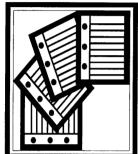


Application Note: 2.0 Rev: 1

## Benefits and Drawbacks of Full Before & After Data

The ISO quality standards require that each company define some method to recall product that has been tested or measured with an instrument that is later found to be out of tolerance. The requirement for recall can be easily determined by the periodic calibration of the test or measurement instrument. The periodic calibration provides the company with information on whether the instrument was within tolerance or not at the time of calibration. However, what data is required on an instrument that is found to be out of tolerance for recall purposes?



Most commercial calibration houses provide their Customers with a single calibration. When an out of tolerance condition is discovered during the calibration, the Technician will normally make several more measurements to confirm the trend. The technician will then return to the original out of tolerance condition point, make the appropriate adjustments and proceed with the calibration of the instrument.

This has the advantage of reducing the turn around times to the Customer. In addition, it reduces the time required to perform the calibration which reduces the costs associated with the calibration. As a result, the Customer normally only pays for one calibration. However, the disadvantage of this method is that there may be other instrument parameters that may also be out of tolerance but, with the initial adjustment or repair, are brought back within tolerance before they were measured.

In recent years, there has been an increase in the number of Customers who have asked for full before and after data. This effectively involves two full calibrations. During the first calibration, all readings are taken and recorded even if they are out of tolerance. No adjustments or repairs are made. Then a second calibration is performed during which the appropriate adjustments or repairs are made. The advantage of this method is that all parameters that are out of tolerance and the degree that they are out of tolerance are noted. The disadvantage of this method is that the Customer is normally charged approximately twice as much for the calibration.

As asked above, what data is required for recall purposes? In most cases, it is sufficient to know that an instrument was out of tolerance because a recall can be performed on all products that were measured or tested with the unit. In these cases, the data is redundant because it does not matter what is out of tolerance. All products tested with the instrument will be recalled and retested.

However, there may be situations where using this method as the basis for a recall may not be cost effective due to the number of products requiring the recall or specific parameters may be more critical than others. In these cases, it may be more cost effective to determine the parameters that were out of tolerance and issue a recall only for those products whose parameters are affected by the instrument. This may bring the number of products requiring a recall down to a reasonable level. In these cases, full before and after data is required.

It should be noted that, in order for the full before and after data to be useful, the company must have the infrastructure in place to support this data. In other words, the company should be able to determine which parameters on which products were tested with the instrument so that a specific recall can be made. If the company's tracking system is not sophisticated enough to allow the use of the full before and after data to recall products, then the company may not be spending their calibration dollar in the most effective manner.

Seeking answers to the following types of questions may help you determine which calibration data is required for your operation and the most effective way to spend your calibration dollar:

- 1) How will you use the data that is provided with the calibration?
- 2) Will you recall all product that was measured or tested with an out of tolerance instrument regardless of the parameters that are out of tolerance?
- 3) Do you want to recall only those products whose parameters were measured or tested with parameters that were out of tolerance on the instrument?
- 4) Is your tracking system sophisticated enough to allow you to track specific parameters measured or tested by specific instruments?

In conclusion, each company should choose the most cost effective approach to calibration keeping in mind their tracking system and overall requirements.