Is your Out-Of-Tolerance Investigation, Out-Of-Tolerance?

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ABSTRACT

Many organizations use internal processes to notify test equipment users when their equipment is either out-of-tolerance (OOT) or significantly-out-of-tolerance (SOOT)[1]. These are often closed-loop processes prescribed by Quality system requirements. In such cases, they typically involve the user in the performance of an investigation to assess possible product measurement impact (PMI)[2]. But how are we to know if these processes are effective? Can we trust the results of these investigative processes? Is a "no-product-affected" statement on a completed investigation, evidence that your investigative process is working? Or does it indicate inherent problems masked by ineffective product traceability? What are the implicit assumptions behind such investigative processes and how are they supposed to mitigate the risk of non-conforming product measurement? In this paper the author will analyze the theoretical assumptions behind a typical OOT/SOOT investigative process and attempt to answer some of these difficult questions.

INTRODUCTION

"You don't know what you don't know," is an adage I've heard from numerous people during my career. Usually said in moments of reflection, this quip is offered up as an explanation for why some things that are obvious in hindsight – routinely escape our notice. It genuinely expresses the limitations of human foresight. We can understand many things – but we cannot take into consideration what is beyond our notice. The subject matter of this paper is one of those subjects that we have experienced, but probably still don't know - what we don't know about it.

The purpose of this paper is to begin a candid discussion about the effectiveness of significantly-out-of-tolerance (SOOT) investigations. It is the result of my experiences in this area and the questions raised by these experiences. It is not intended to be an exhaustive treatment of the subject. I expect that if you are reading this paper, you are somewhat familiar with the idea and purpose of a SOOT investigation. If not, perhaps this is not the best primer to become acquainted with the subject. The intended audience are those who might have harbored vague suspicions about the effectiveness of their own SOOT processes or investigations.

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[1] For purposes of this paper, SOOT and OOT notifications are considered interchangeable terms.
[2] Product includes hardware or data. Product impact will be abbreviated as PMI (product measurement impact) in this paper.

In this paper I will quickly revisit the reasons for having a SOOT investigative process, identify the necessary elements for an effective SOOT investigation, offer possible explanations for why SOOT investigations may or may not be effective, and finally, explore the question of how to improve your confidence in your SOOT investigative process.

WHY SOOT PROCESSES?

According to Joseph Juran, "except in small companies, the number of conformance decisions made per year is simply huge. There is no possibility for the supervisory body to become involved in the details of so many decisions. Hence the work is organized in such a way that inspectors or production workers can make these decisions. To this end, they are trained to understand the products, the standards, and the instruments."[3] Juran makes this statement in his handbook on Quality Control with respect to the conformance decision. Although he is speaking generally of product conformance in production, the point certainly applies to measurement conformance in general. Kimonthi in his book on "The Uncertainty of Measurements" says it this way – "There is a purpose for every measurement. Irrespective of the nature of a measurement, it is always followed by decision."[4] That is the essence of Metrology. We as Metrologists make decisions about the conformance of test equipment, and our customers make decisions about the conformance of their products or data. They rely on our assessment of the equipment to determine if it is fit for its intended use. When the equipment does not conform within the expected margin, the potential exist for an invalid measurement and therefore an incorrect decision.

It is the validity of these decisions that the topic of nonconforming measuring equipment directly affects. If my measuring equipment is found to be nonconforming (or SOOT), how do I assess the impact upon my prior decisions? This is the fundamental question that drives us toward the SOOT investigative process. In fact most modern Quality System standards (e.g. ISO 9001, AS9100, QS900) require an investigative process to assess the potential impact of nonconforming measuring equipment on products or services delivered to the end customer.

With respect to deliverable product, nonconforming measuring equipment can be a contributing factor to both producer and consumer risks (false reject and false accept). SOOT investigations are an attempt to quantify this contribution to both types of risk with the larger emphasis on the mitigation of consumer risk.

