.2.4 Guidance to be used for improvements.

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

4.7 Testing and Calibration Results obtained from Subcontractors

4.7.1 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.

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

4.8 Electronic Transmission of Results

4.8.1 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)

4.9 Format of Reports and Certificates

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

4.9.1.1 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.

4.9.1.2 The headings should be standardized as far as possible.

4.10 Amendments to the Test Reports and Calibration Certificates

4.10.1 When an issued report needs to be changed, amended or re-issued, any change of information shall be clearly identified and, where appropriate, the reason for the change included in the report.

4.10.2 Amendments to a report or Calibration Certificate after issue shall be made only in the form of a further document, or data transfer, which includes the following statement "Amendment to Report, Serial Number (or as otherwise identified), or an equivalent form of wording:

"Amendment to Test Report [or Calibration Certificate], serial number… [or otherwise identified]",

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

4.10.4 When it is necessary to issue a completely 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 Lab 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.

6.2 All issued reports shall be retained as Technical Records

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 Operation Planning and Control 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.

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.

CTDP for Client Test Data Program

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 QEHSIS 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.

QEHSIS Policy Manual – Document specifying the Quality, Environmental, Occupational Health, Safety, and Information Security Management System of an Organization.

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).

Revision	Section	Description	Effective Date
26		- Updated QEHS to QEHSIS throughout manual due to addition of ISO27001:2022 Information Security. - Added ISO 27001:2022 to Table of Contents. - Updated Table of Contents section titles to reflect ISO9001:2015 clauses. - Updated Reference documents in all sections; deleted obsolete documents; added applicable procedures, and renamed manual sections to align with table of contents.	
	02	- added Beltsville, MD location in section 4.1.3.	6/27/2024
	10	- Changed the purpose from "this section is to determine, review, and communicate product requirements for requirements for products and services" to "this section is to determine, review, and communicate product and service requirements"	
	14	- Added "services" to the Purpose	
	15	- Removed PFMEA from definitions.	
25	02	- Updated HEV Plant Process Map and Interaction - Remove Process FMEA Program (section 2) - Add16134 114 Ave NW Edmonton AB T5M 2Z5 – Canada site (section 4.1)	7/27/23
	03	-Remove Control Plan Procedure – Doc. No. 2P-851-001(section 2)	
	04	-Remove Control Plan Procedure – Doc. No. 2P-851-001(section 2) -Remove Continual Improvement and Innovation Procedure – Doc. No. 2P-851-002 (section 2)	
	05	-Add Section 5.6 Notification process for Dynamic Manufacturing Inc	
	06	-Add Section 4.3.1.10 with IATF supplemental for management review outputs - Remove ISO/IEC 17025 – PEP Validation Lab: Results of interlaboratory comparisons or proficiency tests (section 4.2) -Remove ISO/IEC 17025 – PEP Validation Lab: Changes in volume and type of work (section 4.2) Remove ISO/IEC 17025 – PEP Validation Lab: Quality Control Activities, Resource and Staffing (section 4.3)	
	07	-Remove 4PD-024 (section 2.17) as became obsolete and now it's part of the 4P-001 Product Design and Development Procedure -Remove PEP Validation Lab and replace for PE Lab (section 4.2.2.4, 4.3.6,4.3.7,4.4.8) - Remove Validation Test QC Procedure -Doc. No. 9P-736-001 and replace with RDE Lab Validation and Test Procedure - Doc. No. 14P-830-002 (Section 2)	
	08	-Remove PEP Validation Lab and replace for PE Lab (section 4.2.6) -Remove Control Plan Procedure – Doc. No. 2P-851-001(section 2)	
	09	-Remove 4PD-024 (section 2.39) as became obsolete and now it's part of the 4P-001 Product Design and Development Procedure -Remove 4PD-015 (section 2.45) as became obsolete and now it's part of the 4P-036 Inventory Control Procedure. -Remove Process FMEA Program – Doc. No. 2P-610-001	
	10	-Remove 4PD-024 (section 2.27) as became obsolete and now it's part of the 4P-001 Product Design and Development Procedure	
	11	-Remove 4PD-024 (section 2.30) as became obsolete and now it's part of the 4P-001 Product Design and Development Procedure	

