Time & Temperature Controlled Materials Management

How optimization of sensitive materials leads to higher quality products.

TIP Technologies, Inc.
The difference between surviving and thriving

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Introduction

Today's manufacturers face increasing challenges and must remain agile to respond to new opportunities. For many of these companies, using state-of-the art materials to manufacture their products is not only necessary, but can be critical in creating a niche for themselves in the marketplace. Companies equipped with a robust Quality Management System (QMS) are well-positioned to successfully respond to market demands and outperform their competition.

A QMS system with functionality that focuses on how to make more efficient use of specialized materials to yield higher quality products can be the key to success. This white paper introduces best practices for handling Time or Temperature-Controlled Materials (TCM) to ensure consistent quality.

The Challenge

Many Quality Management Solutions can help companies track manufacturing components in the production cycle, but when it comes to managing multiple phases of controlled material that is sensitive to time or temperature deviations, those solutions often fall short.

Controlled material can refer to any sensitive material that has a shelf life such as composites, resins, rubber, etc. The breadth of functionality that a typical quality management system offers, lacks the specific tracking mechanisms needed to carefully the control costs and consumption of these specialized products, and produce higher quality goods.

Industry Overview

Controlled materials are increasingly used in high-performance manufacturing applications and emerging technologies within the Aerospace, Defense, Marine, Automotive and Energy/Power sectors. These products can help meet the mechanical and weight specs required of many new product designs. Additional requirements for the handling of sensitive materials are required in highly regulated industries. One such specialized regulatory requirement is within the Aerospace Industry, which regulates the types of adhesives that must be used to manufacture products.

Industry leaders should be prepared to quickly react as market demands develop and should be proactive about maintaining consistent quality by creating a controlled environment where performance is repeatable and reliable.

Business Drivers

Why do manufacturers seek Time & Temperature Controlled Materials functionality? In addition to daily productivity gains, this functionality when used in concert with a best-in-class quality solution, can help manufacturers meet these important business objectives and achieve quantifiable gains beyond their initial expectations.

- Demand for integrated processes
- New product introduction initiatives
- Control over cycle time
- Evolving compliance & regulatory standards
- Audit Preparation

TCM Functionality Overview

Time & Temperature Controlled Materials functionality allows manufacturers the ability to optimize the shelf-life of high-performance materials, while maintaining a master record for each specific material within the system. Complete traceability and product genealogy is stored within the database and can be tracked in several user-defined ways.

Materials Manufacturing

TCM functionality is necessary for companies who consume these sensitive materials, as well as those who manufacture these products. Materials manufacturers can take advantage of an advanced Quality Management Solution that seamlessly integrates with a Shop Floor Execution Solution to facilitate the manufacture of high-performance materials, while maintaining Work Instructions, Bills of Materials, and the generation of the master inventory record for each specific material within the system. Just as complete traceability and product genealogy is stored within the database for consumers, it is also readily available for manufacturers at each point in the production process.

Concerns for Perishable Items

Perishable items have a shorter work-in-process shelf life. Most of these materials are expensive and need to be tracked for shelf life, freezer/cooler times, as well as exposure to room temperature prior to curing. To maintain effective control over these products, companies need a robust warning system for material that is about to expire, so that as workers are transacting with a substance and it is getting close to its expiration, they will be warned.

Labeling in the factory and in storage is critical and it is important to have a solution that supports that effort. Tracking things such as rolls, containers, or cans is simplified when the expiration date and material traceability is clearly visible.

With effective Time & Temperature Controlled Materials functionality, traceability and expiration is recorded on each container, as well as when the material is allocated and consumed. Users can record cure times and stop times and monitor in and out transactions. Open containers such as resins are affected by oxygen that will impact shelf life. As such, users can track overall shelf life as well as the life of an open container.

