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Instron® Quality and Survey Information Packet

18-July-2018

Dear Customer,

As an ISO 9001:2015 registered company, Instron recognizes and understands your need to maintain accurate and up to date information on all of your suppliers.

We currently receive annual requests for almost identical quality related information from our over 35,000 installed bases in the US alone. Completing individual forms and responding to these requests consumes a significant amount of time and resources which we could use elsewhere to better serve you, our customer.

We ask for your understanding in this matter and request that you accept and use the information in this packet and found at the links below to address your individual survey requirements.

In this packet you will find the following items:

- Instron's Quality Manual is published to our website.
- Copies of our ISO 9001:2015 certificates and ISO 17025 certificates are updated on our website.
- Finally, we have complied a list of Frequently Asked Questions, which was developed from review of a number of surveys can be found in the following pages.

We pride ourselves on having the most robust and effective Quality Management System possible. We believe that the information we have provided will address your needs. If for any reason, you require information beyond what we have provided here, please visit our website at Instron.com for more information. If you have any questions, please contact me at any time.

Sincerely,

Courtney B. Coyle
Quality Manager – Instron Static

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Instron Supplier Survey FAQs (July 2018)

General Information

Company Name	Instron
Address	825 University Ave Norwood, MA 02062
Phone	800.877.6674
Fax	781.575.5750
Type of Business	Manufacturer of Material Testing Instruments, Services, and Accessories
Date Established	1946
Owner	ITW
Federal Tax ID	MA:361-258-310-01
Web Address	www.instron.com

Remittance Information

Address	75 Remittance Drive
	Suite 6826
	Chicago, Illinois 60675-6826
Phone	781.575.5230
Contact	Jessica Grey

Key Contacts

Quality	Courtney Coyle	781.575.5509
Sales	Bill Wagner	781.575.5618
Manufacturing	Dean Hoyt	781.575.5570
Engineering	Jon Wyman	781.575.5282

Facility Description

Number of Employees	409, 1 shift
Total Quality Employees	4
Facility Size	104,000 Sq. Ft.

Quality System & Management Responsibility

Questions	*Answers*
Q1. Does a quality policy/manual exist which contains quality objectives and commitments?	*Yes*
Q2. Does management with executive responsibility ensure that the policy is understood, implemented and maintained at all levels of the organization?	*Yes*
Q3. Does management with executive responsibility review and document the suitability and effectiveness of the quality system at defined intervals?	*Yes*
Q4. Have procedures been established to support quality objectives?	*Yes*
Q5. Are regular Management Reviews held and documented via meeting minutes with action items both assigned and tracked?	*Yes*
Q6. Is Instron compliant to 10 CFR Part 21 (US Code of Federal Regulations for the Nuclear industry)? *Instron's policy is that we do not comply with 10 CFR §21 or §50 Appendix B. We can provide a calibration certificate upon request that states: "This is a commercial grade calibration certificate provided in accordance with the principles of 10 CFR part 21 and Part 50 App. B"*	*No*

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Quality Audits

Questions	*Answers*
Q1. Are there established procedures for quality audits that assure the quality system is in compliance with requirements?	*Yes*
Q2. Are the quality audits conducted by individuals who do not have direct responsibility for the matters being audited?	*Yes*
Q3. For deficiencies observed during an audit, is there a system to ensure prompt corrective action?	*Yes*

Training and Resource Requirements

Questions	*Answers*
Q1. Is completion of a specified training program required to individuals performing a related job or task?	*Yes*
Q2. Are personnel training records kept?	*Yes*
Q3. As part of training, are personnel made aware of defects that may occur from the improper performance of their specific jobs?	*Yes*
Q4. Is training competency verified by test, interviews, etc.?	*Yes*
Q5. Are employees trained on appropriate company procedures?	*Yes*
Q6. How often is re-training provided? *This depends and varies from job to job. In general, retraining is provided after a major change happens in the process.*	
Q7. Is an organizational chart available?	*Yes.*

Document Controls

Questions	*Answers*
Q1. Have procedures been established to ensure that all documents utilized for design, development or production are approved by a designated individual(s) for adequacy?	*Yes*
Q2. Are there procedures to ensure all obsolete documents are promptly removed from all points of use or otherwise prevented from unintended use?	*Yes*
Q3. Are changes to documents reviewed and approved by an individual(s) in the same function or organization that performed the original approval?	*Yes*
Q4. Are records maintained which include a description of change, identification of the affected documents, signature of approving individuals, the approval date, and the effective date?	*Yes*

Q5. Is there a system in place to control customer specifications?	*Yes*

Purchasing Controls

Questions	*Answers*
Q1. Are suppliers, contractors and consultants evaluated and rated for their ability to meet specified requirements?	*Yes*
Q2. Are the types and extent of controls to be exercised over the products, services, suppliers, contractors and consultants defined based on an appropriate evaluation?	*Yes*
Q3. Are the requirements of the contracts to suppliers adequately defined and documented?	*Yes*
Q4. Are the suppliers provided with documents that clearly describe the requirements of the part on order including the revision?	*Yes*
Q5. Are qualifications performed on purchased components?	

