Celotex   Technical Report

To: PLCP   From: Ian Parker

Circulation: RP, JA, CK, PE, JM, RW

Ref: Hipchen thermal Sampling 2009   Issue Date: 09/12/2009

Department: Quality

Following the decision to pursue lambda 22 on the Hipchen the following is a summary of the current and proposed process for the collection of thermal sample result against which external auditors will Audit.

Current Process.
The current process (process flow 1) is set-up to record all results regardless of the actual value of the result.

1) 4 to 6 thermal samples are measured per day on the themal machine(s) which automatically generates a.htm data file of the test and stores it into a local folder on the thermal machine PC.
2) The thermal result along with the measure thickness is logged by QC on the daily record sheet which is used to collect all the data for the days production.
3) At the end of the shift / day the daily sheet information is inputted into the QC database and the daily recorded filed in the QC lab for reference.
4) Any thermal falling outside the selection bands of 19.4 to 20.4 (to give a declared lambda 22) have a check box unticked so the result is not displayed on a separate record sheet within the same database. i.e. An auditor will only see the thermals in the selection band.

Issue with process which could be identified by an auditor if they followed the process trail.
   a) The "selected" data is contained within the same database as ALL the data so there is potential for an auditor to pick up all the data due to human error.
   b) The daily records contain ALL the results which if they were audited would highlight the fact "extra" thermal samples are not in the "selected" database
   c) The thermal machine data files are automatically saved in to the thermal machine PC log folder which contain both selected and out of range files. Again an auditor could pick this up.

This results in a logistic issue of having to manage the data to avoid an auditor finding evidence that thermals are selected to give lambda 22 rather than recording the results regardless of their value. With Circa 100 samples per month and a "failure" rate of 40 to 50% this represents a high degree of data management and manipulation which is all down to human interaction to make decisions on what to keep or reject.

Option 1. – Retains all thermal data but offers the highest opportunity for human error in the process resulting in auditor queries.
   A) Retain a 2 tier database with the auditor only seeing selected results but with ALL the data available internally to track actual progress towards 22 on a non statistical line improvement. BUT, data management is critical and human error is the issue.
   B) Daily sheets have to be modified to "remove" the out of range thermal data so they are not picked up on any audit process. – Again, data management is critical.
   C) The thermal machine log will require the machine data file to be relocated into a separate location- Again, data management is critical.

Summary option 1 – Data management is labour intensive and human error is potentially high. All data is retained for future use.

Option 2. – Retains only thermal data within the selection range.
   D) Maintain a 1 tier database for only thermal data in range to give a Lambda 22. Eliminate human error of selection process and a 2 tier data management process.
   E) Daily sheets have only the good thermal data logged and out of range data is not recorded.
   F) The thermal machine log will require the machine data file to be relocated into a separate location to retain historical information - Again, data management is critical.

Summary option 2 – Data management is far less intensive but the ability to review ALL Hipchen thermal data is lost without having to refer to the thermal machine data file which would be a labour intensive process to extract and compile.

Summary.

Hipchen Lambda 22 by statistical method is data intensive under either option relying on those testing and data input to make the right decision and human error over 100 samples per month will occur at some stage.

From a data management / risk perspective Option 2 would be the preferred method but the negative side is the loss of thermal data from the database for analysis – this would be my preferred option.

Ongoing there needs to be progress into achieving a Declared Lambda 22 via process / chemical improvements and not the statistical method which does not represent the actual population of the true lambda of the product being produced.

Actions to complete for option1.

1) Transfer all the cut of range thermal machine .htm files for the last 2 months (this is the BBA data set for the declared 22) to another location – Ian Lockwood
2) Delete or re-write the daily sheet information for the out of range information for the last 2 months – QC
3) Ensure the database is correctly tagged for in range data.- QC
4) Ongoing all thermal .htm files to be transferred to another location - QC

Actions to complete for option2.

1) Transfer all the cut of range thermal machine .htm files for the last 2 months to another location – Ian Lockwood
2) Delete or re-write the daily sheet information for the out of range information for the last 2 months – QC
3) Ensure the database has all the out of range thermals deleted for the prior 2 months. - QC
4) Ongoing any thermal test out of range is not recorded on the daily sheet or input into the database. - QC
4) Ongoing all thermal .htm files to be transferred to another location - QC

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Current Process flow for Hipchen Thermal Sampling

HIPCHEN

4 to 6 samples per day.

Thermal Tester

Selected Database

Auto

Manual

Manual

Thermal Datafile

QC Daily Sheet

MAIN Database

Manual

C_04981
C_10280

CEL00010272_0003

CEL00010272/3