Parameters Give Users Control Over Inventory

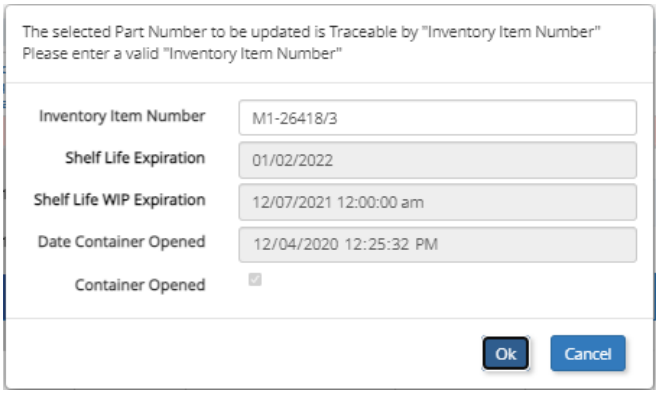
Special provisions exist to maintain effective control over controlled materials. Users should set specific parameters to maintain careful control over inventory. An advanced Quality Management Solution will provide these controls. A Project Validation parameter will ensure material is consumed against the proper work order. An Overconsumption Parameter will trigger a notification to alert the planner if a user is consuming more than what is required on the Bill of Material.

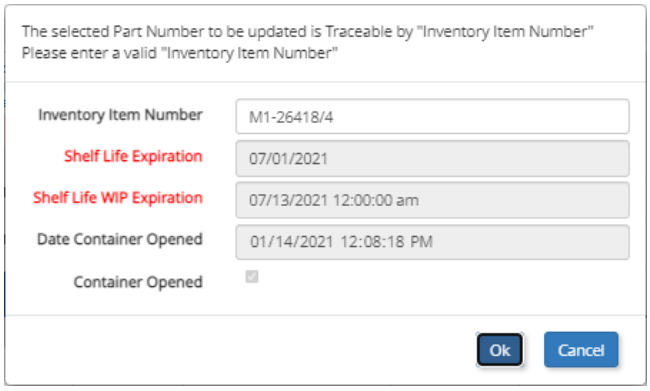
Effective TCM functionality will allow for role-based access. This important security layer can limit a user to change inventory status only, perform inventory re-qualifications, check out pre-release containers, split containers, or allow transactions for lab work.

Managing the Inventory Master

Effective Time & Temperature Controlled Materials functionality provides the ability to maintain all aspects of the material in terms of life expectancy within the master record. Material is traceable by PO, Work order, Receiver, or Part Number. The inventory item number is automatically allocated to the work order and the allocation record is sent to the host.

With an advanced Quality Management Solution, transactions are updated and integrated to the shop floor, informing users of in and out records, material marked for consumption, and material designated for requalification.





Traceable part numbers show critical expirations.

Key Attributes of TCM

The following are key attributes that should be monitored for Time or Temperature Controlled Material. Without this specific data, manufacturers risk significant waste.

Shelf-Life Days

Shelf Life is measured in days. The system sets the Shelf-Life Expiration Date. It includes a Warning Number of Days.

Shelf-Life Days – WIP

Shelf-Life WIP is measured in days. The system sets Shelf-Life WIP Expiration Date for Work In-Progress or "Open Container." It includes Warning Number of Days.

Cooler Life Minutes

Cooler Life is measured in minutes. The system sets the Cooler Life Expiration Date. It is common for this Frozen Material to be temporarily stored in a cooler *(refrigerated).* It includes Warning Number of Minutes.

Room Life Minutes

Room Life is measured in minutes. The system sets the Room Life Expiration Date *(TCM at room temperature)*. It includes Warning Number of Minutes.

Life Limit Days

Life Limit is measured in days *(maximum life expectancy from date of manufacture*).

Requalification Limit

Requalification Limit is numeric. It defines the number of times material can be tested and re-qualified.

Minimum Warmup Minutes

The Minimum Warmup Minutes are printed on the label. This tracks the number of minutes before the frozen material can be handled after removing from the freezer.

A Day in the Life of Time or Temperature Controlled Frozen Material

Let us take a look at how some controlled material would typically be handled within a Quality Management Solution with Time & Temperature Controlled Materials functionality.

By managing the process through a series of logical steps, companies can ensure optimal use:

1) Date Manufactured

2) Shelf-Life Expiration based on Date of Manufacture *(Adjusted at Receipt as needed*).

