

Conference Call 2/18/2011

Attendees: Joe Franklin, Gil Reinhard, Jason Bowden, Adam Bowden, Matt Bowden, John Mattern, Udo Boecker, Mike Kasimirsky, Gefei Wu, Mike McMillan, Bill (Savant)

Joe Franklin prepared a proposal for the new elastomer batch referencing process. The proposal is attached (Seal test proposal 021711.pdf).

The group discussed Joe's proposal. Joe suggested incorporating the data from each new batch into the historical data.

Joe made the motion to accept the proposal. John Mattern gave the second.

The motion carried with 8 approval, 0 negatives, 0 abstentions, and 1 waive.

Jason Bowden agreed to send out Batch 7 material.

The meeting was adjourned.

## From the minutes 10-28-2010

Original motion/proposal:

When a new batch of material is procured by the CPD a sufficient sample will be provided to the test labs for 2 reference tests to be run at each lab. These tests should be started within 2 weeks of receipt of the new material. The reference test will be reported as donated tests and the bath calibration status will not be affected by the results. Any currently running candidates will need to be validated with references run on previous batches of material as they should only be running on the previous batch. Once a minimum of 3 labs have reported these initial results they shall be compared to the current mean and standard deviation for the material. If the data indicates that they are part of the same distribution of data then they will use the same reference acceptance criteria as the previous batch. If the data indicates that they are not likely to be part of the same distribution of data then a minimum of 10 data points total will be generated by the participating labs to establish new acceptance criteria for the new batch.

Consensus of the group seemed to be that the proposal, above, has merit, but the specifics on exactly how to determine if the new batch was different than the old batch needed to be nailed down before going forward.

New proposal:

When a new batch of material is procured by the CPD a sufficient sample will be provided to the test labs for 2 reference tests to be run at each lab. These tests should be started within 2 weeks of receipt of the new material. The reference test will be reported as donated tests and the bath calibration status will not be affected by the results. Any currently running candidates will need to be validated with references run on previous batches of material as they should only be running on the previous batch. Once a minimum of 3 labs have reported these initial results they shall be compared to the current mean and standard deviation for the material. If the mean of the new batch data is  $\leq 0.5$  standard deviations different ( $\pm$ ) then the current target for all parameters, ~~data indicates that they are part of the same distribution of data then they~~ we will use the same reference acceptance criteria as the previous batch. ~~If the data indicates that they are not likely to be part of the same distribution of data~~ If the mean is  $> 0.5$  standard deviations different than the current target for any parameter then a minimum of 10 data points total will be generated by the participating labs to establish new acceptance criteria for the new batch.