**QUALITY ADDENDUM FOR INTRINSIC SAFE PRODUCTS**

1. **SCOPE**

The purpose of this document is to provide a roadmap from the ISO/IEC 80079-34 2018-08 standard to the Larson Davis Quality Management System (QMS). This addendum documents the requirements and procedures of ISO/IEC 80079-34 not covered in the LD QMS.

1. **REFERENCE DOCUMENTS**

ISO 9001:2015 Quality Management System

IEC 60050-426, International Electrotechnical Vocabulary – Part 426: Equipment for explosive atmospheres

IEC 60079-0, Explosive atmospheres – Part 0: Equipment – General requirements

D0001.0001 LD Quality Management System and associated procedures, policies and instructions.

ISO/IEC 80079-34 Explosive atmospheres—Part 34: Application of quality systems for equipment manufacture.

1. **TERMS AND DEFINITIONS**

**BSD:** Business System Data. Often referred to as ERP (Enterprise Resource Planning) program or MRP (Manufacturing Resource Planning program) program.

**Certificate:** document that conveys the assurance of the conformity of a product, process, system, person, or organization with specified requirements

* Note 1: This is equivalent to the term “certificate” defined in IEC 60079-0
* Note 2: The certificate is either the supplier’s declaration of conformity or the purchaser’s recognition of conformity or certification (as a result of action by a third party) as defined in ISO/IEC 17000.

**Manufacturer:** organization, situated at a stated location or locations, that carries out or controls such stages in the manufacture, assessment, handling and storage of a product that enables it to accept responsibility for continued compliance of the product with the relevant requirements and undertakes all obligations in that connection

* Note 1: The term “manufacturer” is used instead of “organization” as used in ISO 9001:2015. For the purposes of this document they are interchangeable.

**Contract:** requirements forming an agreement between different parties and transmitted by any appropriate means

**Customer Complaint:** reported, written or verbal allegation made by a customer which concerns the identity, quality, durability, safety, security, conformity or performance of any equipment or protective system or component as defined in the certificate

**Ex Product:** Ex equipment, protective system, safety device, Ex Component and their combination, as well as software and services

**Protective System:** device other than components of equipment which are intended to halt incipient explosions immediately and /or to limit the effective range of an explosion. Note: Protective Systems can be integrated into equipment or separately released for use as an autonomous system.

**Safety Device:** device intended for use inside or outside explosive atmospheres but required for or contributing to the safe functioning of equipment and protective systems with respect to the risks of explosion

**Schedule Drawing:** drawing or document listed in the certificate or test report. These drawings shall not be released or revised until reviewed by the approval body first.

**Related Drawing:** drawing or document not listed in the certificate but linked to the schedule drawing, and used for example, for detailed manufacture of purchase of component parts. These documents shall not be released or revised without first being reviewed by Engineering and the ISP manager.

**Technical documentation:** documentation that enables the conformity of the product with the requirements of the standard(s) to be assessed.

* Note 1: this includes schedule drawings.
* Note 2: It covers
  + the design, manufacture and operation of the product and can contain: a general description;
  + design and manufacturing drawings and layouts of components, sub-assemblies, circuits, etc.;
  + descriptions and explanations necessary for the understanding of drawings and layouts and the operation of the product;
  + a list of the standards referred to in the certificate, applied in full or in part, and descriptions of the solutions adopted to meet the requirements of the standards;
  + results of design calculations made, examinations carried out , risk assessment etc.;
  + test reports

**Manufacturer’s Documentation:** documents required by a manufacturer but not subject to assessment by body responsible for verification when making an application for a test report or a certificate

* Note 1: For example, manufacturing instructions, related drawings, data sheets, and sales literature
* Note 2: The manufacturer’s documentation can be either in paper form or electronic form

**Body responsible for verification:** body which conducts documentation review and periodical audits as appropriate

* Note 1: The body can be a manufacturer (first party), purchaser (second party), or a Certification body (third party).

1. **CONTEXT OF THE ORGANIZATION**

The Larson Davis Quality Management System is certified as being compliant to the ISO 9001:2015 standard. The details of how Larson Davis complies with the standard may be found in the Quality Management System procedure, D0001.0001.

* 1. **Understanding the organization and its context**

See D0001.0001 Sections 1.5 and 4.1

Products are given unique identifying names and/or numbers as detailed in the Document Control procedure, D0001.1017. Item numbers can then be linked to a product to create a bill of materials that is unique to the product being sold. The bill of materials provides the various levels of each product, the processes, and documentation required to produce the desired product. This assures that products being built conform to the requirements and technical documentation of the Ex certificate issued for those products.

