HIRSH PRECISION

PROTOTYPE PRODUCTION

HIRSH PRECISION SUPPLIER QUALITY MANUAL

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1. PURPOSE AND SCOPE

The purpose of this manual is to document the requirements Hirsh suppliers must comply with to ensure that Hirsh's customers receive the highest quality product every time and on time.

All suppliers are required to comply with every applicable requirement in this manual. Additional part and job specific requirements will be flowed down by our team. Any questions regarding the content and requirements in this manual should be directed to your Hirsh contact or the team member on the purchase order.

2. DEFINITIONS

Audit: An official inspection of a supplier's capability, capacity, special processes, quality management system, and other critical performance factors.

Certificate of Conformance: Documentation provided by and authorized by the Seller or a certified competent authority that the products or services meet all specifications

Counterfeit: A suspect part that is a copy or substitute without legal right or authority to do so or one whose material, performance, or characteristics are knowingly misrepresented by a supplier in the supply chain.

Foreign Object Debris (FOD): A substance, debris, or article that is not a part of product design that may potentially cause damage or interfere with the performance of the product.

Rework: Act of repairing or reprocessing a nonconforming product into a product that meets all product requirements.

3. REQUIRED DOCUMENTS

The following documents, as applicable, must be agreed to and completed by Hirsh suppliers prior to starting work:

A. NDA
B. Code of Ethics
C. Terms & Conditions

4. SUPPLIER EVALUATION

4.1 Supplier Assessment

The first step in being onboarded as a Hirsh supplier is to complete the HPS Supplier Survey. Please be as accurate and thorough as possible when completing this assessment. The assessment allows us to gain an understanding of your organizational structure, operations, business strategy, capabilities, and quality system processes in order to determine the work best suited for your organization.

Following completion of the assessment and evaluation of the response, you will be added to our Approved Vendor List (AVL). A supplier audit or visit may be scheduled by Hirsh prior to addition to the AVL at the discretion of Hirsh.

The supplier survey will be re-issued on a periodic basis to ensure that the information we have about your capabilities is accurate and current. If the scope of work you perform has changed since the last

time a survey was completed, you are encouraged to reach out to our team so that we can update our information.

4.2 Audits & Visits

As deemed necessary, Hirsh may schedule a visit or audit at your facility. This is done to gain a more thorough understanding of your processes and capabilities and to grow our relationship. Supplier audits and visits allow us to evaluate your process strengths to determine what new work would be a good fit and to also give feedback on strengthening them further for future projects.

Hirsh reserves the right to visit your facility based on Customer Requests. Hirsh customers and regulatory authorities may request that these visits be performed due to contractual obligations. All information accessed during the audit will remain confidential and is only used for audit purposes.

4.3 Supplier Evaluation Criteria

Hirsh evaluates our suppliers continuously for quality and performance. The following metrics are used to monitor and evaluate supplier performance:

- Quality: Defect Rate, Supplier Corrective Action Requests (SCARs), Repeat SCARs;
- Delivery: Order Accuracy, On-Time Deliver; and
- Supplier Relationship: Communication, Quality Support, and Responsiveness.

We expect our suppliers to monitor their own performance and initiate corrective actions when performance is not meeting expectations. Not meeting the performance metrics may trigger corrective action requests, scorecards, audits, visits, and other actions to address the issues arising.

Continued failure to meet expectations may result in the cancellation of purchase orders and removal from our AVL.

4.4 Supplier Scorecards

Hirsh utilizes scorecards to measure overall performance in the metrics in section 4.3 for their critical suppliers. These suppliers are encouraged to use these to measure their performance and make improvements to their processes. Scorecards are issued quarterly by email.

If your scorecard ratings are decreasing overtime or are below average, a supplier audit or corrective action may be requested. If performance does not improve or if performance continues to decrease following completion of corrective actions, you may be put on probation or removed from our AVL.

