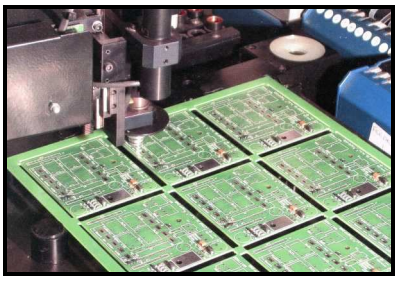
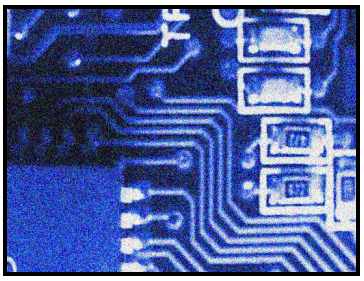
Quality Assurance Manual





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Definition of abbreviations and terms that may appear in this manual

QA	Quality Assurance
QMS	Quality Management System
QAM	Quality Assurance Manual
Customer	A purchaser or end-user of a SCIDYNE product or service
TP	Test Procedure
Supplier	An entity that SCIDYNE purchases materials or services from
NCM	Non-Conforming Material
Document	Information and its supporting medium
Record	Document stating results or evidence of activities performed
ECO	Engineering Change Order
RMA	Return-Material-Authorization - Uniquely identifies a product return authorized by SCIDYNE
WO	Work-Order - Authorizes and uniquely identifies a production lot of one specific product type
SR	Service Record - Uniquely assigned for parts and labor toward any single previously purchased item returned to SCIDYNE for evaluation and possible repair
SN	Serial Number - Uniquely indentifies a single SCIDYNE Product

Introduction

Purpose

This manual provides a framework to all employees and evidence to customers, and suppliers of what specific controls are implemented by SCIDYNE® Corporation (hereafter referred as SCIDYNE) to ensure product and service quality. It is reviewed periodically and revised, as necessary, to reflect the quality system currently in use.

The text has been intentionally kept short and concise to allow easy comprehension by all levels of the organization. Where necessary, greater detail shall be provided through separate documentation to expound and highlight specific and important concepts, processes, and procedures.

Quality Assurance Statement

Quality assurance is a far-reaching process that declares products are designed, built, inspected, and tested properly and that quality and performance is retained during a products intended operational use and life cycle. This process ensures that systems, procedures, and methods are developed and maintained according to plans and requirements to achieve this goal. Quality requirements will be considered to have been fulfilled only when each customer receives a highly reliable product, which fully conforms to all applicable specifications.

SCIDYNE recognizes its responsibility as a manufacturer of quality products and provider of quality services. To this end, SCIDYNE has developed and documented a Quality Management System (QMS). The QMS covers the design and production of the company's products and services. The QMS is not modeled after any particular quality system but instead addresses common core requirements identified within most universally accepted industry quality standards.

SCIDYNE Quality Policy

SCIDYNE accepts responsibility for the complete satisfaction of its customers. We exercise this responsibility through adequate training of our employees, adherence to proven procedures, and total commitment to providing our customers a competitive advantage through innovative, and defect-free products and by maintaining an organizational culture that fosters continuous improvement.

QAM Distribution

This document is issued on a controlled copy basis to all internal functions affected by the quality system and on an uncontrolled copy basis to customers and suppliers.

Online availability of most current manual

The most recent (uncontrolled copy) of the Quality Assurance Manual can be downloaded from our corporate website at:
http://www.scidyne.com/ftp/quality/scidyne-qam.pdf

Company Overview

About SCIDYNE Corporation

SCIDYNE is a privately held company established in 1996 and incorporated in the state of Massachusetts. Our core business is the development, production and sales of standard and proprietary electronic devices. We serve domestic and international markets by supplying our customers with reliable high-quality off-the-shelf components which they integrate into their designs, products, and systems.

Mission Statement

Our mission is to make the products and services offered by SCIDYNE be prominent and pervasive worldwide by being the preferred source for embedded electronic components and devices.

Contact Information

Mailing Address: **SCIDYNE Corporation**
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Quality Management System

Scope

The Quality Management System and this manual applies to all products and services directly produced by SCIDYNE. For finished goods not directly manufactured by SCIDYNE a database of relevant product information and associated supplier qualifications are maintained and deemed sufficient to meet or exceed the quality standard defined is this manual.

Control of Documents

SCIDYNE utilizes a hierarchical Document Control System. All documents managed within the Document Control System are under formal revision control. Changes to the documents can be initiated by anyone in the company. However, all changes must be evaluated and approved by all functions affected at the appropriate level before changes can be realized. An Engineering Change Order is used to document any changes. Whenever practical, all documents to be changed are first archived facilitating future reference.

