

ISO 9001:2015 QMS

This form is a summary of typical quality survey questions from Pleora customers requesting details of Pleora quality management system. Pleora is accredited by BSI ISO 9001:2015. Pleora has historically received dozens of surveys that both conflict with the ISO standard and our OEM design and verification standards. This form is the only QMS response available from Pleora. Additional customer audits at Pleora are welcomed however there will be charged fee for such audits that repeat or exceed ISO requirements. The additional QMS audit fee for Pleora is \$3000.00 Canadian funds. In addition, as an OEM Pleora is obligated to our sub tier suppliers under NDA (non-disclosure agreements) not to expose sub-tier suppliers IP property to external parties. Customers can view supplier certs and FAIRS on-line or on site and no copies may be made.

All Policies externally available are posted under Policies Pleora website for review.

Pleora Supplier Survey:

Pleora periodically assess the Quality Management System (QMS) of approved critical suppliers (preferred AS9100 or ISO9001:2015 registered). These survey's shall be completed by suppliers and reviewed internally by Pleora QA Manager and Operations Supply Chain Manager. Initial on-boarding supplier surveys are conducted and repeated every three years in accordance with the criticality risk assessment excel file maintained by QA and SC Managers.

Pleora cannot and does not audit franchised distributors for raw material supplier OEM we rely on their accreditation. Pleora complies with JEDEC standards and monitors OEM supplier change notices using SILICON EXPERTS ™. PCN changes to our customers and follow JEDC mechanisms.

Exception:

If the supplier retains AS9100/AS9120 or ISO 9001:2015 accreditation or possess a technical accreditation such as ISO17025-DLA QTSL/QPSL/NADCAP no audits or supplier surveys are conducted. QMS investigations or SCARS may arise if a significant condition is determined/communicated such as re-location of the site, significant change in product or service supplied or a significant process change or cessation of those technical accreditations. Consult the Pleora QA Manager for guidance if such a scenario occurs.

For additional clarification or information please contact the Pleora QA Manager for Guidance. Responses are subject to on-site verification by Pleora Supplier Quality Engineering and Chargeable fees.

Pleora Compliance to US DOD DFARS: Not assessed. Pleora is a COTS OEM any compliance is noted on our website under policies.

Pleora Office Name:	Larry McHenry Mgr QMS ME and ENV	Date:	29-Feb-2024
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Pleora QMS Contact Person:	See abov	e								
Cage Code:										
Headcount:	Proprietar	у								
Counterfeit Mitigation Plan AS5553/AS6081	Complian	Program is Proprietary								
FOD Program	NAS 412	NAS 412 Compliant			Other NA					
Environmental Controls (Yes or NA)	Temp YES	S		Humidity	YES	Clean room NO		Class Not	applicable	
Workmanship (list)	IPC/Class request)	2 (class	3 upon	JSTD 001		J STD 001		Other IPC Specs WHMA 620		1A 620
IPC Instructor on site	Yes			Staff teste	d Yes	Solder training on site	9	CEM used as well accredited		
Shifts:	multiple									
Certified QMS an technical certs (ISO-AS9100-NADCAP-ISO 17025-ISO14001-ISO10012) Attach copy of cert	Yes	No	ISO 13485 NO ISO 9001 YE ISO 14001 NO AS 9100 NO IATF 16949 NO Nadcap NO See Pleora web	S)))	S certs and expiry dates	5				
Street, City, Postcode:	See Pleor	Are Places Website				Are quality attachments included with this survey?				
Telephone Number:	See Pleora	See Pleora Website				YES	NO	N/A		
Fax Number:	See Pleor	See Pleora Website					Х			
Pleora:	See Pleor	a Websi	te							