Revision	Section	Description	Effective Date
		-IATF definition was corrected (section 3) -Remove Control Plan Procedure – Doc. No. 2P-851-001(section 2)	
	12	-Remove 4PD-024 (section 2.25) as became obsolete and now it's part of the 4P-001 Product Design and Development Procedure	
	13	-Section 2.23 Procedure title changed since 2021 4P-036 is since then Inventory Control Procedure -Remove 4PD-024 (section 2.34) as became obsolete and now it's part of the 4P-001 Product Design and Development Procedure -Remove 4PD-015 (section 2.39) as became obsolete and now it's part of the 4P-036 Inventory Control Procedure -Remove Control Plan Procedure – Doc. No. 2P-851-001(section 2)	
	14	-Remove PEP Validation Lab and replace for PE Lab (section 4.11, 4.12) -Remove Validation Test QC Procedure -Doc. No. 9P-736-001 and replace with RDE Lab Validation and Test Procedure - Doc. No. 14P-830-002 (Section 2)	
	15 & 16	-Remove Control Plan Procedure – Doc. No. 2P-851-001(section 2) -Remove Process FMEA Program – Doc. No. 2P-610-001(section2)	
	17	-Remove Continual Improvement and Innovation Procedure – Doc. No. 2P-851-002 (section 2) -Remove Process FMEA Program – Doc. No. 2P-610-001(section2)	
	18	-Remove Continual Improvement and Innovation Procedure – Doc. No. 2P-851-002 (section 2) - Remove PEP Validation Lab and replace for PE Lab (section 4.2.8) - Remove Validation Test QC Procedure -Doc. No. 9P-736-001 and replace with RDE Lab Validation and Test Procedure - Doc. No. 14P-830-002 (Section 2) -Remove Process FMEA Program – Doc. No. 2P-610-001(section2)	
	20-1	-Replace Validation Test QC Procedure Doc. No. 9F-736-001 with RDE Lab Validation and Test Procedure - Doc. No. 14P-830-002 (section 2) -Added Lab DKRM (section 2) -Replace QC Manager with Lab Manager (section 5) - Added the Document-Knowledge-Record-Management - Doc. No. 14F-830-001 (section 6)	
	20-2	-Replace Validation Test QC Procedure Doc. No. 9F-736-001 with RDE Lab Validation and Test Procedure - Doc. No. 14P-830-002 (section 2) -Added Lab DKRM (section 2) - Replace QC Manager and with Lab Manager and Remove QC Data Specialist (section 5)	
	20-3	- Replace Validation Test QC Procedure Doc. No. 9F-736-001 with RDE Lab Validation and Test Procedure - Doc. No. 14P-830-002 (section 2) -Added Lab DKRM (section 2) -Replace QC Manager with Lab Manager (section 5)	
	20-4 20-5 20-6 20-7	-Replace Validation Test QC Procedure Doc. No. 9F-736-001 with RDE Lab Validation and Test Procedure - Doc. No. 14P-830-002 (section 2) -Added Lab DKRM (section 2) -Replace QC Manager with Lab Manager (section 5)	
	Glossary	Added CTDP	
24	7	-Section 5.1 – Further defined -Section 2.0 – Removed duplicate procedures	
	15	-Section 4.3.2 – Updated reference to reflect changes in 2.0	
23	All	- Restructured the document hierarchy in Reference Documents - Removed Social Infrastructure Systems Group on the title block - Revised all contents refer ISO/IEC 17025:2005 to ISO/IEC 17025: 2017	
	2	- Clarified last sentence of the Purpose to include Internal & External Issues, instead of Internal & External Environmental Issues. - Added reference documents 2.17 to 2.19	