LD provides access to all manufacturing documentation and facilities whereby the notified body may audit the aspects of the suppliers operations that affect the type of protection granted.

* 1. **Understanding the needs and expectations of interested parties**

See D0001.0001 Section 4.2

* 1. **Determining the scope of the Quality Management System**

See D0001.0001 Section 4.3

Larson Davis has a comprehensive document control program that is detailed in the “Document Control” procedure, D0001.1017. Documents are filed by their unique product and/or part number and organized for ease of access, protected and audited for completeness on a regular basis.

Changes to documentation occur through the “Engineering Change Order” procedure, D0001.1022 or the “Document Change Order” procedure, D0001.1021. Both procedures require that the changes be reviewed for their effect on regulated or related products or parts prior to the approval process.

* 1. **Quality Management System and its processes**

See D0001.0001 Section 4.4

The LD quality management system ensures that Ex Product conforms to the type described in the certificate and technical documentation. Additionally see statements with regards to conformity to Ex certificates in section 4.1 above and how these bills of manufacturing are maintained.

1. **LEADERSHIP**
   1. **Leadership and commitment**

See D0001.0001 Section 5.1

* + 1. **General**

See D0001.0001 Section 5.1

* + 1. **Customer focus**

See D0001.0001 Section 5.1.1

* 1. **Policy**

The PCB/Larson Davis quality policy is *“Total Customer Satisfaction”*

* + 1. **Establishing the quality policy**

See D0001.0001 Section 5.2.1

* + 1. **Communicating the quality policy**

See D0001.0001 Section 5.2.2

* 1. **Organizational roles, responsibilities and authorities**

The focus, functions and responsibility of management are provided as part of the Quality Management System document, D0001.0001 see section 5.3.

At LD the Ex authorized person is the Intrinsic Safe Products (ISP) Manager. The ISP Manager is a member of the Engineering group and has the following responsibilities:

* Companywide coordination of all activities with respect to Ex Products.
* Acting as the lead contact for all communication with the notified (certifying) body issuing the Ex certificate. This includes all and any proposed changes, approvals, concessions, and technical documentation to the design defined in the certificate.
* Act as the liaison with the body responsible for the verification of the quality system with respect to intended updates to the quality system. The ISP Manager will also notify the verification body of any changes to the Ex authorized person.
* Approving all changes to drawings, work instructions, literature, etc. related to potentially explosive atmosphere products.
* Authorize all concessions.
* Assuring the accuracy of relevant information regarding Ex Product given to the customer for any applicable special conditions for safe use and also providing a schedule of limitations for the product. This may be accomplished by approving all sales literature, operating manuals or other means of communication deemed appropriate.
* To effectively coordinate manufacturing processes related to Ex Products including externally provided products, services and processes detailed in 8.4.
* Review all Ex certificates, standards, regulations, external specifications, and technical documentation and identify any changes that affect product compliance with the certificate and report to Management at its Quality Management Reviews the results of findings with recommendations for improvement and/or change that is needed.

The Marketing Manager has the responsibility of working with the ISP Manager to communicate to the public, specifications and changes to products used in potentially explosive atmospheres. This includes approval of all Manufacturing Documents (literature, press releases, brochures web pages, manuals, data sheets, advertisements, etc.) related to these types of products.

Sales management has the responsibility to inform customers of applicable special conditions for the safe use of the equipment and any schedules of limitations for the customers’ stated application as approved by the ISP Manager.

The QA Manager has the responsibility of working with the ISP Manager and certifying body on changes that need to be made to the quality system in order to meet the requirements of producing products that may be used in potentially explosive atmospheres.

The Production Manager has the responsibility to coordinate the manufacturing of products intended for use in potentially explosive environments and to ensure that the products are manufactured to the approved documentation.

The listed responsibilities and authorities are included in the job descriptions for these positions. Other responsibilities and authorities related to the Quality Management System are documented in the individual procedures, processes and instructions.

1. **PLANNING** 
   1. **Actions to address risks and opportunities**

See D0001.0001 Section 6.1

* 1. **Quality objectives and planning to achieve them**

See D0001.0001 Section 6.2

* 1. **Planning of changes**

See D0001.0001 Section 6.3

Substantial quality updates or changes, as defined by Larson Davis, are communicated to the notifying body. A substantial change to the quality system would be characterized by a change from an ISO standard based quality system to a non-ISO standard based system. Another change that would constitute notification would be a change of the ISP Manager position.