Although necessary, SOOT processes represent a departure from the ideal Quality System that focuses on prevention. While calibration is primarily a preventive process (intended to prevent nonconformances), SOOT investigations are inherently remedial as they rely on detection and correction after-the-fact. Because of the remedial nature of SOOT processes, it is entirely appropriate to question the effectiveness of this process.

WHAT IS SOOT?

Beyond the acronym "significantly-out-of-tolerance," SOOT describes a threshold at which the measurement system is suspected of being compromised. Practically speaking – it represents a

[3] *Juran's Quality Handbook* 5th edition (1999) McGraw-Hill, page 23.4)
[4] *The Uncertainty of Measurements* (2002) ASQ Quality Press, page 14)

theoretical value at which the test equipment user might reasonably expect that his/her measurements (and therefore product acceptance or data) would be impacted.

To properly understand the role that the SOOT investigative process plays in the measurement system, test equipment users should have at least a working knowledge of test design and the role of measurement uncertainty, familiarity with the company's SOOT policy, and should recognize that "product" can be measurement data as well as physical hardware. The importance of understanding measurement uncertainty cannot be overstated. Unawareness of this subject can of course later inhibit the performance of a SOOT investigation when the operator has no direct knowledge of how the test equipment's SOOT condition relates to the overall test uncertainty.

KEY ELEMENTS OF THE SOOT PROCESS

SOOT processes contains four primary elements. Notification, investigation, corrective action, record keeping. Each element is a prerequisite for an effective system but is not evidence of effectiveness.

Notification is the process by which the Metrology organization informs the cognizant individuals that a measurement device has crossed the significance threshold defined in the company's SOOT policy. Investigation includes the assignment of the investigator, the collection of facts, the analysis of the facts, and the determination of potential product impact. Corrective action becomes necessary as an element of the process only if the analysis has determined a potential product impact. Regardless of outcome, standardized record keeping is a vital element of the entire process.

Of the four elements – the quality of the investigation is the most important. Figure 1.0 depicts the typical SOOT process from the laboratory perspective.