Yes. An AQL sample is inspected for conformance. Critical measurements are recorded in the part database. Upon successful acceptance on three distinct batches, the part is qualified for our dock to stock program and monitored via our Non-conforming material process.

Major Deliverables

Questions	*Answers*
Q1. List the major deliverables produced in the design, development, testing and support of our product(s):	

a. Requirements
b. Specifications (aka Use Cases)
c. Source Code Reviews
d. Tests Cases
e. Test Plans
f. Test Results
g. Traceability Matrix

Production and Process Controls

Questions	*Answers*
Q1. Are there documented instructions, standards operating procedures and methods that define and control the manner of production?	*Yes*
Q2. Are process parameters and quality attributes monitored during production?	*Yes*
Q3. Are processes and process equipment evaluated and approved for production use?	*Yes*
Q4. Have procedures been established to prevent contamination of equipment or product by substances that could reasonably be expected to have an adverse effect on product quality?	*Yes*
Q5. Are all MSD's available?	*Yes*

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Facilities

	Questions	*Answers*
Q1.	Are the environmental control systems periodically inspected to verify that the systems, including necessary equipment, are adequate and functioning properly	*Yes*
Q2.	Are there documented security procedures covering physical and /or logical security for the facility? *Visitors Policy* *Safety Policy* *Card Access Policy*	*Yes*
Q3.	Are procedures in place to control pests (i.e. insects, rodents, etc.) *Yes. The building is leased. Management of the facilities pest control program is under the jurisdiction of the leasor. Instron facilities (Norwood) also actively maintains and manages a pest control regiment.*	

Inspection, Measuring and Test Equipment

	Questions	*Answers*
Q1.	Have procedures been established to ensure inspection, measuring and test equipment is routinely calibrated, inspected, checked and maintained?	*Yes*
Q2.	Are calibration standards traceable to national or international standards?	*Yes*
Q3.	Do calibration records include equipment identification, calibration dates, the individual performing each calibration and the next calibration due date?	*Yes*
Q4.	Is information regarding the calibration status available to the personnel using the equipment?	*Yes*
Q5.	Are all inspections performed using calibrated measurement equipment with sufficient accuracy to distinguish between acceptable and unacceptable materials?	*Yes*
Q6.	Is all calibrated measurement equipment clearly labeled with the last date of calibration and due date for calibration?	*Yes*

Receiving, In-Process, and Finished Product Acceptance

	Questions	*Answers*
Q1.	Have procedures been established for acceptance of incoming product?	*Yes*
Q2.	Have procedures been established to ensure that specified requirements for in-process product are met?	*Yes*
Q3.	Is the identification of acceptance status maintained throughout manufacturing, packaging, labeling and distribution?	*Yes*

Q4. Is latex used during production or manufacturing processes? *Operators may use latex gloves during some assembly processes*	

Material Handling, Packaging and Shipping

Questions	*Answers*
Q1. Is there a procedure in place which assures proper handling, packaging, storage, preservation, and shipping methods are employed so as to meet customer requirements?	*Yes*
Q2. Are procedures in place that address the care and handling of customer supplied material?	*Yes*
Q3. Is material having a shelf life identified, dated and removed when expired?	*Yes*

Non-conforming Product

Questions	*Answers*
Q1. Have procedures been established to control product that does not conform to specified requirements?	*Yes*
Q2. Do the procedures address the identification, documentation, evaluation, segregation, and disposition of non-conforming product?	*Yes*
Q3. Have procedures been established that define the responsibility for review and the authority for the disposition of non-conforming product?	*Yes*
Q4. Have procedures been established for reworking non-conforming product that includes retesting and reevaluation to ensure product meets established specifications?	*Yes*

Corrective and Preventative Action

Questions	*Answers*
Q1. Have procedures been established for implementing corrective and preventative action?	*Yes*
Q2. Do the procedures include requirements for:	
a. Investigating the cause of nonconformities?	*Yes*
b. Identifying action needed to correct and prevent the recurrence of non-conforming product?	*Yes*
c. Ensuring that the information related to quality problems or non-conforming product is disseminated to those responsible for the quality of such product or the prevention of such problems?	*Yes*
Q3. Are documented internal quality audits performed in all areas using an independent person to ensure compliance?	*Yes*