1. **SUPPORT**
   1. **Resources**
      1. **General**

See D0001.0001 Section 7.1.1

* + 1. **People**

See D0001.0001 Section 7.1.2

* + 1. **Infrastructure**

See D0001.0001 Section 7.1.3

* + 1. **Environment for the operation of processes**

See D0001.0001 Section 7.1.4

* + 1. **Monitoring and measuring resources**

See D0001.0001 Section 7.1.5

LD uses a number of labs to assure that it’s measuring and monitoring equipment is properly calibrated and maintained when used to verify Ex Products. The preferable method is to use a calibration lab were the calibration certificate bears the accreditation logo issued by an accredited calibration laboratory. In these cases the laboratory need not be subject to additional evaluation.

Where calibration certificates do not bear the accreditation logo of a national accreditation authority, each calibration certificate and/or conformance for monitoring and measuring devices shall contain the following information as a minimum:

* Unique identification of the item certified (model/serial number, ID number, etc.)
* Evidence of traceability to national and/or international measurement standards
* Method of calibration (process, procedure reference, etc.)
* A statement of compliance with any relevant specification
* Results of calibration
* Uncertainty of measurement, where necessary
* Environmental conditions, where relevant
* Date of calibration
* Signature of the person under whose authority the certificate was issued
* Name and address of issuing organization
* Date certificate was issued
* A unique identification of the calibration certificate (certificate number)

Calibration / certification service providers that are not accredited by a national body are assessed by Larson Davis to demonstrate that the provider has a valid relationship and traceability to international or national measurement standards. This is accomplished through site assessment, inter-laboratory comparisons or other methods of validation.

* + 1. **Organizational knowledge**

See D0001.0001 Section 7.1.6

* 1. **Competence**

See D0001.0001 Section 7.2

The ISP Manager will hold a training review for all LD personnel who may have an impact on Ex Products at least annually. The ISP Manager will report to the Management team that the training took place and provide evidence of those in attendance at the training. The ISP Manager will determine the training items that will be covered in this training review.

The production manager assures that all personnel working on Ex Products are properly trained for the work (jobs) they will perform. Records of this training are retained in the companies Learning Management System (LMS) or by the production manager directly.

* 1. **Awareness**

See D0001.0001 Section 7.3

* 1. **Communication**

See D0001.0001 Section 7.4

Internal and external information relating to Ex Products shall be controlled by the ISP Manager. This information shall include manufacturing documentation (which is controlled by ECOs or DCOs for which the ISP Manager will be a signatory), technical documentation, certificates, non-conforming products placed on the markets, etc. External communication includes communication with clients, certification bodies, providers, authorized representatives, importers, distributors, external providers, and authorities.

* 1. **Documented information**
     1. **General**

See D0001.0001 Section 7.5.1

All requirements and provisions adopted by LD to ensure compliance of Ex Products with their certificates and technical documentation, and to demonstrate compliance to ISO 80079-34, shall be appropriately documented in a systematic and orderly manner in the LD QMS. This is achieved in the form of manuals, policies, procedures, instructions, flowcharts, spread sheets, forms, or other appropriate means. The LD quality management system documentation provides a consistent interpretation of quality programs, plans, manuals and records.

* + 1. **Creating and updating**

See D0001.0001 Section 7.5.2

* + 1. **Control of documented information**

See D0001.0001 Section 7.5.3

All technical documentation and manufacturer’s documentation is controlled by means of the LD document control procedure D0001.1017 and the Design Control procedure D0001.10009.

Quality records are retained per the Quality Records procedure (D0001.1126) and the Quality Records Matrix (D0001.1126-1).

**Schedule Drawings**

The numbers of all Schedule Drawings (including their Item Numbers in the BSD) shall have the suffix -IS-SD appended to them. (This suffix -IS-SD will be used regardless of whether the product will be approved through ATEX, MSHA, or any non ATEX approval body). For assembled PCB drawings, the schematic drawings shall have the suffix –SCH-IS-SD and the assembly drawing shall have the suffix –ASM-IS-SD appended to the end of the drawing number.1

Although Schedule Drawings should generally follow their associated Related Drawings, they shall be generalized and only contain the minimal amount of details and information to allow them to pass the notifying body’s assessments and approvals. This generalizing would, for example, include leaving out dimensions, allowing for large tolerances in the drawings, as well as not calling out part numbers. (e.g. schedule Drawing calls out just ‘LCD display’ or ‘back case’ instead of actual part numbers).1

Schedule Drawings shall include the verbiage “Do not change drawing without approval from the notified body. Any changes could result in an unsafe condition.” This verbiage shall be placed on every page of the Schedule Drawing.