Scope of products and/or services Pleora:				Please list all attachment in this section (add as needed):				
		Frame grabbers, sensors and software	1.)Hardwar	1.)Hardware OEM				
			2.)SW OEM					
			3.)Larry Mo	Henry				
			4.)3 QE/ME	on staff				
Quali	ty Manager: (If different		5.)					
from	above)		6.)					
			7.)	7.)				
			8.)	8.)				
Mana	gement Involvement		YES	NO	N/A			
1.)	Is a Senior Manager resp	ponsible for quality at your facility?	X					
2.)	Does your Senior Manag	gement routinely review the whole quality system for effectiveness?	X					
3.)	Are reviews planned and	d scheduled, if so what is your Frequency?	X					
Quali	ty System (ISO9001 com	pliant)	YES	NO	N/A			
1.)	Do you have a quality sy	stem manual? If Yes, please e-mail an uncontrolled copy of your manual with this Survey.	X					
2.)	Is your quality manual a	pproved by management?	X					
3.)	Is it certified?		Х					
4.)	Is the quality manual av	Х						
5.)	Are quality procedures i	Are quality procedures incorporated as part of the quality manual?						
6.)	Do you have a Standard	Operating Procedure Manual (SOP)?	X					



7.)	Do you have a procedure for initiating quality plans?	X		
		X		
8.)	contracts are reviewed by Sales and if special terms forwarded to Quality for quality planning			
9.)	Do you have procedures for internal audits?	X		
10.)	Does the procedure specify training for auditors?	X		
11.)	Do you use ISO90003 or CMMI for your software development program?		Х	
12.)	IS Software under configuration control?	Х		
Docu	nent Control /Configuration Management (Compliant ISO:9001)	YES	NO	N/A
1.)	Do you have procedures for the control of procedures, specification and engineering drawings/software/programs/Travellers/PLC and operating systems used in your manufacturing or servicing process and are they under configuration control?	Х		
2.)	Are controlled documents identified to prevent unauthorized or obsolete copies from being used?	X		
3.)	Do you maintain a file of obsolete drawings and procedures?	X		
4.)	Do quality and manufacturing procedures go through a review and approval cycle?	Х		
5.)	Do engineering drawings and software go through a design review?	X		
<i>c</i>)	Do you have a procedure for destroying documents?	X		
6.)	Method for disposal: secure	X		
Purch	asing (ISO9001:2015 Compliant)	YES	NO	N/A
1.)	Do you have an Approved Suppliers List?	X		
2.)	Does Quality participate in suppliers' selection?	Х		
3.)	Do you have procedures for qualifying a supplier?	X		
4.)	Do you have a method for tracking supplier quality?	X		
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5.)	Do you report these results to suppliers?	X		
6.)	Do you have a segregated area for incoming products and materials?	X		
7.)	Are source inspections preformed?	X		
8.)	Are Brokers/Non authorized distributors used to procure raw material or component parts	Х		
9.)	Are certificates or JEDEC compliant packing lists are reviewed and retained for traceability?	X		
10.)	Are suppliers issued corrective action for significant non-conformity?	X		
11.)	IS there a dock to stock program?	X		
12.)	High critical suppliers are audited periodically?	X		
13.)	If No- Franchised Brokers may be used by Pleora without customer approval following Pleora Authenticity Testing Process and supplier details. Is anti-counterfeit procedures compliant with AS6171 and AS5553 and AS6081?	X		
Proces	s Control (ISO 9001 compliant)	YES	NO	N/A
1.)	Are shop routing, or process sheets, and/or inspection instructions used during the manufacturing process?	X		
1B.)	Are shop routings workflow electronic or digital?	X		
2.)	Are written procedures for qualifications of special processes, equipment and personnel, documented?	X		
3.)	Are there written procedures for maintaining the traceability of products during all stages of production?	X		
4.)	Is a preventative maintenance program documented?	X		
5.)	Do you maintain quality records on quality and the manufacturing process? 7 years and or digital ERP	X		
6.)	Do you define the procedure which records are included and time of retention?	X		
7.)	Are quality records current, complete and accurate?	X		
1.)				
8.)	Does Management review quality records?	Х		