5. SUPPLIER REQUIREMENTS

5.1 Quality System Requirements

Hirsh suppliers should strive to maintain a documented quality management system (QMS) that meets or exceeds industry standards. Hirsh suppliers that do not have a documented QMS may be added to our AVL after review and approval by Hirsh management. All suppliers are expected to be certified or compliant with the current revision of ISO 9001. More specialized certifications (e.g., ISO 13485, AS9100, NADCAP) are encouraged and may be required to be considered for customer-specific work. Suppliers must notify Hirsh immediately if any certifications are suspended or revoked. Failure to do so can result in cancellation of purchase orders or removal from the AVL. Suppliers are highly encouraged

to notify Hirsh of any upgraded or new certifications so that we can update our AVL and the scope of work they may be considered for in the future.

All supplier quality systems should include:

- A formal document control process;
- A system for controlling changes including part revisions, programs, and software;
- Provisions and processes for inspecting product and retaining evidence that product meets all requirements;
- A documented process for controlling nonconformances; and
- A documented Corrective and Preventative Action (CAPA) program.

If Hirsh work is sub-contracted out, the above requirements and any other requirements herein this manual and through the purchase orders must be flowed down. It is still the supplier's responsibility to ensure conformity to this manual, contractual requirements, and product conformity.

5.2 Traceability

Hirsh expects suppliers to maintain a sufficient level of traceability throughout all manufacturing processes. Suppliers must ensure that product status is controlled and identified at all times. Suppliers must be able to produce, in a timely fashion, information on the manufacture of a specific purchase order upon request.

As specified on purchase orders and other contractual agreements, lot tracking must be carried throughout all steps, including related records. Suppliers must maintain this traceability in accordance with applicable regulatory requirements.

5.3 Material Sourcing

Suppliers are required to use specified sources when listed on the purchase order, print, or other documentation. If the source is not available, please contact Hirsh for assistance. If there is a better or preferred source, Hirsh must approve the source prior to use.

Suppliers performing contractual work under AS9100D may only source from a third-party distributor if the distributor is also certified to AS9100D.

If material certifications and test results are required, the test results *must* have traceability to the material certification including any heat and lot numbers.

5.4 Counterfeit Prevention

Counterfeit parts continue to be problematic for manufacturing across many industries. Counterfeit parts are defined as "a suspect part that is a copy or substitute without legal right or authority to do so or one whose material, performance, or characteristics are knowingly misrepresented by a supplier in the supply chain" (AS5553).

Keeping counterfeit parts out of the supply chain and our parts is a team effort between Hirsh and our suppliers. We expect all suppliers to be diligent in ensuring that only authentic product is passed through to Hirsh and our customers. A strong prevention program is key to preventing counterfeit parts. AS5553 and AS6174 are available to help develop an approach of avoidance, mitigation, detection, and development for preventing counterfeit parts. The simplest way; however, is to only order directly from original equipment/component manufacturers and authorized distributors or sources.

5.5 Competence

Suppliers must ensure that employees working on or with Hirsh products are aware of all the applicable requirements including the importance of ethical behavior, their contribution to product safety and conformity, the relevant requirements in this manual, and all other specific process instructions. When specific process instructions are included with the purchase order, employees must be trained to perform the work per these instructions unless a written deviation has been approved and authorized by Hirsh.

5.6 FOD Control

Hirsh expects its suppliers to maintain a process for controlling foreign object debris. All products must be received clean, undamaged, and contamination free. Proper material handling practices must be employed throughout the manufacturing process to prevent damage.

All suppliers performing work for aerospace or medical industry parts are required to have their FOD control process documented.

5.7 Change Notification & Approval

Hirsh encourages suppliers to continuously improve and refine their processes; however, certain changes require evaluation by the Hirsh team to determine if there is a risk to product conformity. It is the supplier's responsibility to evaluate changes to determine if notification is required. The following changes require Hirsh evaluation and approval prior to implementation:

- Critical parts of the manufacturing process, tooling, or equipment;
- Location of manufacturing, storage, or distribution;
- Composition of raw material for product;
- Product specifications;
- Decreasing of or significant changes to inspection plans (increases to inspection sampling or changes to a more accurate measurement method does not require notification or approval);
- Documentation maintained in the Device History Record or Medical Device File (as applicable); and
- Significant business changes.

