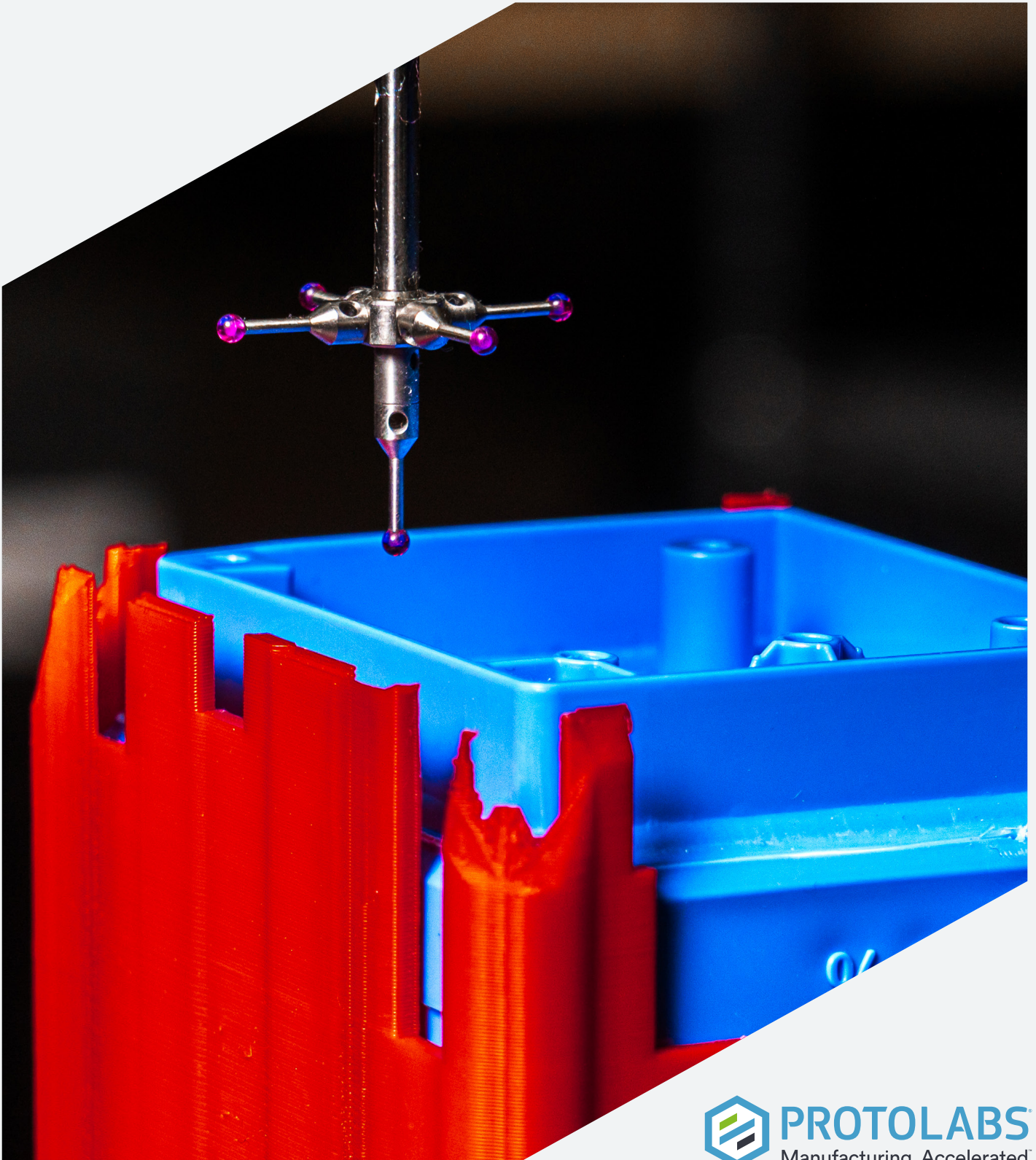


# Quality & Compliance Guide

An Introduction to Protolabs' Quality Policy



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This guide covers our standard quality and compliance measures. If you have elevated needs, please reach out to us at 877-479-3680 or [customerservice@protolabs.com](mailto:customerservice@protolabs.com) to find a solution.

# Protolabs Quality Policy

Customer satisfaction is the primary objective of Protolabs' Quality Management System (QMS). When you work with us, you are working with a manufacturer that adheres to stringent ISO standards and applies continuous improvement to everything we do. Our ProtoExcellence continuous improvement culture is rooted in the Shingo principles for organizational excellence. We know that customer satisfaction is a result of highly skilled employees who continuously seek perfection through operational excellence and drive quality assurance to improve quality, reduce costs, and deliver value to our customers at unprecedented speeds.

