Protecting Data Integrity for Raw Materials Producers

Market Overview:

The rising trend in test data falsification is a concern for both metals producers and the customers that rely on their results. Since 2019 the misrepresentation of mechanical properties has led to over $800 million in assessed fines, multiple federal convictions, and enormous challenges in the requalification of parts and suppliers. More often than personal enrichment, the motivation for individuals involved in these cases has been an improvement in mill yield. This motivation has heightened with increased capacity utilization and rising raw materials pricing.

In many cases when a discrepancy in test methodology or report is observed, it can be very difficult or impossible to determine when, how, and by whom the change was made. This challenge increases both the cost and time required to resolve these cases and raises the liability of the laboratory involved.

To prevent the escape of falsified data or mitigate its damage, metals manufacturers should employ revision tracking software to maintain full records of changes to methods, tested samples, and report templates.

Challenges:

Lab employees face growing productivity pressures to approve material. However, mistakes and misjudgment can lead to costly errors and burdensome mitigations.

- **Operators and engineers can feel pressured to approve non-conforming materials by adjusting test methods or revising past specimen results.**
    - Record high utility and raw materials prices have driven up the cost of metals production processes. Compounded with high capacity utilization and tight supply chain constraints, the cost of scrapped material due to failed mechanical tests is increasing.
    - Pressure to pass non-conforming material can occur throughout the value chain and lead to costly recalls as additional value is added to material that should have been identified as failing in an earlier process.
- **New employees may accidentally adjust settings and it can be a challenge to return them to their correct values.**
    - Discrepancies don't always start with malicious intent. Employees who are new to the lab may make accidental changes to parameters or past tests. It is important to return these values to those appropriate for the tests and specimens.
    - Without a records trail, the process of returning parameters and results to their original values can be time consuming and cumbersome. Calculations may be challenging to recreate after even slight adjustments.
- **After a discrepancy has occurred it is critical to quickly isolate, retest, and potentially recall affected material. Time is of the essence, and it may be difficult to identify what is and is not affected by the discrepancy.**
    - Once a discrepancy has been identified, the urgency to quarantine affected batches and their downstream components cannot be overstated.
    - Without a trail of records, costly over-quarantining will be necessary to prevent further escaped material. It may be difficult to determine when the discrepancy began, which may lead to excessive retesting as well.
    - Production may be dramatically impacted or stopped during this time of identification, isolation, and correction. The challenges of restarting increase with the difficulty of resolving discrepancies and may result in penalties and costly requalification requirements.

Ways to Address Testing Challenges:

Approach 1 – Establish an automatic record trail

Whether intentional or accidental, the challenges in identifying when a test method or specimen result was changed can weigh heavily on a lab team. Aside from the cause, it can be unclear who made the change, how much material was affected, and what the values need to revert back to. All the while, an increasing quantity of material may be subject to reinspection, quarantine, and even recall. Production output may be affected as well.

It can be challenging to manually track the records vital for restoring operations after a discrepancy; however, through the implementation of an automatic records trail including revision history, your changes can be automatically stored in their method, sample, and report template files. Additions, modifications, and deletions will be recorded along with timestamps, users, and previous values, enabling quick identification of discrepancies and simple reversion to the correct values.

By using this simple automated software solution already included in your Bluehill Universal software, you can increase confidence in the integrity of your testing procedures as well as trust in your recorded results. In the event of an identified discrepancy, you can quickly isolate only the affected data and easily restore operations to their previous settings and values.

Through additional user-based security measures, certain functionality can be restricted only to trained personnel, limiting the opportunity for mistaken changes. However, for enhanced security, a more thorough approach is required to prevent all discrepant revisions.

Approach 2 - Raise your security with Electronic Signatures and Audit Trail

While revision history is a valuable partner in resolving discrepancies in your data once they have occurred, additional measures are needed to prevent discrepancies from occurring at all. Traceability of testing methods and data can be improved with the addition of two further controls on additions, revisions, and deletions: electronic signatures and audit trails.

Many lab operators and engineers are familiar with the process of hard copy signature approvals to maintain testing quality and consistency. Unfortunately, many are also familiar with the ease with which these procedural requirements can be violated without supervisors or other operators being alerted to the problem. Through the implementation of electronic signatures, the ability to violate signature requirements can be effectively stopped by incorporating primary, secondary, and tertiary signoffs into the software, preventing changes from taking effect in testing. Because these approvals are electronic, they can be executed quickly and remotely as needed, enabling authorized changes to take effect promptly with the proper approval chain intact.

An additional measure to be considered for improving the integrity of lab data is the utilization of an audit trail to track all activities on the test frame itself. This includes usage data such as log-ins and log-outs in addition to all additions, modifications, and deletions in Bluehill files. The addition of electronic signatures and audit trails to your testing software package significantly enhances the ability of your team to prevent discrepant activity on the machine, altogether avoiding costly mitigations measures.

Summary

Metal products are relied on every day to ensure the safety of our vehicles, buildings, and infrastructure. Our confidence in these products depends on the integrity of the mechanical testing data used to evaluate them. With rising pressures to revise methodology and results in process, it is critical to add tools to your lab to prevent unauthorized additions, revisions, or deletions. Doing so can not only save costly excessive quarantine and recall expenses, but more importantly it can prevent these disruptions altogether, securing the trust of your customers and preserving your company's reputation.

There are two approaches a lab can take today to improve the integrity of their testing data. The first involves implementing an automatic records trail to track changes to method, sample, and report template files with timestamps and user identification. The second approach goes further by requiring electronic signatures and audit trails to verify all modifications. Both approaches aim to protect your lab and the confidence and trust you have in your results.