LDEOC/EOEC SURVEILLANCE PANEL

A LDEOC/EOEC conference call was held on July 9th, 2012 at 9 am central standard time. The following members were on the call:

Jennifer Keiter – Lubrizol
Mike Kasimirsky – TMC
Jason Bowden – OHT
Joe Franklin – Intertek
Kevin Rettmann - Intertek
Udo Becker – ISP
Mike McMillan – Infineum
Geifu Wu – Ashland
Allison Athey – Volvo
Mike Birke – SwRI
Becky Grinfield - SwRI

Topic Number 1 - Batch 8

Mike Birke began the conversation explaining his interpretation of how the limits for batch 8 should be adjusted. There were several varying opinions on the topic, and there is no doubt that confusion exists as to how and when limits should be adjusted. The current procedure, below, outlines the protocol for updating limits, however, ambiguity still exists.

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 ≤ 0.5 standard deviations different (±) then the current target for all parameters, we will use the same reference acceptance criteria as the previous batch. 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.

Mike Kasmirsky of TMC asserts that batch to batch variations can't be resolved given the fact that lab bias plays a larger role in the results. Based on his analysis of the data, he drew the following conclusions and made suggestions on how to move forward (the entire presentation is also attached to the minutes, below are just a few slides).

Analysis Conclusions

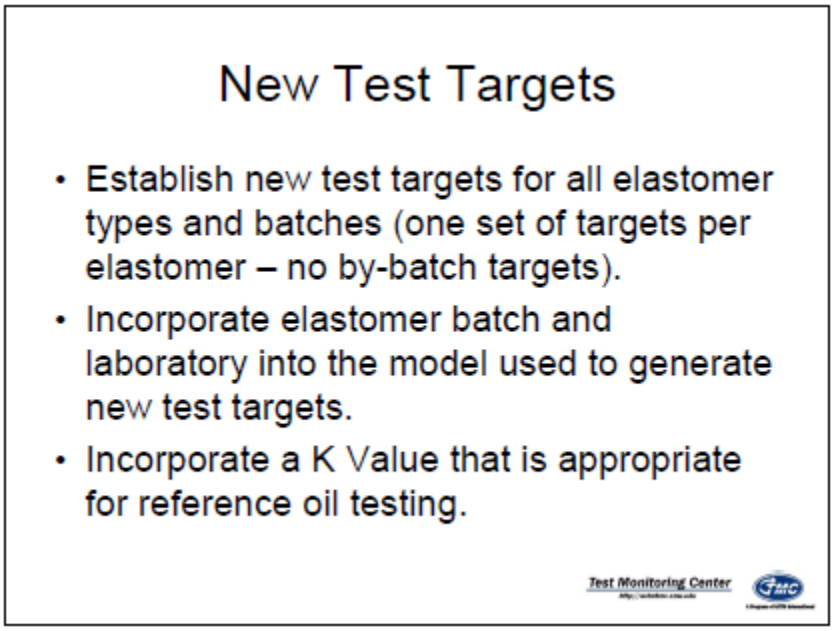
- It is impossible to separate lab effects from batch effects, due to not all batches being run in all labs
- Lab appears to be a bigger driving factor in test severity than elastomer batch.
- It appears that any differences found in elastomer batch can be readily explained by differences in lab performance.

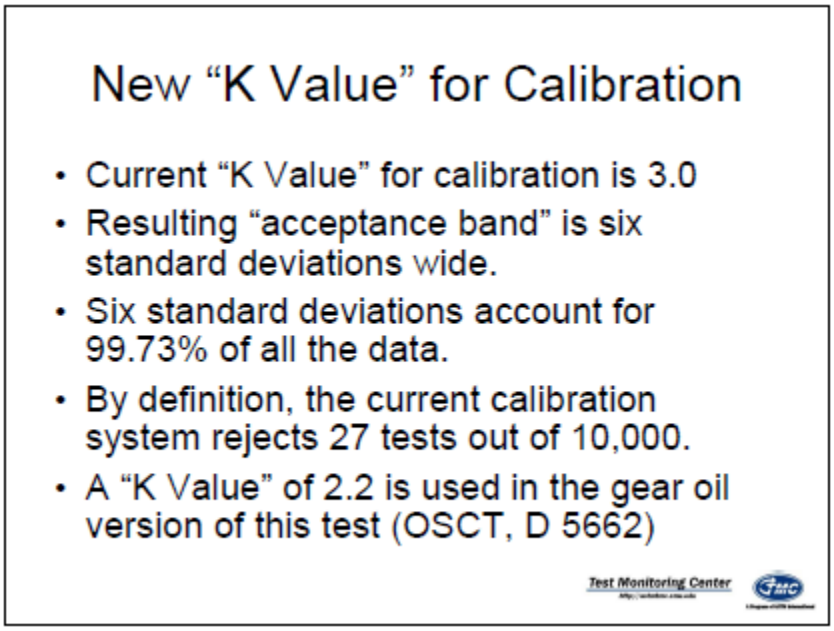
Test Monitoring Center

Solutions going Forward

- Setting test targets by elastomer batch is most likely not appropriate.
- Differences in laboratory performance need to be addressed by the Surveillance Panel.
- Any elastomer batch approval process must include all laboratories in the industry.