Quality control is a key part of our manufacturing services. Whether in our own factories or our manufacturing network, a dedicated team of Protolabs' employees will perform final inspection on your order with the goal of preventing escapes. We've developed a set of processes to ensure the highest manufacturing standards are applied to every order, including tracking the performance of manufacturers in our network to ensure orders meet our quality standards.

With that as the backdrop, our quality policy is concise and encompassing, and our employees live it every day.

We achieve customer satisfaction through:

- Quality Parts. On Time.
- Meeting Requirements
- Continuous Improvement
- Employee Development



# Protolabs Registered Certifications

Service	Site	ISO 9001:2015	AS 9100D	ISO 14001:2018	ISO 45001:2018	ISO 13485:2016
Global Headquarters	5540 Pioneer Creek Dr, Maple Plain, MN USA 55359	✓	✓			
CNC Machining Injection Molding 3D Printing Sheet Metal	<b>Protolabs Network HQ:</b> <ul style="list-style-type: none"><li>Danzigerkade 23A, 1013 AP Amsterdam, Netherlands</li></ul> <b>Inspection Operations:</b> <ul style="list-style-type: none"><li>Nieuwe Hemweg 7E, 1013 BG Amsterdam, Netherlands</li><li>Halesfield 8 Telford, Shropshire, TF7 4QN, UK</li><li>8500 Wyoming Ave, Brooklyn Park, MN USA 55445</li></ul>	✓	✓			
CNC Machining	8500 Wyoming Ave, Brooklyn Park, MN USA 55445	✓	✓			
	15 Charron Ave, Nashua, NH USA 03063	✓	✓			
	Halesfield 8, Telford, Shropshire, TF7 4QN, UK	✓		✓	✓	
Injection Molding	2600 Niagara Lane N, Plymouth, MN USA 55447	✓				
	15197 Boulder Ave, Rosemount, MN USA 55068	✓				
	Halesfield 8, Telford, Shropshire, TF7 4QN, UK	✓		✓	✓	
3D Printing	3700 Pleasant Grove Church Road, Morrisville, NC USA 27560	✓				
	3615 Pleasant Grove Church Road, Morrisville, NC USA 27560 (DMLS)	✓	✓			✓
	Hermann-Oberth-Straße 21, 85640 Putzbrunn, Germany	✓		✓		
Sheet Metal Fabrication	22 Charron Avenue Nashua, NH 03063	✓				

Note: Protolabs Network has numerous manufacturing partners with additional certifications, including ISO 13485 and IATF 16949.



# Suppliers & Partners

Whether it is our own digital factories or our network of manufacturing partners, we evaluate and select external providers for their ability to meet our requirements. The type and extent of control applied to our suppliers and purchased product is dependent upon the risk to our ability to deliver products that meet requirements. We communicate requirements to suppliers and apply appropriate controls to suppliers of raw materials and external service providers as needed. In addition, we monitor the performance and on-time delivery of the most critical suppliers to ensure they consistently deliver to our requirements.

## Traceability

### Identification and Traceability

We identify outputs of manufacturing processes by capturing relevant manufacturing information and identifying product status in our intranets. It is our policy to identify, store, and issue materials that meet requirements specific for each order.

Material certificates, mill certificates, and Certificates of Analysis, as well as DFARS-compliant material certification, and domestic compliant material certifications may be available upon request.

### Customer Property

We identify, protect, and maintain customer property provided for use or incorporation into the product. Customer property includes customer-owned material, components, intellectual property, and personal information. Customers who opt for the on-demand manufacturing option in injection molding have ownership of their molds; Protolabs retains ownership of customer molds for those using prototype tooling. Whenever customer-specified requirements for property management are beyond our control or capability, it is our policy to refuse custody of such property. All proprietary 3D CAD files, intellectual property, or customer information is protected. Server redundancies are also in place, so data is protected and backed up.



# Inspection Process

The scope of our product monitoring and measurement system includes receiving inspection, machine-based inspections such as automated part probing and tool checks, quality control (QC) checks, in-process inspection, and final inspection. Our own digital factories and Protolabs Network both have in-house quality control teams whose primary purpose is to ensure our customers receive quality parts.

## Receiving Inspection

Incoming materials are not used or processed until they have been inspected or otherwise verified as containing materials required by the purchase order. Material certificates, Mill certificates, and Certificates of Analysis, as well as DFARS-compliant material certification, and domestic compliant material certifications may be available upon request.

## In-process Inspections

In-process inspections are performed, where applicable, by manufacturing personnel in accordance with work instructions and Protolabs' policy. Records of in-process inspections are maintained in customers' electronic batch record. Records are available upon request.

