



## Statistical Studies: What Is Required? .....

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### Upfront definition eases compliance.

It is a huge and important endeavor to maintain an effective calibration system in any machine shop. Performing appropriate statistical studies on the equipment that makes up this system is also a necessity that must be managed properly. An improperly defined Repeatability and Reproducibility (R&R) program can drain a company of resources and reduce the effectiveness of the shop.

The automotive requirement of both TS-16949 (7.6.1) and QS9000 (4.11.4) identifies the need for the shop to provide evidence of statistical studies: "Statistical studies shall be conducted to analyze the variation present in the results of each type of measuring and test equipment system. This requirement shall apply to measurement systems referenced in the Control Plan."



Some auditors have counseled shops to ensure that all gages have statistical studies performed on them. Others believe that if a gage is listed in the control plan, a statistical study must be performed. Many of us tend to defer to an auditor's interpretation of the standard.

These standards allow you the flexibility to define what is effective for your organization. By properly designating the measurement techniques for your systems—measurement, inspection and test—you can avoid the need for irrelevant and redundant gage studies that add no value. You are justified in limiting your statistical studies to those systems cited in your control plan.

The following systems can be used to check product status, product characteristics or process equipment:

**Measurement System.** This precision measurement technique is used to check product characteristics. Statistical studies are appropriate because an operator could alter

the reading of the equipment with an improper method. Examples of measurement systems include micrometers and hardness testing machines.

**Inspection System.** This is a non-precision measurement technique. Tolerances are large enough to limit the possibility of operator error. Instrumentation classified as an inspection system does not lend itself to measurement system analysis studies. Examples of inspection systems include a visual inspection, or the use of a ruler and tape measure.

**Test System.** A test system is a precision measurement technique used to generate a reading that prompts a pass or fail decision. Instrumentation classified as a test system does not lend itself to measurement system analysis studies. Test system techniques are used mostly when checking equipment

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that supports the process (for example, a pyrometer, psi gage or UV light meter).

By taking the time to define the techniques you use, you have made it clear that statistical studies are only applicable to your measurement system or just what the standard identifies. It's important to make the distinction between the three systems to ensure that the R&R process is used only on those gages where it is logical. To perform a statistical study on measurement techniques by using a tape measure, PSI gage and visual inspection is impractical and wastes resources.

The purpose of analyzing your measurement system is to understand the sources of variation that can

influence the results produced by the system. The standard's "each type" requirement does not mean that every micrometer must have evidence of an R&R associated with it.

The analysis of "each type" of gage can be performed by selecting a representation of both gages and operators. One hundred percent R&R inspection for each gage would provide no additional value. It is the system that is being measured, not individual gages. Any competent auditor would understand that a massive R&R production process based on 100 percent inspection would add no greater value and would be statistically irrelevant.

Examine your control plan and locate

the space where you are to identify the measurement system used. The Evaluation/Measurement Technique is the column within the control plan that references the statistical studies requirement. These studies should be performed only on those measurement systems defined above.

Do not lose focus of the spirit of the quality standards. The goal of requirements is not to burden an organization. However, the standards allow the company the flexibility to make the best choice to ensure the validity of the systems used.

It is your business and your system. The auditor's role is to audit your compliance to your systems, not to create non-value-added work.