Change requests are to be submitted in writing to Hirsh. Please allow for 60 days for our team to evaluate and approve the change. If the subject part or part family required a FAIR, process validation, or PPAP, depending on the change, a partial or new submission may be required.

When changes are proposed that involve the decrease, significant change, or elimination of inspection activities, evidence supporting the change and proving process stability must be included with the change request.

5.8 Record Retention

Suppliers are required to keep all production records, lot information, inspection data, and other documentation for Hirsh products for at least 15 years. Suppliers must be able to produce requested records in a timely fashion at the request of Hirsh, Hirsh's customers, or regulatory authorities.

Any special record retention requirements will be communicated on the purchase order or through other contractual agreements. Where a conflict exists, the purchase order/contractual record requirements shall take precedence. Disposal and destruction of records must be done in a manner consistent with the sensitivity of the information held by each record, customer and supplier confidentiality requirements, and regulations controlling their disposal.

6. INSPECTION REQUIREMENTS

6.1 General Requirements

Suppliers are expected to inspect product to ensure that all product characteristics and requirements are conformed to across the entire shipment. When used, sampling plans must be based on industry recognized standards. When specified on a print or through other communications, the supplier must follow the required inspection methods and frequencies.

All parts must be visually inspected for cleanliness, blemishes, and other visual defects.

6.2 Calibration

Hirsh suppliers must use properly calibrated tools and equipment when inspecting product. The supplier must:

- Ensure calibration standards are traceable to NIST or other known and accepted national/international standards. If no such standard is available, the process used must be repeatable and adequately documented;
- Maintain calibration records for the record retention period in this manual;
- Have a process for the investigation of failures and method for notifying Hirsh if delivered product is or may have been affected by the equipment, tool, or instrument; and
- Utilize only properly certified (e.g., A2LA, ANSI/IEC/ISO 17025) calibration providers if outsourcing calibration.

Compliance to ANSI Z540 or ISO 10012 is encouraged but not required unless specified in contractual agreements or the purchase order.

6.3 Hirsh-Supplied Quality Plans

Hirsh may provide a quality plan to be used for inspection activities for a part. The supplier is required to follow this plan and is responsible for ensuring the part revision on the plan is current. It is acceptable to transfer the plan into your inspection software, but it is the responsibility of the supplier to ensure that it is accurate and current with the Hirsh-issued plan. It is acceptable to increase inspection frequencies; however, inspection frequencies may not be reduced, or the inspection method changed, without written authorization from Hirsh.

6.4 FAIRs

When requested, suppliers must submit a first article inspection report (FAIR) with the first delivery of a new part or revision. A FAIR may also be requested following a process change – this will be communicated by our team during the approval process. The part used for a FAIR must be included and identified with the first delivery.

If the FAIR must be completed and approved prior to production, this will be communicated by our team.

The FAIR must include the following:

- Ballooned drawing;
- Individual characteristic for each item on the drawing;
- Individual tolerance or accept/reject criteria;
- Inspection results for each characteristic;
- Inspection method used;
- Verification of sub-components, as applicable;
- Report date;
- Inspector; and
- Reference to the purchase order or control/lot numbers.

The supplier is responsible for flowing down this requirement to their sub-tier suppliers as required and ensuring availability to Hirsh.

If an AS9102 FAIR is specified, the supplier may use any form as long as all required information on the AS9102 form is included.

6.5 Certified Inspection Reports

When required on purchase orders, a certified inspection report (CIR) must be submitted with the shipment. The following information must be included with all CIRs:

- Ballooned drawing;
- Individual characteristic for each item on the drawing;
- Individual tolerance or accept/reject criteria;
- Range of inspection results for the lot for each characteristic;
- Inspection method used;
- Verification of sub-components, as applicable;
- Report date;
- Inspector; and
- Reference to the purchase order or control/lot numbers.