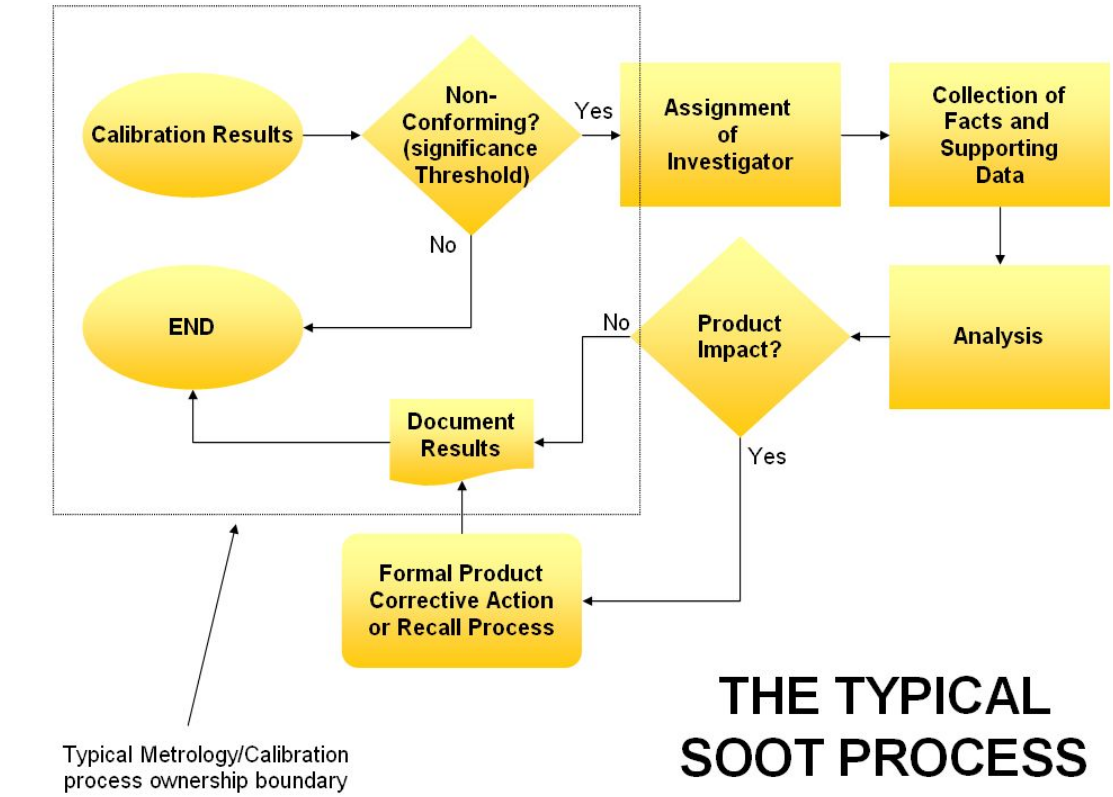

Figure 1.0

QUALIFICATIONS FOR A GOOD INVESTIGATOR/INVESTIGATION

As noted, the quality of the investigation is the key to an effective system. Two prerequisites are necessary to perform an effective investigation; a Qualified Investigator, and Enabling Infrastructure (e.g. data systems). See figure 2.0.

Figure 2.0 Prerequisites for Effective Investigations

The investigator's qualifications should include:

- Familiarity with the instrument
  - Proper application and use
  - Specifications, and limitations (capability)
- Familiarity with the test application
  - Expected or nominal results
  - Potential sources of error
- Knowledge of test design
  - Proper equipment selection criteria
  - Sufficient understanding of measurement uncertainty
- Attention to detail
  - Aware of subtle deviations from expected performance
  - Sensitive to variations in process

The enabling infrastructure should include:

- Easy access to technical specifications for the instruments and tests in question
- Records or data systems capable of associating a particular serial number instrument to either a particular product or range of products
- A system to isolate or segregate products under investigation

It is vital to consider what the possible affect on the investigation might be were any of these prerequisites missing. For example, consider the consequences of an investigator who was unqualified by his/her lack of familiarity with the instrument's specifications or application. Such an investigator may easily miss a potential product impact simply out of ignorance. Worse, an investigator in such a situation would likely assume that they had performed a valid investigation and report the false outcome. Clearly the qualifications of the investigators are of

great importance. But what if the enabling infrastructure were missing or inadequate? For example, if records could not associate a particular product to the instrument under consideration, the investigator again might wrongly conclude that no product was impacted. Again this false result would be reported. It is easy to see when considering the quality of the investigation, that these investigations can easily be compromised without either intent to do so, or direct evidence that the investigation has been compromised.

THE PROBLEM FROM MY PERSPECTIVE

I have worked in the field of Metrology since the early 1980's with several different organizations. I have worked as a calibration bench technician, laboratory lead, quality auditor, and manager. I have visited numerous calibration activities and spoken with dozens, if not hundreds, within the field of Metrology. Over these twenty plus years in the field of Metrology I have had multiple affiliations with SOOT processes. As a technician, I have initiated dozens of SOOT investigations. Calibration inevitably provides technicians with this opportunity. Dutifully I have filled out the necessary paperwork and filed the necessary reports. I have updated the database and followed-up to ensure the paperwork was completed. As an auditor I have reviewed these investigations. I have ensured that the necessary procedures were in place and sufficiently detailed. I have sampled the records for completeness and reviewed metrics that indicate the process is functioning. As a laboratory lead and manager, I have supervised the administration of the SOOT process after authoring procedures that describe how to perform the investigations. I have coached equipment users on how to perform them and have reviewed hundreds of investigations for completeness. I have even coached and instructed senior management on the importance and necessity of the SOOT process itself.

Yet with all of this experience and hundreds of investigations behind me, the number of times that I have witnessed a SOOT investigation indicate a PMI, is so low as to be statistically insignificant. Anecdotally, I cannot even recall an incident where a SOOT item was definitively linked to a product nonconformance.