All Schedule Drawings shall be reviewed by Engineering and the ISP Manager before being submitted to the notifying body for approvals. This ensures that no factor (type, characteristic, position etc.) defined within the Ex certificate and technical documentation (e.g. schedule drawings) is modified unless otherwise permitted by the issuer of the Ex certificate.

If there are common schedule drawings associated with more than one Ex certificate, then the ISP manager is required to ensure that any changes to shared components have approval from the notifying body and responsible persons for all end-products using those shared components.

**Related Drawings**

The numbers of all Related Drawings (including their Item Numbers in the BSD) shall have the suffix -IS appended to them. Related Drawings will have the same drawing numbers as Schedule Drawings differing only in the suffixes -IS vs. -IS-SD. All Related Drawings shall be reviewed by Engineering and the ISP Manager before being released or revised to ensure compliance with the Schedule Drawings.1

Any Related Drawings shall have the verbiage placed into it “This is a Related Drawing, relating to the Schedule Drawing axxxx.nn-IS-SD, which has been approved by a notifying body for the purpose of being used in an explosive environment. Do not revise this drawing without first having it reviewed by Engineering and the ISP Manager. Any changes to this drawing could result in an unsafe condition.” 1

**Manufacturer’s Documents**

The numbers of all Manufacturer’s Documents (including their Item Numbers in the BSD where possible) shall have the suffix -IS appended to them. All Manufacturer’s Documents shall be controlled and shall first be reviewed by Engineering and the ISP Manager before being released or revised. Top level part numbers may not have the -IS suffix due to marketing or other requirements, but still should have a note in Syteline and on any drawings. 1,2

The item’s description in the BSD shall have an \* placed in front of it. There will be a note placed in the BSD for the document stating “\*This is a Manufacturer’s Document related to a product that has been approved by a notifying body for use in an explosive environment. This document shall be reviewed by Engineering and the ISP Manager before it is released or revised. Any changes to this document could result in a misleading statement to the end user that could result in an unsafe condition.”1

For work instructions, there will be a note placed at the beginning of the document stating “\*This is a Manufacturer’s Document related to a product that has been approved by a notifying body for use in an explosive environment. This document shall be reviewed by Engineering and the ISP Manager before it is released or revised. Any changes to this document could result in modifications to approved design that could result in an unsafe condition.”2

*1 Procedures are used for drawings and documents created after 09/2013.*

*2 Procedures are used for work instructions created or modified after 09/2018.*

**Other documentation**

D0001.0014-1 is a listing of the examination certificates and approvals issued to LD. The list details the notifying body that is responsible for the issuance of the certificates.

Documentation provided to outside suppliers and other third parties is verified and controlled as detailed in the Purchasing procedure, D0001.1068. This is to ensure that all documentation shall be provided in a way that is not misleading.

The Intrinsic Safety Product (ISP) Manager will review at least annually and report to management during the ISO 9001 Management Reviews the validity of all Ex related certificates, standards, regulations and other external specifications. Additionally the ISP Manager will report on all external audits, internal ECOs and quality system effectiveness and training as it relates to intrinsic safety products.

Quality records are maintained and retained per the Quality Records procedure (D0001.1126) and the Quality Records Matrix (D0001.1126-1).

1. **OPERATION**
   1. **Operational planning and control**

See ISO 9001 Section 8.1

Per ISO 80079-34 Annex A verification for type protection ‘i', the following items ensure proper control and acceptance of processes for Ex Products.

A sampling of components used on Ex products shall be verified during ATEX vertical audit by comparing component parameters on Contract Manufacturer’s Bill of Materials against schedule drawing components list (see A.4.1). Additionally, component features listed in Table A.1 of ISO 80079-34 will be verified on component packaging used at Contract Manufacturer.

Varnish and coatings shall be controlled with respect to specification of material and effectiveness of the application in documentation provided to Contract Manufacturer or in house and verified as part of the ATEX vertical audit. Incoming inspection shall verify the application of varnish and coatings are in conformity with the certificate and/or schedule drawings.