Please reach out to Hirsh if you wish to submit the CIR electronically. Otherwise, the CIR must be included within the shipping container along with any other paperwork.

6.6 PPAP

If a PPAP is requested, suppliers are to follow AIAG 4th Edition Level 3 unless specified otherwise. If only specific elements are requested at the time of the purchase order and *not* PPAP, only those elements need to be completed and submitted.

7. PURCHASE ORDERS

7.1 Purchase Order Requirements

Suppliers are expected to carefully review all purchase orders (POs). Each line item must be reviewed for quantity, pricing, product revision (when applicable), delivery dates, and any other additional requirements (e.g., material certs). Suppliers are responsible for ensuring that they are manufacturing to the correct revision level.

Confirmation is to be sent back to the buyer/purchasing agent listed at the bottom of the PO. By confirming the PO, you agree to all the terms and conditions listed and this Hirsh Supplier Quality Manual linked at the bottom of the page.

Any questions regarding purchase orders, including any additional requirements listed, are to be directed towards the buyer/purchasing agent listed at the bottom.

7.2 Order of Document Precedence

When any conflict arises between requirements in documentation, the following order of precedence shall apply:

1. Deviations, Concessions, and other written authorizations;
2. Purchase Order;
3. Drawings/Specifications (including part specific procedures);
4. Supplier Manual.

7.3 Certificate of Conformance (COC)

When requested on the purchase order, a COC must be included with the shipment and include, at a minimum, the following information:

- Part number;
- Revision;
- Lot/Date code;
- Purchase Order number and line number;
- Quantity;
- Relevant specifications (e.g., regulatory requirements – RoHS/REACH, industry standard or Hirsh specifications); and
- Authorization signature.

8	318	LB	Vend #: Hirsh #: RAANBF,2.500x3.000 Desc: ALUMINUM,6061-T6511,BAR,FLAT,2.500x3.000 Notes: 3 - 12 FT BARS *** MATERIAL CERTIFICATION REQUIRED WITH DELIVERY ***	10/5/21	$3.170	$1,008.06

Additional requirements for each line item will be listed here. This may include material certifications, material test results, FAIRs, CIRs, etc.

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Purchase Order

P.O. #:	
Date:	04/01/2024

Bill To

Hirsh Precision Products, Inc.
4300 Godding Hollow Parkway
Frederick, CO 80504
303-530-3131 | www.HirshPrecision.com

Vendor

Supplier Information

Ship To

Hirsh Precision Products, Inc.
4300 Godding Hollow Pkwy
Frederick, CO 80504

Our purchase order number must appear on all Invoice, B/L Bundles, Cases, Packing Lists, and Correspondence.

F.O.B.	Ship Via	Terms
Hirsh	Vendor Delivers	.5%10 / Net 30

Line/Rel	Quantity	U/M	Item	Due to Hirsh	Unit Price	Extended Price
			61-T651 2.500" ecision plate cut to 8x8" +/-1/8	4/9/24	$126.500	$126.50
					Total:	$126.50

PO number and contents must be on the packing slip (see section 8.1).

All ordered material/processes must be REACH and RoHS 3 2015/863/EU compliant.

ADDITIONAL TERMS AND CONDITIONS:

1. HPPI **MUST** be notified of any changes made to products or services on this Purchase Order.
2. Please notify the HPPI buyer immediately if the requested delivery date cannot be met.
3. HPPI utilizes delivery performance and measures of product quality to monitor and evaluate suppliers.
3. HPPI compliance requirements may require on-site review of Supplier processes and records relating to this order upon reasonable notice from Buyer.

Link to the Hirsh Supplier Quality Manual

All line items must comply with the terms and conditions.

Buyer / Purchasing Agent: William Behlow (will.behlow@hppi.com)

Send confirmation to email of the buyer listed on the PO.