3) Material Placed in storage based on temperature requirements such as Freezer, Cooler, or Room Temperature.

4) Material Removed from Freezer/Cooler and thawed to Room Temperature to Start Room Temperature Expiration Date based on minutes allowed.

5) (Option) Material cannot be consumed yet, so it is placed in the Cooler *(instead of re-freezing)* to stop Room Temperature Clock.
    a. Starts Cooler Expiration Date
    b. When Removed from Cooler: Material thawed back to Room Temp to recalculate Room Temp Expiration Date and stop Cooler Clock

6) Material placed in a fixture to begin forming shape.
    a. Stops Room Temp Clock and starts Material Handling Expiration Date Clock

7) Material is placed in oven and cured.
    a. Stocks all clocks

8) Lastly, the system will control the number of times the material can be tested and re-qualified to rest all data elements *(until end of life)*.

Temperature Control Setup records various data elements.

Shelf Life Days

Shelf Life Warning Days

Shelf Life Days - WIP

Life Limit Days *Note: 0 represents no limit.

Temperature Control Setup

Require 'Date of Manufacture' on Inventory Master Record ☐

Number of Days Past the 'Date of Manufacture' for Receipt to Activate a Warning

Temperature controlled item ☐

Room Life Minutes

Room life warning minutes

Cooler Life Minutes

Cooler Life Warning Minutes

Minimum Warmup Minutes

Requalification limit

TCM in Additive Manufacturing

A growing number of leading manufacturers are using the additive process to produce their products. Additive manufacturing is often applied within military, aerospace, medical, and automotive environments, where it can save time and increase performance. Additive manufacturing can be used to make nearly anything from a small part to larger complex items traditionally made as assemblies. Just as with traditional manufacturing methods, achieving a consistent level of quality in additive manufacturing is critical to success.

The powders used in additive manufacturing need to be inspected, stored, controlled, and are highly susceptible to temperature, moisture content, and contamination in addition to Shelf-Life controls. Once validated during inspection, they need to be stored in a traceable controlled manner. A Quality Management Solution with material control capabilities can facilitate the entire inventory control to support the manufacturing process from procurement or manufacture, through allocation, cure/consumption, completion, and inspection. The shelf life of these expensive materials can be extended if efficient controls are in place.

Additive manufacturing requires extensive documentation including lot traceability, design documents, work instructions, and inspection records. Comprehensive electronic document history is achievable with an advanced quality solution. Software can support electronic document approvals, recognize when a change occurs, and document who it was that made the change. All documents related to additively manufactured parts, including photos, can be archived, and immediately referenced for audit purposes.