Vertical audit will also verify pick and place machines have calibrated measuring of resistor values and visual verification of correct placement at Contract Manufacturer.

A list of all safety critical components used in production will be maintained for each Ex product (e.g. resistors and Zener diodes). Final product checklist for each Ex Product will have visual verification of all safety critical components as called out on production documentation.

Production documentation and work instructions includes all relevant variations to the product design and specifies workmanship standards for component mounting and soldering. (See D0001.1094 for list of specified standards)

For Ex products with ingress protection rating specified, appropriate sealing arrangement will be verified on final product checklist.

* 1. **Requirements for products and services**

See ISO 9001 Section 8.2

* + 1. **Customer communication**

See ISO 9001 Section 8.2.1

* + 1. **Determining the requirements for products and services**

See ISO 9001 Section 8.2.2

* + 1. **Review of the requirements for products and services**

See ISO 9001 Section 8.2.3

When the product has been released to the market with appropriate product identifiers, the Sales group works with the customers to determine which products they desire to purchase. Customers receive quotes via the Quotation instructions SM02 and contracts are reviewed by the appropriate Sales personnel per the Contract Review procedures SM1005.

Per PCB Piezotronics’ quality document SM1005, any ATEX requirements specified by the customer, or requirements not stated by the customer but required may be confirmed for compatibility against customer’s proposed application, when known, by an Application Engineer, Regulatory Affairs Certification Specialist, or the ATEX Representative prior to acceptance of order (order acceptance by PCB is evidence of successful completion of this review). Not every order requires this level of review, but only when the customer asks for assistance or the end application is known.

* + 1. **Changes to requirements for products and services**

See ISO 9001 Section 8.2.4

The LD ISP Manager shall be involved in any changes e.g. changes to manufacturer’s documentation, quality management system, and marketing documents that could affect Ex Product compliance. This is accomplished through the ECO (D0001.1022) and DCO (D0001.1021) procedures.

* 1. **Design and development of products and services**

The design procedure, D0001.1009, is comprehensive to taking a product from conceptualization through completed design. When products are determined to require an Ex certificate, they will comply with the requirements of the appropriate product design safety standards applicable to the certificate desired. The ISP Manager will have responsibilities as outlined in 5.3 of this document. All changes and designs of Ex certificate products will be reviewed and approved by the ISP Manager.

* + 1. **– 8.3.5 See Design procedure D0001.1009**
    2. **Design and development changes**

See ISO 9001 Section 8.3.6

The LD ISP Manager will be a signatory on all Ex Products and shall be involved in the approval process of any modifications or change that could affect Ex Product compliance e.g. changes to manufacture’s documentation, quality management system or marketing documentation.

* 1. **Control of externally provided processes, products and services**
     1. **General**

See ISO 9001 Section 8.4.1

The Purchasing procedure, D0001.1068 is comprehensive for the type of products manufactured by LD and the requirements listed as unique to the intrinsic safe products have been incorporated as part of the standard process and in this procedure. A few of the key points that were specifically identified in the ISO/IEC 80079-34 that are covered either in the Purchasing document or this procedure include:

* The manufacture, test and final inspection of product may be sub-contracted out but Larson Davis has the responsibility to ensure the conformance of the product to its specifications. LD takes this responsibility and ensures compliance by doing 100% inspection and final quality check.
* Suppliers providing products or services that affect the product’s compliance with the Ex certificate are selected only after an approval process demonstrates their ability to meet all specified requirements e.g. an acceptable Ex quality system. This approval process may include: documentation provided by the supplier from an accredited body that they comply with ISO/IEC 17021 in scope an content; other documented evidence that the supplier can provide product, processes or services that are fit for the purpose intended; and periodic site assessments of suppliers are conducted, as deemed necessary by QA, Purchasing or Management; to ensure that relevant controls are available, documented, understood and effective for the manufacturing of IS products.
* Where the features affecting the type of protection cannot be verified at a later stage, e.g. encapsulated intrinsically safe circuits, then the product process or service shall only be accepted by one of the following methods.
  + The manufacture can demonstrate that the control process implemented by the subcontractor ensures Ex compliance.
  + The body responsible for the verification of the quality system performs periodic audits at the sub-contractors.
* Calibration service suppliers are evaluated on their ability to meet LD traceability and accuracy requirements as outlined in 7.1.5 of this document.
* Suppliers not used for a period exceeding twelve months shall undergo a re-evaluation process prior to the placing of a contract or a purchase order. The ongoing ability of the supplier to provide conforming product shall be reviewed at intervals not to exceed twelve months. The review process may include review of incoming inspection reports, on-site inspections and other means whereby the supplier demonstrates their ability to meet requirements.
* LD will facilitate the body responsible for the verification of the Ex quality system access to any supplier or subcontractor’s operations that affect the Ex type of protection.
  + 1. **Type and extent of control**