## Machine-based Inspections

We use many proprietary machine-based automated checks to ensure that processes are adequately controlled.

## Dimensional Inspections

Dimensional checks are performed on parts against QC-check dimensions set up by our technical operations staff when processing a customer quote. It is Protolabs' policy to perform dimensional inspection on the x, y, and z extents of a customer's part, whenever possible. A customer may specify additional inspection requirements, which we support through our range of metrology services.

## Final Inspection

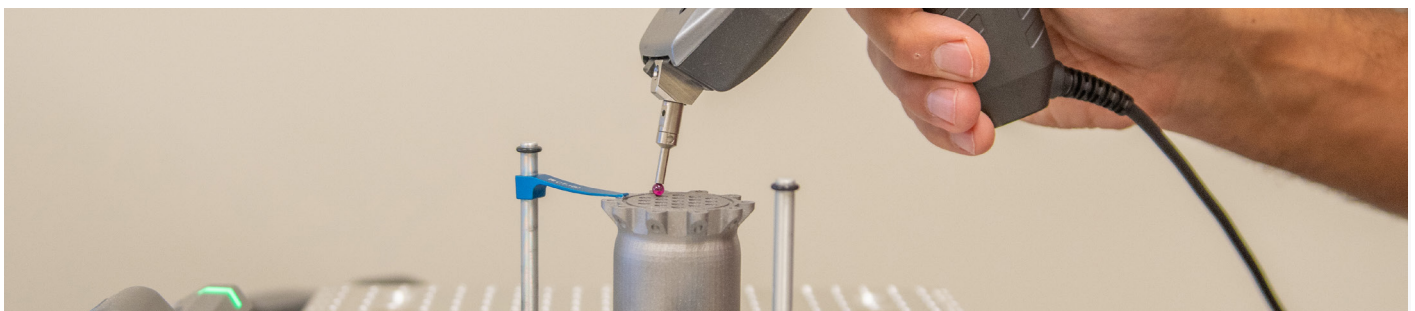
Finished products and completed services may be verified by final inspections specified in work instructions. Orders are inspected by qualified quality control (QC) personnel using an appropriate sample sizes, and are inspected dimensionally and visually for cosmetic quality. Our QC teams have access to an array of calibrated inspection tools and equipment, including Coordinated Measurement Machines (CMM) with proprietary process augmentations to accelerate the inspection process. Various reports are available to document inspection results, including Dimensional Inspection Reports (DIR), First Article Inspection (FAI) reports, and Production Part Approval Process (PPAP).

## Evidence of Conformity

Inspection records are maintained for a minimum of ten years. These records include final inspection authority and identify and confirm that the part produced conforms to the customer-provided 3D CAD file or print when appropriate. Various inspection reports, as well as Certificates of Conformance (CoC), can be generated with shipments.

## Product Release and Delivery

Product is not normally released or delivered until all planned inspections have been completed, and records have been maintained providing evidence of conformity with acceptance criteria and identifying the person(s) authorizing release of product for delivery to the customer.



# Calibration

The calibration of our measurement equipment is outsourced to an ISO 17025-certified third party. National Institute of Standards and Technology (NIST)/United Kingdom Accreditation Service (UKAS) traceable records are kept for all measurement equipment.

We ensure monitoring and measuring equipment used to verify product are properly controlled and maintained. The third-party calibration service is called in annually (or more often as needed) to check, calibrate, and if necessary, repair equipment. Users check equipment for any signs of wear or damage prior to use. When deterioration is apparent in equipment, the user requests a replacement.

All calibrated equipment is clearly marked with calibration due date, date calibrated, gauge ID number, certificate number, and designated location of use.

When measurement equipment is found to be out of calibration, a quality engineer investigates the effect the out of tolerance condition may have had on finished product. Appropriate action is taken, when necessary, to rectify the situation.

# Risk Mitigation

With facilities around the world that offer various digital manufacturing services, we can provide unmatched in-house capacity, along with a broad network of global manufacturing partners, to ensure your parts are shipped on time, every time. We have a robust disaster recover program in place for our owned digital factories that includes:

- IT Disaster Recovery
- Emergency action plans for quick employee notification
- Strategically located generator backups
- Tested process to shift work between regions
- Risk analysis of natural disasters

We also collect surveys and request disaster recovery plans from critical suppliers.

# Nonconformance Controls

It is our policy to ensure that outputs that do not conform to requirements are identified and controlled to prevent unintended use or delivery. The controls and related responsibilities and authorities for dealing with nonconforming outputs are defined. We deal with nonconforming outputs in one or more of the following ways:

- By taking action to eliminate the detected nonconformity.
- By authorizing its use, release, or acceptance under concession by the customer.
- By taking action appropriate to the effects or potential effects of the nonconformity when nonconforming outputs are detected after delivery.

