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Honor Your Scope

Your quality system's scope statement minimizes risk as well as describes what you do.

Shops today have quality management systems (QMS) registered and compliant with various quality system standards. ISO 9001:2015, TS-16949 and AS9100D come to mind as typical QMS standards in precision machining today. Shops that achieve and demonstrate compliance are awarded certificates which they display in their lobbies and feature prominently online. A key feature of these certificates is a statement of scope.

- "The manufacture of pins, shafts, and similarly configured parts for Aerospace, Defense, Medical, Technology, and other precision industries, worldwide." (Horberg Industries ISO 9001-2015/ AS9100D) **bit.ly/PMPA-PM0524A**
- "The Manufacture of Precision CNC Milled/Turned Products, Precision Swiss CNC Products, Precision Progressive Die Stampings, Precision Slide formed Products and Chaplets" (Smith and Richardson ISO 9001:2015) **bit.ly/PMPA-0524b**
- "The Provision of Precision Ground Bar Materials, Custom Mechanical Components and Pin Gage Products [Boston Centerless AS9100:2016 (techn. equiv. to EN9100:2018 & JIS 9100:2016) & ISO 9001:2015] **bit.ly/PMPA-PM0524c**
- "Development, Production, and Distribution of Grooving and Groove Milling Tools." (Horn USA Inc. ISO 9001:2015) **bit.ly/PMPA-PM0524d**

The purpose of a scope statement is to precisely describe the products and services that your company provides, including the regulatory requirements, activities, locations and facilities supported by your company's QMS. The scope statement describes fully and completely, exactly what your business does.

The failure to include some aspect in your company's scope statement similarly proclaims to the world what is not covered by your QMS. What is not providable by your company. What is excluded.

Engineering and Design

Look at your company's quality certificate. Read the scope. Does it say "design and development of…" or "engineering design, development and…" or words to that effect? In our precision/production machining and contract manufacturing shops, we typically do not include design scope in our QMS. Our core competencies are the production of high-precision components from customers' drawings or prints. We are not in a position to know, understand or engineer solutions for end-use applications for which we have no data.

What does this mean to you? There are three potential traps when you receive a job to quote that can expose your company to full or partial liability for product failure — because you are operating outside the scope authorized by your company's QMS.

Trap 1: Here is the print — you pick the grade.
On what basis? As a manufacturer, you will likely choose to maximize manufacturability, not some needed performance aspect unknown to you. How would you know?

Trap 2: We can't get the grade we want, will grade X work for this part?
Again, as a shop you can answer about your ability to fabricate, but you have no idea as to whether that substitute will perform in the same manner as the originally requested material. What design aspects are important to performance? All that you know are the dimensions and geometric relationships on the drawing. You know nothing of stresses, pressures or torques applied or to be withstood in the end use.

Trap 3: We don't care what grade you use as long as it is (fill in the blank … aircraft quality, medical quality and so on).
Perhaps this is the most dangerous trap, as you may think that you are ok to share that another material is, in fact, an aircraft quality or medical quality material. It probably is,

I mean you trust the supplier and their cert, right? But by warranting that the material is aircraft or medical quality did you just become the "Engineer of Record?"

These three traps can be avoided by recognizing that they share a common trait — they are asking you to do something that is outside the scope of your QMS. Probably outside your education and licensing, too.

Bottom Line — Who is the "Engineer of Record?"

"The Engineer of Record shall be responsible for the final design and construction of the project and the submittal of all required documents. a) all judgement decisions affecting the design or altering the design will be the responsibility of the engineer of record"
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Who is the Engineer of Record? In California, the engineer of record is defined as "the Engineer who has prepared the plans and specifications." In many states, this requires state licensure as a professional engineer (PE).

Engineer of Record can also mean the PE that develops the criteria and concept for the project, performs the analysis and is responsible for the preparation of the plans (drawings) and specifications of the work.

When the customer invites you to "pick the grade," "confirm to them that a substitute material will work for their application" or "assure them that the material chosen is suitable," because it meets some broad classification, the question you must ask yourself is "on what basis of authority can you answer?" If you are *not* a licensed professional engineer, if your company's QMS scope does *not* include design, development or engineering, then you must decline their invitation.

Stay out of these traps! You lack the credentials, the authority, the knowledge of all necessary factors needed to be considered for the application. Without these, you are "hazarding a guess," which is defined by the Cambridge Dictionary as "to risk doing something that might cause harm to someone or something else."
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Avoid the hazard. Honor your scope.

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