My experiences have left me somewhat troubled. Recalling Juran's reference to the 'huge' number of conformance decisions, intuitively it appears to me that I should have observed some quantifiable number of defective products. Certainly one would think that we could after so many years associate a given level of SOOT investigations with a corresponding expected level of product nonconformance. Yet this is not the case. My intuition informs me to expect at least an occasional event of significance, but my experience does not validate that expectation.

Yet intuition is not science. A gut level feeling does not always correspond with reality. Science starts with logical questioning and forms hypothesis around these questions. Logically, there are only a limited number of possibilities with respect to the effectiveness of a SOOT process. The SOOT process is either capable of detecting and reporting PMI or it is not. And if detected and reported, these reports can either be representative or unrepresentative of the factory conditions. Refer to table 1.0 for an illustration of the possible conditions.

Possible Condition	Investigation Detects and Reports Measurement Impact?	Investigation Accurately Represents Reality?	Comments
C1	Yes	Yes	Useful outcome
C2	Yes	No	Undesirable outcome Defective system
C3	No	No	Undesirable outcome Defective system
C4	No	Yes	Preferred outcome

Table 1.0 SOOT System Possible Conditions and Outcomes

C1 represents a situation where the SOOT system detects and reports a measurement related impact to product, and the results of this investigation fairly represent the reality of what is actually occurring in the factory. It indicates product measurements have been compromised and it is useful information. Contrast this to a system that might correctly detect and report a single incident of measurement impact, yet does not do so consistently. This would be the situation in C2. A system that did report measurement impacts but could not do so consistently would be an indicator of a defective system. Through circumstance or good fortune I have not experienced either C1 or C2 and cannot comment further on whether these possible conditions reflect the reality within the organizations where I've worked. This leaves me with two remaining possibilities, C3 and C4.

C3 describes a situation where the system does not detect product related measurement impact, yet this indication is unrepresentative. The reader will note that this represents the highest risk to the SOOT system. Specifically – a system that appears to work, yet is incapable of detecting measurement related product nonconformances. The final possibility (C4) is that the system is capable of detecting PMI but does not, and that indication truly represents reality. This is of course our preferred outcome – to have a system capable of detecting PMI, but never actually having one.

Having eliminated conditions C1 and C2 from the discussion, the question remains - 'which condition is representative of my experience?' This question is the Genesis of this paper. Either the systems that I have worked with are functioning exactly as I would wish them to, or they are not and the true condition is masked by a system incapable of detecting the PMI. From these alternate possible conditions, I began to hypothesize explanations that might fit either condition three or four.

POSSIBLE EXPLANATIONS

Given a history of little or no PMI upon completion of investigations – what are the alternatives?

Explanations for C3
If C3 were true, what might cause such a condition? You will recall C3 would be a system that did not detect and report PMI and that lack of detection and reporting was unrepresentative of reality. In other words, the system falsely reports no PMI. Assuming the existence of a defined SOOT process, we must use our imaginations to hypothesize and explore what might produce such a condition.

Returning to our four elements of a SOOT process (notification, investigation, corrective action, and record keeping) you will notice that we are able to demonstrate the effectiveness of notification and record keeping. We cannot validate the effectiveness of corrective action that has not occurred so we are left with the investigation as a possible defective element.

Recall that investigations require both a "qualified investigator" and the "enabling infrastructure." If these pieces are missing or inadequate, which might lead to the false outcome noted in C3? Assuming the investigator lacked familiarity with the instrument and application, knowledge of test design, or attention to detail, would it be reasonable to expect the investigator to detect a product nonconformance traceable to the instrument? In each case you would likely conclude that an investigator lacking in these qualifications might easily miss an indication that the equipment had compromised the measurement.

Consider the infrastructure. Would the lack of access to specifications, records, or data systems contribute to a false indication of "no product affected?" Clearly the absence of easy access to specifications makes the research more difficult but in itself shouldn't result in a false indication. However, the lack of traceability between the instrument and the product or data produced could easily mask the detection of affected product.