The Importance of Integration

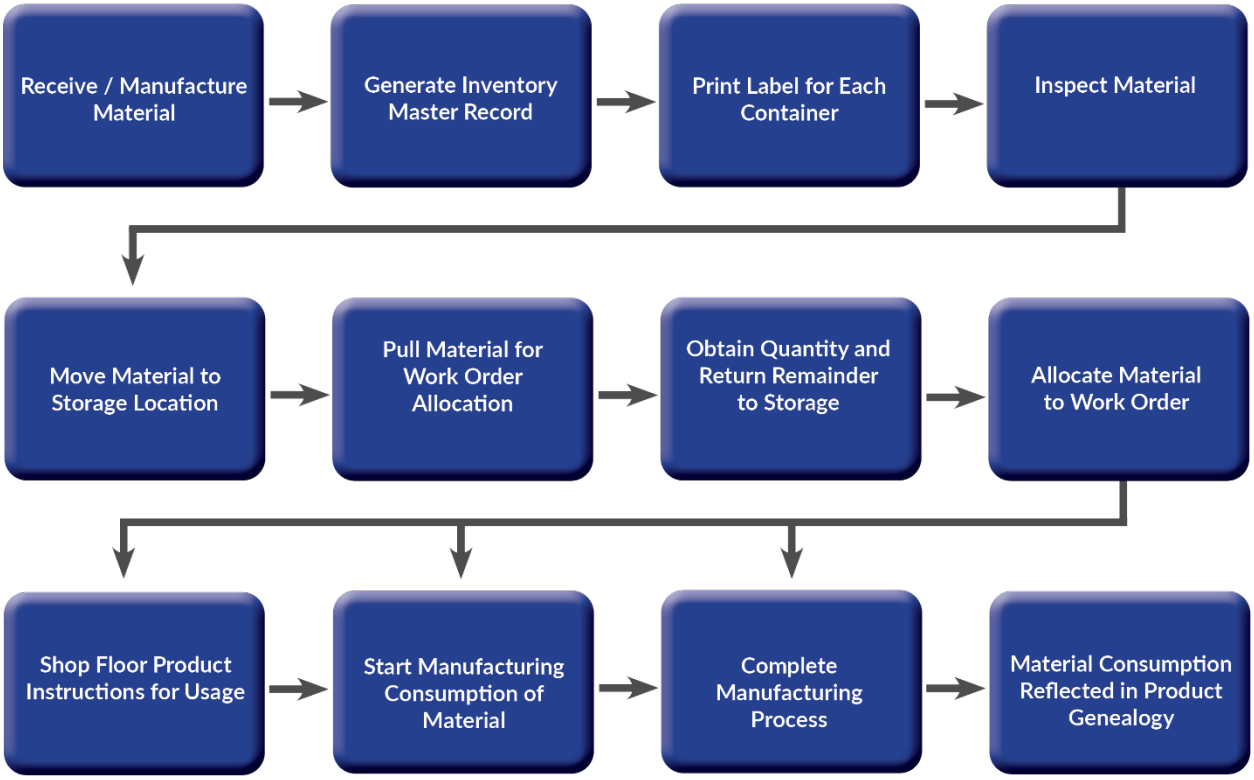
Best-in-class Time & Temperature Controlled Materials functionality will be part of an integrated quality management solution. This functionality should fully integrate with Receiving Inspection. Material can be integrated to the receiver as part of the acceptance record. When the material is consumed in the shop, the inventory item number can be recorded on the traceable configuration. This then becomes part of the product genealogy, including the validations for that material.

It is critical that TCM functionality also integrate with the shop floor. A fully integrated solution that synchronizes quality and manufacturing data will record stocking and consumption transactions to better manage operations on the shop floor. This gives operators the ability to send work order material transactions to the host.

Asset usage for controlled materials can also be recorded in an integrated quality solution and help users determine if a tool is overdue for calibration or preventive maintenance.

TCM Workflow

The following is an overview of how an advanced Quality Management Solution with Time & Temperature Controlled Materials functionality handles quality processes and workflow.



The Value in Materials Monitoring

Real-time Time & Temperature Controlled Materials functionality helps companies move away from paper-based data collection and disparate systems. Strategic use of this information can dramatically improve management's decisions. With immediate visibility into material variances, issues can be resolved before production is complete, which in turn enables you to:

- Maintain product integrity
- Reduce product loss
- Control manufacturing costs
- Improve on-time delivery
- Achieve a paperless shop floor
- Deliver higher quality products

Conclusion

The optimization of valuable controlled materials can make a significant impact on an organization's bottom line. Compare a manufacturer who uses TCM functionality to one who does not. They both compete in the same environment and may have similar production processes, but the one who does not maintain strict control over its controlled materials is at greater risk.

Manufacturers should take a closer look at their processes to improve productivity and increase time to market. Planners will worry less about data collection, reduce complexity in manufacturing, and will be free to focus their energy on operations when a reliable system for sensitive materials is in place.

These best practices have been used by a wide variety of industry leaders to achieve consistent quality. Companies can avoid unpredictable results with a mature quality management solution that is well-equipped to handle the various time and temperature elements needed for success.

About TIP Technologies

Founded in 1989, TIP Technologies was one of the first to provide integrated quality assurance software using a commercial, off-the-shelf strategy. Now a recognized leader in the industry, TIP Technologies continues to develop highly respected software that is used by some of the world's largest corporations.

TIP*QA*, an industry-leading quality management solution from TIP Technologies, seamlessly integrates with inspection and shop floor operations to facilitate the successful production of critical time and temperature-controlled materials from procurement through allocation, cure, completion, and inspection.

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