See ISO 9001 Section 8.4.2

Ex certificate products require that verification take place as appropriate during the manufacturing process. The specific verification requirements unique to these products are as follows:

* Purchased product that has the potential to compromise the Ex certificate compliance are designated as critical components by engineering and a method for verification of the products’ compliance is defined by engineering.
* The need for and the type of verification required is dependent on the nature of the product being supplied, the supplier and how critical the product is to the Ex compliance.
* Verification may be carried out by supplier if the evaluation of the supplier indicates that the supplier is qualified to do the work and that a certificate of conformity is provided with each batch of supplied product(s). The supplied certificate of conformity shall comply with the ISO/IEC 17050-1 standard.
* Where the Ex certificate specifies routine tests or inspections to be performed on each and every product, the responsibility for those verifications is designated on the purchase order if the work is to be done by the supplier or on the work flow documentation when performed by Larson Davis. If done by the supplier then a certificate of conformity is required with each shipment.
* The requirement of ISO/IEC 80079-34 8.4.2(e) is not applicable to Larson Davis products since the completed products can be verified after manufacture.
* The requirement of ISO/IEC 80079-34 8.4.2(f) is not applicable to Larson Davis products since the completed products are verified 100% after manufacture.
* Verifications, whether completed by Larson Davis or a supplier, that require specialized knowledge and/or training are completed by personnel for whom documentation of their training or experience is available from the supplier or in the case of LD employees, from the Human Resource Manager.
* Tests that are carried out for Larson Davis by a supplier at the suppliers’ place of business are under the responsibility of Larson Davis.
* Where an external provider provides product with evidence of conformity applicable to use in an explosive atmosphere, (e.g. certificate), then further verification is not required unless the LD considers it necessary.
* A Certificate of Conformance will be required of purchased product that relates to the material (metals, alloys, non-metallic parts, resins and similar) where such items are specified in the Ex certificate for intrinsic safe products.
* Supplier verification and approval is detailed in the Purchasing procedure, D0001.1068.
  + 1. **Information for external providers**

See ISO 9001 Section 8.4.3

The Purchasing procedure, D0001.1068 contains specific requirements to include adequate information, with the purchase order, necessary to ensure that the purchased items meet the specified requirements. Engineering specifies and/or controls the documentation provided to Purchasing.

Purchasing will comply with the following requirements for all Ex products, their subassemblies, components and outside services.

* The purchasing document shall clearly describe the specific requirements pertaining to subcontracted product set out in the Ex certificate and the technical documentation provided by engineering for process controls, testing and or inspection and will require a Certificate of Conformance from the supplier.
* Items where conformance cannot be verified after manufacture e.g. encapsulated intrinsically safe circuits, the purchasing information shall set out the specific quality procedures, resources and sequence of activities relevant to the particular item. The supplier will be required to provide a Certificate of Conformance for the product supplied.
* LD tracks Ex products and service by purchase order and markings placed on the products or with the products that are traceable to a specific purchase order.
* When LD does not provide documents with every order it will require a Certificate of Compliance for the product being supplied that the products or services are the revision level specified on the purchase order. LD will through compliance audits assure that the integrity of supplied documents is being maintained.
  1. **Production and service provision**

Refer to the Larson Davis Quality Management System, D0001.0001, for details of how Larson Davis meets this provision. Larson Davis products are manufactured using controlled processes, procedures and documentation. Ex certificate products are identified throughout the manufacturing process by unique identifying numbers.

* + 1. **Control of production and service provision**

See ISO 9001 Section 8.5.1

LD shall provide procedures, production equipment, working environments and inspection/testing facilities that together provide assurance with respect to the compliance of the Ex Product with its technical documentation.

Where a process can affect the integrity of a Type of Protection, and where the resulting integrity cannot be verified after manufacture (e.g. the environmental conditions required for curing an encapsulated item), that specific process shall be measured or monitored and documentary evidence shall be maintained to demonstrate compliance with required parameters.