Even this brief analysis of the prerequisites of an investigation reveals the potential for a system that does not detect and report PMI. In a system that reports little or no PMI, we cannot rule out the possibility that C3 exists.

Explanations for C4
If C4 were true, what might cause such a condition? C4 represents a system that is capable of detecting and reporting PMI accurately but never actually detects a PMI. Assuming a defined and functional SOOT process, what explanations might we hypothesize for why PMI seldom or never occurs?

My first consideration was that perhaps our test design processes are sufficiently robust that the errors introduced by SOOT equipment do not encroach on the product tolerances in a meaningful way. This is typically referred to as margin for error. The assumption behind this explanation is that test equipment users and test designers include sufficient margins between the instrument accuracy and the required product tolerance. I am skeptical that this is a valid explanation for a lack of PMI indications. I have had sufficient experience with both test designers and test equipment users to believe that many are generally unaware of the accuracy of their own test equipment. In order for this to be a credible explanation, most test design functions would have to have a high degree of expertise in equipment accuracies.

I next considered the possibility that deviations from nominal "expected values" effectively act as a check standard against the instrument in question. To illustrate this concept, consider a machine shop where an operator is engaged in machining an item with a published nominal value. In this example the machinist cuts the part using a numerical control program and then inspects the part with a calibrated dimensional hand tool. If the process is even remotely under control, the machinist would expect a degree of repeatability in this measurement process. Now suppose that the instrument has been dropped between production runs and has consequently become SOOT. Would we expect the operator to notice? Would the operator, having previously been engaged in producing good parts, question the part or the instrument first? Further, what actions would an average operator take in such a circumstance?

When I posed this question to others, most concluded that the typical operators would immediately question the instrument's accuracy, and set out immediately to verify the reading. This verification could be as simple as borrowing another instrument from another operator, or in seeking out another operator to perform an independent check. In any event, it is highly unlikely that defective product would leave the area labeled as "good" product. I consider this scenario to be highly probable considering most measurements involve a degree of predictability and the expected value is usually well known. Even supposing that the operator ignores the aberrant indication and assumes the SOOT instrument's reading is correct, he/she will most likely be rejecting "good" product based on bad data. This is a classic example of producer risk. It adds cost, but does not increase the risk to the end customer.

I believe, this is a very strong argument for why I have witnessed so few PMI. Most equipment users will perform informal corrective and preventive actions when they suspect their test equipment has been compromised. That many of these actions are taken informally and not part of a documented corrective action system makes proving it difficult. Further, many of the measurements within our factories carry a degree of redundancy either upstream or downstream in the processes. Parts must fit and function within other assemblies or systems. The correct function of these other assemblies or systems, acts as a secondary cross-check against up-stream measurements.

It is paradoxical that the measurements most vulnerable to SOOT instruments may be those tests that are highly experimental – such as R&D. In such cases, measurements may be performed with a high degree of uncertainty about what the nominal or expected value is. A SOOT instrument in such cases might actually contribute to errors in the initial product definition without becoming obvious. Without a clear expectation of the measurement result, errors in the equipment may become embedded in the design. This is paradoxical because many R&D functions hold themselves above a strict application of the Metrology system requirements, precisely because they "don't deliver product to the customer." Such thinking is obviously shortsighted. But when considering a product that has already been defined and is in production, operator vigilance and system redundancy appears to be a credible explanation for why a system might have few PMI.

CONCLUSIONS

Unfortunately these hypotheses defy experimental validation. For example, how would you test the number of times defective product was prevented by operator vigilance? Does an operator even realize that they have done something significant when they do so? Do operators that segregate equipment they believe is nonconforming - routinely document the condition?

Prevention is just plain difficult to measure. There is no direct way to measure the effectiveness of the SOOT process because it deals with historical events for which an independent evaluator/assessor was not present. Further, it is not an experimentally repeatable occurrence. Ineffective investigations are inherently difficult to identify.