Revision	Section	Description	Effective Date
		- Added 2.25 Strategy Deployment Procedure 4P-046 to Reference Documents. - Clarified 4.1.2.2 - Clarified 4.1.2.3 to state commitment to understanding internal, external, and environmental issues. Rather than just internal and external environmental issues. - Moved 2121 Nao Asahi-cho, Mei-gun Mie-ken 510-8521 Japan to before 4.1.3.4 Okanella Warehouse - Updated 4.1.3.4.3 Okanella Warehouse address: 10420 Okanella Rd, Houston, Texas 77041 - Updated 4.2.2 QEHSIS Management systems are maintained by department and/or process owners. - Updated 4.4 from Policy to QEHSIS Policy - Removed 4.4.1.1 Key QEHSIS Policy Features - Revised 4.4.1 Quality Policy - Updated HEV Plant Process Map and Interaction	
	3	- Added Reference documents 2.9 to 2.14 - Added 2.25 Strategy Deployment Procedure 4P-046 (HEV) to 2.0 Reference Documents - Added 4.5 Planning for Meeting Automotive Requirements	
	4	- Added reference documents from 2.13 to 2.21 - Changed TS to IATF in 3.0 Definitions - Changed TS to IATF in 4.1.2.3	
	5	- Added 2.1 and 2.6 Clause numbers for the standard. - Added reference documents 2.9 to 2.11 - Changed TS to IATF in 3.0 Definitions - Updated Responsibility in 4.2.1 and 4.2.2 - Added 4.2.2.2.1 For HEV Plant Business Unit Manager works with Plant Manager in determining Annual Goals and Objectives. - Updated responsibility in 4.2.7, 4.2.9, 4.2.10, 4.2.11 and 4.2.17	
	6	- Removed 4.7 & 4.8 reference clauses from Ford CSR in 2.0 Reference Documents - Added reference documents 2.17 to 2.19 - Revised 4.2.1.3, 4.2.1.6 4.2.1.7 and 4.2.1.9 Review Inputs requirement.	
	7	- Added “and Data” to 2.11 in 2.0 Reference Documents - Changed TS to IATF in 3.0 Definitions - Corrected FEMA to FMEA in 3.0 Definitions - Revised from QEHSIS Management System Manual to QEHSIS Manual in section 4.1.2.2, 4.1.2.3, 4.2 and 6.0 - Remove 4.3.3 “records are a special type of document and are controlled” and refer to Section 4.4 Control of Record - Removed “We are not responsible for performing service on HEV parts once delivered.” From 4.2.2.1	
	8	- Removed 4.9 & 4.10 clause reference from Ford CSR in 2.0 Reference Documents. - Updated 5.3 from Quality Systems Manager to Quality Assurance Manager - Updated 6.1 from QEHSIS Management Systems Manual to QEHSIS Manual	
	9	- Added reference documents 2.18 to 2.30 - Updated document name “Operational Control 4PD-012 (HEV)” in 2.0 Reference Documents - Added 2.37 Production Planning 4PD-026 (HEV) to 2.0 Reference Documents - Removed 2.37 ISO/TS 16949:2009 from 2.0 Reference Documents - Changed TS to IATF in 3.0 Definitions	

Revision	Section	Description	Effective Date
		- Updated 4.1.9	
	10	- Added Clauses 8.2.1, 9.1.2 to 2.1, 2.2, 2.3 in 2.0 Reference Documents - Removed Clauses 4.16, 4.17, 4.18, 4.19 from 2.3 in 2.0 Reference Documents. - Added reference 2.12 to 2.17 - Changed TS to IATF in 3.0 Definitions - Added 4.1.4.1.3HEV Plant: The Organization shall monitor performance and customer satisfaction metric as defined per Q1. - Updated 6.1 from QEHSIS Management Systems Manual to QEHSIS Manual	
	11	- Removed Clauses 4.22, 4.23 from Ford CSR in 2.0 Reference Documents -Added reference documents 2.15 to 2.18 - Changes TS to IATF in 3.0 Definitions - Added "in writing" to 4.1.1 > k > 7th bullet point. - Added 8th bullet point to 4.1.1 > k. - Added 4.3.3 HEV Plant/FMC CSR; The organization shall perform Design Verification (DV) to show conformance to the appropriate Ford Engineering requirements. - Added 4.3.4 HEV Plant/FMC CSR; The organization is responsible for the quality of the parts it produces and for any subcontracted services, including sub-tier suppliers specified by Ford Motor Company without a Multi-Party Agreement. - Added 4.4.1 e - Added 4.4.2 HEV Plant/IATF 16949; The product design output shall be expressed in terms that can be verified and validated against product design input requirements. - Added 4.4.3 HEV Plant/IATF 16949; The organization shall document the manufacturing process design output in a manner that enables verification against the manufacturing process design inputs. - Removed "and" from 2.2 in 2.0 Reference Documents	
	12	- Added document number to 2.12 and reference document 2.13, 2.15 and 2.16 - Removed Clauses 4.31, 4.34 from Ford CSR in 2.0 Reference Documents	
	13	- Added reference documents 2.19 to 2.22 - Updated document name "Operational Control 4PD-012 (HEV)" in 2.0 Reference Documents - Added 2.45 Production Planning 4PD-026 (HEV) to 2.0 Reference Documents - Changed TS to IATF in 3.0 Definitions - Changed "workstation" to "designated work area(s)" in 4.2.11 - Added 4.2.12 HEV Plant/FMC CSR: The organization shall ensure that work instructions contain reaction plans for non-conformances showing the specific required steps. - Moved 4.5.3 from 4.5 Preservation of Product to 4.3 Identification and Traceability. - Changed 5.4 Supply Chain Manager to Materials Manager. - Added reference documents 2.10 and 2.11 - Changed TS to IATF in 3.0 Definitions	
	14	- Changed TS to IATF in 4.8 - Removed Clauses 4.40 & 4.41 from Ford CSR in 2.0 Reference Documents	
	15	- Added reference documents 2.10, 2.15 to 2.19 - Changed TS to IATF in 3.0 Definitions - Updated 4.3.2 from QEHSIS Management Systems Manual to QEHSIS Manual - Removed Clauses 4.44 & 4.45 from Ford CSR in 2.0 Reference	