Records of the nature of the nonconformities and any subsequent action taken, including concessions obtained, are maintained. When nonconforming outputs are corrected they are subject to re-verification to demonstrate conformity to the requirements.

# Training

Staff members performing work affecting product quality are competent on the basis of appropriate education, training, skills, and experience. Training and subsequent communication ensure that staff are aware of:

- Our quality policy
- Relevant quality objectives
- Their contribution to the effectiveness of the management system, including the benefits of improved performance.
- The implications of not conforming with the management system requirements

Records of training are retained.

## Product Stewardship

Protolabs is committed to being a socially responsible corporation that conducts business ethically, respectful of the rights of humans, communities, and the environment. Visit our website for more information on our policies, including Conflict Minerals, REACH, RoHS, Prop 65, TSCA PBT, and PFAS, POPs. As a custom manufacturer of parts based on our customer's designs and raw material selections, we respond to product stewardship requests (e.g, RoHS, REACH, Prop 65, Conflict Minerals, TSCA PBT, PFAS, POPs) on a part-specific basis.

Requests for information can be directed to [customerservice@protolabs.com](mailto:customerservice@protolabs.com).

## ITAR



We ensure that employees outside of the U.S. don't have access to any parts or part information for ITAR-classified projects. This means keeping separate databases for different countries, having procedures in place to ensure that any parts or information we share publicly or between locations aren't ITAR controlled, and not allowing non-U.S. persons access to the manufacturing floor or other secured areas. We also prohibit photo, video, and audio recording from visitors in our offices and manufacturing facilities.





# Environmental Health & Safety

Protolabs complies with all local, state, and federal environmental regulations, and other regulatory requirements pertaining to environmental law and conservation. Protolabs maintains all relevant statutory documentation and permits. Leadership ensures that specific environmental regulations and best practices are adhered to and that educational resources for best practice decision making are available throughout the company.

- We conform to all regulatory body standards.
- We maintain all appropriate permits related to: storm water, industrial wastewater, air quality, hazardous waste disposal, and Form R & SARA reporting. We are in good standing with OSHA and have no open or outstanding citations.
- All workplace accidents, injuries, and near misses are documented and tracked. Injuries are investigated for root cause and to identify corrective action plans.
- We have a personal protective policy in place, which is adhered to by employees.
- We conduct training including, but not limited to: new hire orientation, employee right to know (hazard communication), forklift training, electrical safety, fire safety, hoist training, lockout tag out training, CPR/first aid, safe lifting, etc.
- We set EHS performance expectations and goals, and communicate the status of those goals to all manufacturing employees through monthly meetings.
- We routinely conduct internal department safety audits. Action items generated during these audits are tracked and completed by the company safety committee.
- We conduct pre-employment background checks, as well as reasonable suspicion and post-accident drug screening.
- We maintain a well-kept facility using a third-party cleaning service on a set schedule. We also have active contacts for pest control, lawn care, snow removal, and other building maintenance services.
- All office and manufacturing areas are conditioned with temperature and controls to maintain consistent and comfortable work conditions for both our employees and our process equipment.

Protolabs' UK and German facilities have ISO 14001 in place for environmental compliance. Protolabs' UK facility has ISO 45001 for health and safety compliance. Protolabs also has a health and safety committee, which reports on all incidents.



# Commitment to Sustainability

Understanding the impact of climate change and the significance of environmental conservation is core to our business operations. Protolabs is committed to actively assessing risks that may have environmental impacts, as well as actively improving the conservation of natural resources and general influence on environmental health. Protolabs is deliberate in the consideration of climate change as a business element, and in fostering a corporate culture that is enthusiastic about the impact made on the community.

Protolabs' leadership is accountable for the administration of our environmental and sustainability policy. Leaders consider environmental impacts and climate change as part of normal operations.

In addition to legal compliance, Protolabs considers best practices relating to environmental conservation, pollution prevention, and sustainable solutions to business operations. As part of its normal business operations, Protolabs will seek to reduce energy consumption, and replace, modify, or remove activities and/or equipment that produce waste, and/or generate negative impacts to air and/or water.

Employees are expected to comply with required training, documented policies, and work instructions. Employees participate in company environmental initiatives, kaizen events, and performance improvement programs. Through a culture of continuous improvement, Protolabs continuously improves its environmental management system and its environmental performance.





**PROTOLABS<sup>®</sup>**  
Manufacturing. Accelerated.

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