TESTING YOUR SYSTEM

If it is difficult or impossible to gage the effectiveness of our SOOT systems, then what can we do to increase our confidence? It is my conclusion that we must analyze our SOOT systems to ensure that they contain all of the necessary elements to conduct a robust investigation. We must ensure that those performing the investigations are well qualified, and that the enabling infrastructures are in place.

Returning to the topic of investigator qualifications, it would be appropriate to ensure that anyone performing SOOT investigations were sufficiently competent. Familiarity with the instrument and application, knowledge of test design, or attention to detail must be the minimum requirements to perform an investigation. It would be relatively simple to screen those performing your investigative process for these qualifications. A simple check-list can be made from the requirements listed earlier in this paper. While this is not a guarantee of effective investigations, periodically sampling the qualifications of those performing the investigations may boost your confidence that the system is capable of detecting PMI.

With respect to enabling infrastructures, we must begin to ask – how difficult are our SOOT investigations to perform? Assuming the availability of specifications and technical data, can we clearly identify those products where the SOOT instrument was used? Refer to figure 3.0. Again, we can create a checklist for those infrastructure elements that facilitate the investigation. We can gage the relative ease by which an investigation may be performed.

In the final analysis, we may not be able to prove that a “no PMI” investigation result is accurate or representative of the systems performance. There are real reasons to believe that the actual risk of PMI is low, but these explanations (though credible), are in themselves difficult to prove. We can however demonstrate that our investigators are qualified to perform the investigations, and that we have the necessary infrastructure in place to do so. Taking these simple steps will increase your confidence that your system is capable, and that your end products are not compromised by SOOT equipment.

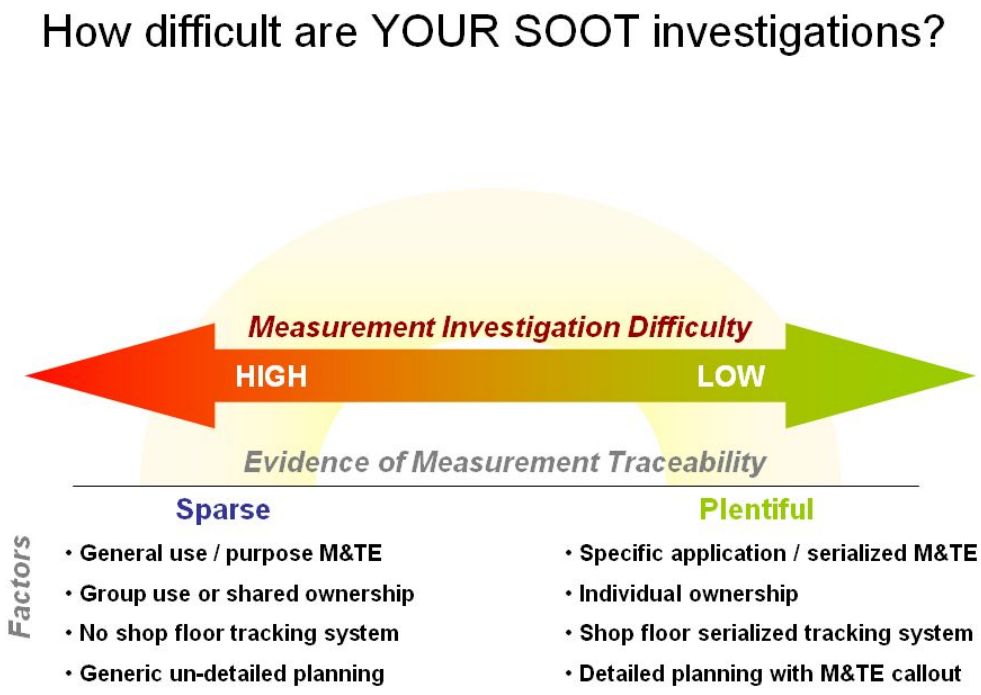

Figure 3.0 Enabling Infrastructure