If a change is determined to be necessary and likely to affect existing customers using a standard product, a notice is published on the SCIDYNE website for that product.

Generation and Control of Records

Records are an important organizational asset; they provide the primary route for evidence based verification and traceability, and demonstrate conformity to product manufacturing specifications as well as compliance to any special requirements. Records are also important in evaluating and proving the overall effectiveness of the SCIDYNE QMS.

Examples of records that are controlled

- Quality Audit / Assessments
- Corrective Actions
- Purchase Orders
- Inspection Reports
- Ship Detail / Certification
- Production Procedures
- PCB Serialization
- Product Test Reports
- Service Reports
- Work Orders
- Product Manuals
- Software and Firmware
- Schematic / PCB files
- Customer Correspondence
- CAD files

Although not directly related to production and product quality other departments are also obligated to retain records they generate and deemed necessary for legal or knowledge preservation purposes.

Retention of Records

Records are suitably kept so that the information they contain is readily accessible, legible and maintained to prevent deterioration and damage. Hard copy records are stored at designated locations where they are protected from physical deterioration, loss and damage due to environmental conditions. They may also be scanned to electronic/digital format for the purpose of making copies or long-term archiving. For electronically generated records, back-up procedures are established for storing secure computer files. Duplicate electronic back-up copies of information considered especially important are stored securely off-premises.

Internal Audits

Audits are a systematic and documented process for obtaining evidence and evaluating it objectively to determine the extent to which the QMS criteria is being fulfilled through identification of problem areas. Audits also provide opportunities for QMS improvement

Internal audits are conducted by SCIDYNE at planned intervals based on the status and importance of the process and area to be audited, as well as previous audit results. An internal audit can also be triggered by an event such as the introduction of new production equipment which could significantly affect manufacturing capability, processes, or methodology.

Auditors shall identify and document any non-conformance for subsequent corrective action and appropriate follow-up. Results are shared and explained to those persons responsible for the area audited in order to initiate and complete necessary corrective and preventative actions.

Records of all internal audit schedules, checklists, findings, corrective or preventive actions shall be appropriately identified and maintained.

Product Identification and Traceability

SCIDYNE uses Work Orders and Serial-Numbers to uniquely identify production lots and individual products during all stages of the production cycle, which includes manufacturing, test, and delivery.

Discovery and Control of Non-Conforming Products

All material/products that are found to be non-conforming are identified and segregated and/or quarantined. Non-Conforming products are discovered through three basic processes:

In-Process

A variety of methods are utilized throughout the manufacturing process as a means of ensuring product quality including visual inspection and computerized functional testing. Inspection/test records, which show clearly whether each product has passed or failed the defined acceptance criteria, are established and maintained.

Any item determined to be non-conforming is segregated and a description of the problem being exhibited is logged with its serial number in the test report associated with the production lot. A cursory investigation is performed by the test technician to determine the root cause and extent of the issue.

If the problem is isolated to one item and easily resolved, such as relocating a misplaced configuration jumper, the item is reworked and returned to the start for testing again. Any item that repeatedly fails is tagged and removed from the production lot for a subsequent and thorough evaluation.

If the identical problem occurs to multiple items or an abnormally high number of different failures occurs within the same lot, production is suspended pending a thorough investigation and resolution.

Final Inspection

For acceptance of completed products, final inspection/testing is utilized. This includes a verification of satisfactory receiving and in-process inspections/tests, as well as completion of any remaining inspections/tests to assure that the finished products/processes conform to specified requirements. Products are not released, and processes are not approved until all inspection/test activities have been satisfactorily completed and the appropriate documentation is available. All final inspections are logged in the work order check-list.

Outgoing Shipping Inspection

Shipping or Outgoing Quality Inspection is performed when there is a customer order. The shipping clerk verifies that the products marking, quantity and shipping labels correspond with the information contained on the Sales Receipt / Invoice / Packing List. Also, special instructions, if any, are checked to ensure that they were followed prior shipment. A Certificate-of-Compliance is generated to satisfy specific customer requirements when requested.

Corrective and Preventive Actions

Failure Analysis

In order to continuously improve product reliability, it is imperative to understand the root cause of failures and prevent their recurrence. A systematic approach is necessary to ensure that the more prevalent failures are eliminated first. SCIDYNE has a policy to analyze every reliability failure for root cause identification. Sources of failures include customer returns and internal reliability evaluations. Analysis of failures is used to target the most common reasons and make necessary adjustments in the design or production of a product with the goal to eliminate future occurrences.

Service Reports

Service Reports are generated and maintained for every product returned to SCIDYNE by customers for evaluation and possible repair. Failures determined to be beyond our control, such as failure due to lightning strikes or physical abuse by the customer, are recorded but no further action is taken.