Test Monitoring Center





Since there is abundant confusion of how and when to establish limits, as a short term measure, to temporarily clarify the situation, Joe Franklin of Intertek put forth a motion proposing to correct the limits back to those used up to and including batch 7 (see below) and that all reference tests run for approvals (non-donated tests) on batch 8 and batch 9 should be evaluated against these corrected limits until we can agree on the final version of the new batch evaluation process.

LDEOC Reference Oil 1006-1 Test Targets ***(Effective on or after 10/19/2010)***			
Elastomer	Parameter	Mean	Standard Deviation
Hydrogenated Nitrile (N=)	Volume Change, %	1.11	0.60
	Hardness Change, pts.	-1.15	0.87
	Tensile Strength Change, %	-2.08	4.87
Polyacrylate Through Batch 4 (N=)	Volume Change, %	4.21	0.32
	Hardness Change, pts.	-5.33	1.03
	Tensile Strength Change, %	-4.82	6.85
Polyacrylate Batch 5 and higher (N=)	Volume Change, %	2.88	0.66
	Hardness Change, pts.	-1.82	1.54
	Tensile Strength Change, %	4.19	8.44
Fluoroelastomer (N=)	Volume Change, %	0.69	0.15
	Hardness Change, pts.	3.47	1.01
	Tensile Strength Change, %	-52.28	4.34
Silicone (N=)	Volume Change, %	32.99	2.67
	Hardness Change, pts.	-21.56	2.04
	Tensile Strength Change, %	-38.06	3.79
Ethylene Acrylate (N=)	Volume Change, %	24.85	0.77
	Hardness Change, pts.	-12.43	0.91
	Tensile Strength Change, %	-15.30	3.87

A vote of eight affirmatives, one negative, and zero abstains carries the motion. The limits will be put back in place as of today.

Moving forward, there are two schools of thought as to how limits should be updated. One presented by Mike Kasimirsky (above), and the other, a clarified version of the current procedure. To that effect, Mike Birke has proposed the following for the group's consideration:

1) 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.

2) 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.

3) Once a minimum of 3 labs have reported these initial results, the mean of *each parameter (volume, hardness, tensile, elongation)* shall be compared to the current mean for the material. This comparison will be done automatically by the TMC when the data is received. TMC will notify the chair as soon as sufficient initial data points have been received and provide statistics

4) If the mean *of any parameter* of the new batch data is ≤ 0.5standard deviations (using the current Standard Deviation for the parameter/material as published by the TMC) different (±) then the current target, we will use the same reference acceptance criteria as the previous batch for that specific parameter. The results of this comparison will be reported by email to the SP as each material evaluation is completed.

5) Only those parameters >0.5 standard deviations will require further testing. I such cases, a minimum of 10 data points total will be generated by the participating labs to establish new acceptance criteria for those specific parameters on the new batch.
TMC will notify the chair as soon as sufficient initial data points have been received and provide statistics.

It was suggested that the group meet in person to discuss the two options in further detail. Southwest Research has agreed to host a meeting, and proposed meeting dates will be sent out to the members.

LDEOC - Batch 9

Elastomers have been sent out to participating labs, and TMC is awaiting results. TMC will then provide statistical analysis (what procedure is to be used remains unclear). Until then, current limits (as defined in the table above) will be used for all batches sold by OHT for LDEOC testing.

EOEC – Batch 13 VMQ-1

OHT is no longer able to make VMQ-1 using the same recipe as the past due to the fact that a component is no longer available.

Per Jason Bowden:

Dow Corning has stated the silicone used in this product has been discontinued (Procedure: Dow Corning Product ID.24122V-BLK has been found satisfactory for this purpose.) . Also, it appears that they do not have a "drop-in" replacement. They did provide a recommendation for something that may be close (21068-V RED).

Preliminary analysis of elastomer properties, specifically tensile and elongation of the fresh material suggests the material is not the same as historical batches. Southwest Research Institute ran the D7216 EOEC procedure with the new material, and their findings echo those of OHT. The tensile and elongation results are outside current limits:

	Batch 13 Silicone (VMQ-1)				Current Limits			
					Lower	**Mean**	**Upper**	**Sd**
Volume	22.22	22.00	22.02	22.17	19.57	26.38	33.19	2.27
Hardness	-21	-22	-22	-22	-25.75	-18.55	-11.35	2.4
Tensile	0.4	2.5	-1.6	-11.7	-26.41	-13.6	-0.79	4.27
Elongation	2.0	2.0	-4.6	-11.4	-44.1	-23.25	-2.4	6.95

* Out of spec

It was suggested that the surveillance panel contact EMA for their input regarding the VMQ-1 elastomer, and its applicability in the "real world". Allison Athey of Volvo will consult with Greg Shank regarding this issue. Mike Birke will also contact EMA for input.

The teleconference was adjourned at approximately 10:00 am.

~~Two methods proposed for future limits adjustments.~~