8. SHIPMENTS

8.1 General Requirements

Suppliers must package product so that product is not damaged during normal handling and shipping. If product is improperly packaged and sustains damage, Hirsh will hold the supplier liable. Extra care must be used for protecting product with cosmetic surfaces. All packaging must prevent the introduction of FOD to the product during transit.

Different part numbers must be packaged separately. Additionally, an effort should be made to separate PO lines and different lots into different containers. A packing slip must be included with all shipments that includes the PO number, line number(s), part number(s), and the quantities contained in the shipment. The shipping method can be found on the PO.

9. NONCONFORMING MATERIALS

9.1 General Requirements

Suppliers are expected to have a documented process in place that detects and prevents nonconformances from escaping and being delivered to Hirsh. If a nonconformance is detected after shipment you must notify Hirsh immediately.

If the nonconformance is found at Hirsh, your cooperation is required. RMAs must be processed in a timely manner (48 hours is the expectation). Upon request, Hirsh will return the suspect product for your investigation.

9.2 SCARs

If the extent and severity of the defect warrants a formally documented corrective action response, a Supplier Corrective Action Report (SCAR) will be issued. This must be returned within 10 business days unless an extension is granted. You are permitted to use your own forms for the SCAR provided that the information requested on our form is present including containment actions, root cause investigation and identification, actions taken, and objective evidence that the implemented corrective and/or preventative actions are effective following implementation.

Suppliers performing work under ISO 13485 or FDA 21CFR820 requirements must submit a SCAR, in lieu of using Hirsh's form, that is compliant to §820.100.

9.3 Deviation Requests

Known nonconforming product cannot be shipped unless the supplier contacts Hirsh with a written deviation or concession. This also applies to product where contractual requirements could not be met (e.g., inspection requirements). A concession or deviation must be approved in writing by Hirsh prior to shipment.

9.4 Rework

Rework on nonconforming product is not allowed without prior written approval from Hirsh.

When requesting approval please include the method with which the product will be verified following the rework. The acceptance activities following rework must include, at a minimum, verifying that the affected and any potentially affected characteristics conform to all product requirements.

10. COMPLIANCE REQUIREMENTS

All suppliers are expected to comply with relevant regulatory requirements specified on purchase orders and other contractual agreements.

Hirsh expects that its suppliers will provide product that is EU RoHS and EU REACH compliant (latest revisions), unless the material on the print is not compliant per material specifications.

Compliance to the Frank-Dodd Act and the Conflict Minerals Regulation is required for all suppliers. Upon request, all suppliers must be able to submit a RoHS/REACH declaration and a CMRT in a timely fashion.

11. REVISION HISTORY

Rev #	Date	Reviser:	Approved:	Summary of Change:
01	10/05/2021	KK	Brian Clark	Initial release of Hirsh Supplier Quality Manual.
02	10/20/2023	James Shimic, Annette Siverling	James Shimic	Grammar and syntax updates for clarity and consistency. Minor formatting updates.
03	04/03/2024	James Shimic, Annette Siverling	Ben Nikkel	Removed Export Control Agreement from section 3. Clarified use of scorecards for critical suppliers, added quarterly frequency, and removed sentence about automatic distribution and encouraging request metrics in section 4.4. Removed AS102 FAIR revision in section 6.4. Clarified PO confirmation sent to buyer/purchasing agent and added confirming PO means agreeing to all terms and conditions in this manual to section 7.1. Updated example PO image. Minor grammar and formatting updates.
04	11/05/2024	James Shimic	James Shimic	Changed language to remove the requirement that suppliers must have a documented QMS. Added that suppliers may be added to the AVL after review and approval by Hirsh management. Replaced “approved vendor list” with “AVL” throughout.
05	11/14/24	Annette Siverling	James Shimic	Paragraph 5.8: Updated minimum record retention to 15 years to match Hirsh Record Retention time period. Added sentence about method of disposal after record retention time period.