9.)	Do quality/test records show failure and cause of failure?	X		
10.)	Is SPC used to control critical characteristics in process?	Х		
11.)	CEM's use a process flow SIPOC or equivalent diagram, define process CTQ's and provide SPC/CPK evidence of such CTQ control. Pleora uses AS9103 CTQ critical character management and control plans for CTQ control and management.	Х		
Insped	tion (ISO9001 compliant)	YES	NO	N/A
1.)	Do you have inspection procedures and are the inspection functions and activities identified?	X		
2.)	Is a document system maintained for evaluation of supplier performance?	Х		
3.)	Are copies of purchase orders, drawings, and specifications available to receiving inspection?	X		
4.)	Is unauthorized use of material pending acceptance by receiving inspection prevented?	X		
5.)	Are inspection and testing procedures in document form?	X		
6.)	Are "first article" inspection results recorded? AS9102 Format YES when required.	X		
7.)	Are "in-process" inspection results recorded?	X		
8.)	Are final inspection results recorded?	Х		
9.)	Have the inspectors been trained and certified? Yes	Х		
10.)	Are non-destructive examinations (NDE) applicable?		X	
11.)	Are records of non-destructive examinations maintained? Yes only during qualification of our new designs or significant RND changes.	X		
12.)	Are raw material receipt sampling plans used?		X	
13.)	Is inspection status controlled by:	Х		
Manu	facturing (ISO9001 compliant)	YES	NO	N/A
1.)	Do you have manufacturing procedures and do they adequately define the production operation?	Х		



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production assembly to: Work Orders	X		
Do you have training program for training production personnel in manufacturing techniques?	X		
Are manufacturing work orders reviewed for inspection points?	X		
Is there a shelf-life control process (MSL) shelf life aging Bake Ovens, Vacuum Bake system, sealing process and desiccant plus MSL indicators?	X		
Is the later recall based?	X		
(ISO9001 compliant)	YES	NO	N/A
Do you have a Testing Department? Provide listing of test equipment capability.	OPS		
Does final testing adequately simulate product capability?	X		
Is re-inspection and test performed on reworked and repaired items?	X		
Are test records maintained?	X		
Do test records show failure rates and cause of failures?	Х		
ng, Storage and Delivery (ISO9001 complaint)	YES	NO	N/A
Are there written procedures for handling, storage, packing, and delivery of product?	X		
Is packing controlled to ensure conformance to specified requirements including identification, preservation, and segregation?	X		
Are ESD systems, infrastructure and controls in place and compliant with ANSI ESD 20.20 latest revision and training artefacts in place?	X		
Are Facility Environmental controls monitoring (temperature and Relative Humidity in place) to address ESD	X		
on-conforming Materials (ISO9001 compliant)			N/A
Are there written procedures for controlling non-conforming materials for?	X		
Receiving?	X		
In-Process Inspection?	X		
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4.)	Testing?	X		
5.)	Final Inspection?	X		
6.)	Do you have a formal Materials Review Board?	X		
7.)	Are Materials Review Board records maintained?	X		
8.)	Are written procedures for the repair, rework and disposition of non-conforming materials?	X		
9.)	Are scrap materials rendered useless by permanent marking or destruction?	X		
Corre	ctive Action (ISO9001 compliant)	YES	NO	N/A
1.)	Do you have corrective action system implemented for?	X		
2.)	Customer Complaints?	X		
3.)	Supplier Defects?	X		
4.)	Internal Defects?	X		
5.)	Is your corrective action system defined by procedure?	X		
6.)	Does Quality interface directly with the Supplier on quality problems?	X		
7.)	Is product examination preformed on scrap and rework to determine the extent and cause of non-conformance?	X		
8.)	Is the effectiveness of corrective action verified and reviewed?	X		
9.)	Do you perform follow up inspections on corrective actions to determine effectiveness?	X		
10.)	Are corrective action reports maintained as part of quality records?	X		
11.)	Do you have a formal MRB board for disposition and approval by technical bodies?	X		
Calib	alibration (ISO9001 compliant)			N/A
1.)	Do you have a calibration system implemented? If Yes, please forward an uncontrolled copy of your Calibration Procedure and Log.	X		