* + 1. **Identification and traceability**

See ISO 9001 Section 8.5.2

Larson Davis finished goods products have serial numbers that can be traced through final certification and sale to customers. Internal pcbA boards have unique identifying numbers to classify them as Ex certificate products. Furthermore all pcbA batches have identifying numbers to indicate the manufacturing batch. The pcbA batch identifying number for each finished goods sold is recorded in the archived final product checklist for the Ex product.

Visual verification of safety critical components on each pcbA board is also recorded on the archived final product checklist as part of production assembly.

* + 1. **Property belonging to customers or external providers**

See ISO 9001 Section 8.5.3

If a customer requests integration of customer-supplied products, Larson Davis has the responsibility to verify the compatibility of those products with the requirements of the Ex certificate and to notify the customer if the integration is not compatible with the Ex certificate. The review process is part of the technical review of a contract as detailed in Contract Review.

* + 1. **Preservation**

See ISO 9001 Section 8.5.4

Each product manual contains the Ex certificate information that is also listed on the product. The manual provides the customer with the necessary instruction for:

* The safe use of the product in the environment(s) for which it is approved
* Determining if the environment of desired use is appropriate for the product
* Special handling or precautions when using the product

The manuals and literature are verified prior to publication, by Larson Davis, to prevent contradiction between multiple sources of product information.

The official language of the manuals and other literature is English. Distributors and/or representatives are educated in the requirement for the translation of manuals and literature into the local Community languages prior to sales into that Community. Translations of manuals and literature into other Community languages are based on the English version.

Larson Davis equipment is not designed for service or repair by the customer, therefore instructions detailing those processes are not provided to the customer.

* + 1. **Post-delivery activities**

See ISO 9001 Section 8.5.5

* + 1. **Control of changes**

See ISO 9001 Section 8.5.6

The LD ISP Manager shall be involved in changes that affect Ex Product compliance. These include changes to manufacturer’s documentation, quality management system, and marketing documents.

* 1. **Release of products and services**

See ISO 9001 Section 8.6

Work instructions, drawings and related product documentation are used to ensure that products are manufactured consistently and to the specifications for each product. Tests that are specified by regulatory bodies are included as part of the manufacturing documentation.

Processes that affect the integrity of the product and the resulting process cannot be verified after manufacture (e.g. environmental conditions required for curing an encapsulated item), the specific process shall be monitored and measured and documentary evidence shall be maintained to demonstrate compliance with the required parameters of the process.

New Ex products shall only be released after final inspection and testing have been satisfactorily completed. LD shall provide customers manuals that include instructions prepared in accordance with the relevant standards or statutory and regulatory requirements, including any Special Conditions of Use or particulars of possible misuse.

* 1. **Control of nonconforming outputs**

See ISO 9001 Section 8.7

In the event of unintentional delivery of products not conforming to their Ex certification:

* The affected customers are identified through the Business Systems Database (BSD) and the Larson Davis Database (LDDB).
* A materials review board is convened per the Non-Conformant Materials and Product procedure, D0001.1034, to address the non-conformity, the degree of associated risk and to recommend the level of action necessary for the level of risk the non-conforming product poses to the customer. The recommendations are reviewed by management and implemented as appropriate.
* When an unsafe nonconforming product has been supplied to customers, Larson Davis shall inform the customers in writing, as well as the body responsible for the verification of the quality system, and the issuer of the safety certificate.
* Where it is not possible to trace unsafe nonconforming Ex Products (e.g. Ex Products supplied via a distributor, or for high volume Ex Products) then a notice shall be placed in appropriate publications providing recommended action to be taken;

The records that are required for all non-conforming products (with Ex certificate approval) that have been supplied to customers are detailed in the Quality Records Matrix, D0001.1126-1.

* serial numbers or identification of products supplied
* the identification of the customers supplied with the product
* the actions taken to inform customers and the relevant notified body in the case of unsafe non-conforming product
* the action taken to implement corrective and preventative action

These records are maintained by Larson Davis for a minimum of ten years following the identification of the non-conformity.

Concessions for the product that take it outside the design, as defined in the Ex certificate and technical documentation, are not permitted.

1. **PERFORMANCE EVALUATION**
   1. **Monitoring, measurement, analysis and evaluation**

Work instructions, drawings and related product documentation are used to ensure that products are manufactured consistently and to the specifications for each product. Tests that are specified by regulatory bodies are included as part of the manufacturing documentation.