Revision	Section	Description	Effective Date
		Documents	
	16	- Added reference documents 2.10 to 2.14 - Changed TS to IATF in 3.0 Definitions - Added reference document 2.17 - Changed TS to IATF in 3.0 Definitions	
	17	- Abbreviated 4.2.5 “Plant’s Process Failure, Modes, Effects Analysis” to “Plant’s PFMEA” - Added 4.3.4 Organization shall maintain ongoing process capability at Ppk >1.33. - Added reference documents 2.15 and 2.16 - Changed TS to IATF in 3.0 Definitions	
	18	- Updated 4.2.1 from QEHSIS Management Systems Manual to QEHSIS Manual - Revised 4.2.5 to emphasize Ford CSR Guidelines. -Updated title to UL Client Test Data Acceptance Program - Externally Provided Products and Services	
	20-2	- Updated ISO 17025:2017 Clause 6.6 in 2.1 -Updated title to UL Client Test Data Acceptance Program Nonconforming Work	
	20-3	- Updated ISO 17025:2017 Clause 7.10 in 2.1 -Updated title to UL Client Test Data Acceptance Program Facilities and Environmental Conditions	
	20-4	- Updated ISO 17025:2017 Clause 6.3 in 2.1 - Updated ISO 17025:2017 Clause 6.4 in 2.1 - Updated ISO 17025:2017 Clause 7.4 in 2.1	
	20-5	- Updated ISO 17025:2017 Clause 7.8 in 2.1	
	20-6	-Added 4.1.1 the results shall be reviewed and authorized prior to release.	
	20-7	- Revised 4.2.1.4 to the name and contact information of the customer - Revised 4.2.1.6 to a description, unambiguous identification, and when necessary, the condition of the items tested or calibration, - Revised 4.2.1.7 to add the date of sampling - Added 4.2.1.9 the date of issue of the report. - Added 4.2.1.11 a statement to the effect that the results relate only to the items tested, calibrated or sampled, - Added 4.2.1.14 Clear identification when results are from external providers. - Revised 4.3.2.3 to the measurement uncertainty presented in the same unit as that of the measurement or in a term relative to the measurement - Revised 4.3.2.3.3 to add measurement uncertainty affects conformity. - Revised 4.3.2.4 from where appropriate and needed to where applicable. - Revised 4.3.2.5 to add authorities - Revised 4.3.3.2 to Unique identification of the item - Revised 4.3.3.4 to sampling methods used. - Added 4.3.3.7 Information required to evaluate measurement uncertainty for subsequent testing - Revised 4.4.1.2, 4.4.1.3, 4.4.1.4 and 4.4.1.5 for calibration certificates requirements - Added 4.5 Reporting statements of conformity section - Updated 4.6 to Reporting Opinions and interpretations. - Revised 4.6.1 to reflect the Reporting Opinions and interpretations requirement. - Updated 4.10.1 and 4.10.2 to reflect requirement of amendments to the Test Reports and Calibration Certificates. - Added 6.2 All issued reports shall be retained as Technical Records	