2.)	Is your calibration system defined by procedure?	X		
3.)	Are your Measuring Equipment (ME) and your inspection, measuring and test equipment (IMTE) in current calibration?	X		
4.)	Is calibration undertaken by personnel within your company?	X		
5.)	Is the (ME) Calibrated by and outside calibration lab?	X		
6.)	Do you have a calibration recall system?	X		
7.)	If calibration is performed internally, are employees performing the calibration process qualified?	X		
8.)	If so, to what Standard? ISO10012	X		
9.)	Are the standards used for calibration certified and traceable to national or international standards-NIST NRC	Х		
10.)	Do employees who perform internal calibration have training and qualification records available in file?	X		
11.)	If calibration is performed by and outside lab, is that lab certified and do you have their certification records in file? ISO1012/ISO17025	X		
12.)	If so, to what Standard are they qualified and/or certified for? (Please specify)	X		
13.)	Are the standards used for calibration certified and traceable to national or international standards?	Х		
14.)	Are all inspection devices identified as to its calibration status?	X		
15.)	Are assessments performed in the production area to check for broken or damaged equipment or tools?	X		
16.)	Are assessments performed to ensure equipment and tools are being used and stored properly?	X		
17.)	Are significantly out of calibration events risk reviewed and if risk=yes are internal Corrective actions used to manage risk of product shipped or in WIP?	X		
18.)	Are customers alerted if product was shipped that was deemed significantly out of calibration?	X		
19.)	Do you conduct Gauge RnR studies (MSA studies) on new equipment or those that depart standard measurement capabilities?	X		
Traini	raining (ISO9001 compliant)			N/A
1.)	Do you have an employee training program?	X		



		X		
2.)	Is your training program defined in procedure?			
3.)	Does you training program address certification training for those areas where certification is required?	X		
4.)	Do you have a training program for inspectors in inspection techniques?	X		
5.)	Do you have a training program for production personnel in manufacturing and service techniques?	X		
6.)	Do you have a mentoring program?	X		
7.)	Are records maintained on personnel for showing progress in on-the-job training or mentoring?	X		
8.)	Are inspectors IPC certified and trained?	X		
Health	a & Safety (ISO9001 accredited Ontario MOL approved)	YES	NO	N/A
1.)	Do you have a Safety Program in place at your facility?	X		
2.)	What is the frequency of your Safety Training / Safety Meetings? Weekly Monthly Quarterly X Semi-annually Annually Other:	X		
3.)	Do you encourage your employees to participate and offer Safety concerns during meetings?	Х		
4.)	Do you maintain employees Safety Training Records at your facility?	X		
5.)	Where required by law and other recognized standards, is PPE provided to your employees and their use of it enforced?	X		
6.)	Do you have Material Safety Data Sheets (MSDS) (WHIMIS program) at your facility?	Х		
7.)	Do your employees know where the MSDS WHIMIS are located and are they trained on how to use them?	X		
8.)	Are flammables and/or hazardous products adequately labelled and stored at your facility?	X		
9.)	Do you have an emergency action Plan and disaster recovery at your facility and is it posted and readily accessible?	X		
10.)	Are exits and isle ways free of materials and/or obstacles which could cause trips or falls?	Х		
11.)	As applicable, is your material storage compliant with standards or State Regulatory Requirements?	X		



12.)		hat Personal Protective Equipment is standard requirement? _X_ Safety Glasses Safety Glasses with Side Shields Steel To potwear Hard HatsOther:					
Enviro	nmental (ISO9001 Comp	oliant)		YES	NO	N/A	
1.)	Is there a system in plac chemicals?	X					
2.)	Is there a system in plac	Is there a system in place to provide for the safe disposal of waste and disposal of hazardous waste is documented?					
3.)	Is there a system in plac	Is there a system in place to prevent spills and leaks and to ensure their will be and appropriate response to unexpected incidents?					
4.)	Is there a system in place resulting from facility or	oundwater contamination	X				
5.)	Are your products and policies	X					
Risk M	Risk Management (ISO9001 compliant)					N/A	
1.)	Does the document system include a Risk/Aspect/Hazard register or similar?						
2.)	Is Risk Management use		Х				
3.)	Is Risk Management use	ed as part of the Contract Review process?		Х			
4.)	Is risk management PFM	MEA or DFMEA used employed for Process and product risk assessment and r	mitigation?	X			
Please	answer each question in	appropriate detail:					
1.) Prin	cipal products of services	provided by your facility: → See Pleora website					
Pleora	Mgr	Larry McHenry	Title:	QE ME EN	V Mgr		
Print N	ame:	Larry Mchenry					