Processes that affect the integrity of the product and the resulting process cannot be verified after manufacture (e.g. environmental conditions required for curing an encapsulated item), the specific process shall be monitored and measured and documentary evidence shall be maintained to demonstrate compliance with the required parameters of the process.

* + 1. **General**

See ISO 9001 Section 9.1.1

* + 1. **Customer satisfaction**

See ISO 9001 Section 9.1.2

The Customer Satisfaction Feedback (CSF) process determines the level of a customer’s satisfaction by evaluating the following Larson Davis, product and service attributes:

* Attitude
* Delivery
* Packaging
* Quality
* Delivery

The report generated by this process is reviewed monthly by Management. Concerns generated from the CSF process are documented via the Corrective/Preventive Action Process, D0001.1020 (Quality Concerns, QC). The QC process is used to track, monitor and resolve customer concerns. Those concerns that involve products with Ex certificates are identified in the QC Log.

* + 1. **Analysis and evaluation**

See ISO 9001 Section 9.1.3

* 1. **Internal audit**

See ISO 9001 Section 9.2

Internal audits of the QMS and this addendum are scheduled and performed in connection with the QMS procedures and those outlined in D0001.1166. The method used to demonstrate the effectiveness of the policies and procedures of the Ex certificate is the vertical audit of an Ex Product awaiting shipment. The auditor will examine all aspects of the system associated with the production of that Ex Product from a certification viewpoint. This normally includes appropriate documentation (drawings, inspection checklists, test records, material certificates etc.). Also included in the audit are Ex Product identification, handling, storage, training records of staff and any other elements of the system which can affect the compliance of the Ex Product certification requirements. This vertical audit is performed at a minimum between 12 to 14 months and records of the internal audit will be maintained in accordance with audit requirements. These audits are outlined in work instruction D0002.2052.

* 1. **Management review**
     1. **General**

See ISO 9001 Section 9.3.1

The management review process is detailed in the Management Review procedure, D0001.1164. The Management Review procedure refers to agendas and meeting minute’s templates that are used to ensure consistency between the Management Reviews.  Senior Management chairs this review that is held periodically, the maximum interval between management reviews will not exceed fourteen months. The ISP Manager will participate in this review as it relates to Ex Products, including results of internal and external audits.

* + 1. **Management review inputs**

See ISO 9001 Section 9.3.2

* + 1. **Management review outputs**

See ISO 9001 Section 9.3.3

1. **IMPROVEMENT**
   1. **General**

See ISO 9001 Section 10.1

* 1. **Nonconformity and corrective action**

See ISO 9001 Section 10.2

* 1. **Continual improvement**

See ISO 9001 Section 10.3

**REVISION HISTORY**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **DCO #** | **REV** | **DATE** | **INITIALS** | **CHANGES MADE** |
|  | A | 10/31/05 | JEB | Initial Release |
| 1212 | B | 5/18/09 | DAR | Updates to reflect changes to other documents |
| 1278 | C | 1/21/10 | DAR | Minor changes to ISP manager duties, typos, and addition of list of certificates and the notifying bodies on D0001.0014-1. |
| 1416 | D | 12/14/12 | DAR | Update to new ISO/IEC 80079-34 standard. |
| 1417A | E | 09/27/2013 | JLD | Updated more to new ISO/IEC 80079-34 quality standard. Updated on control of Scheduled Drawings, Related and Manufacturer’s Documents. |
| 1604 | F | 01/06/2016 | ADB | Updated clarification about providing documentation in way that is not misleading. Also updated to state that concessions outside the design are not permitted. |
| 1702 | G | 05/04/2017 | ADB | Updating reference of ATEX directive to 2014/34/EU |
| 1802 | H | 05/02/2018 | ADB | Changing document suffix for new drawings to be generalized to all Intrinsic Safe product certification, not just ATEX.  Updated Management Review section to be in line with updates for ISO 9001:2015 |
| 1858 | I | 10/29/2018 | ADB | Update to current procedures. |
| 1861 | J | 12/4/2018 | ADB | Updates to reflect changes in ISO 9001:2015 standard and other clarification |
| 1980 | K | 8/4/2020 | DAR/ADB/TB | Update to bring current with the new ISO 80079-34: 2018 standard and cross reference to ISO 9001:2015 |