Seq. VI New Supplier Entry Procedure Task Force 7/3/2019

Scope:

The ASTM Sequence VI Surveillance Panel requested a Task Force be formed to develop a procedure containing the requirements a new supplier shall fulfill before becoming a viable supplier.

Objectives:

The Task Force will:

- Review previous analysis of data regarding fuel batches changes.
 - When and why changing fuel batches were allowed?
 - Was there a stats analysis completed to see the impact of changing fuel batches?
 - If yes, was the significance of the change comparable to what was observed between batches from Texas and Michigan?
 - Will the variability of the previously mentioned be used for the new supplier?

Fuel batches changes were not allowed until approximately 5 years ago. The fuel economy test sponsor preferred not to change batches. Approximately 5 years ago data was generated to and presented for the approval of changing batches at any time needed. Batch change effect has been analyzed multiple times finding no significant variations in result (see presentations attached to the minutes). For the most part, Haltermann fuel blended in Michigan is distributed to the labs closer to it, fuel blended in Texas is distributed to labs in Texas. Will changing fuel from supplier A to B within a test be acceptable? The answer to this question may depend on what data shows for the new fuel, but, for other test types such as the Seq. V, mixing a new batch once the current batch has been depleted down to 10% is allowed. The Seq. VI used Baseline Before and Baseline After to calculate FE and this could help absorb the effect of changing fuels within a test.

• Review current procedure to introduce new batches of Baseline and reference oils, hardware.

SwRI presented a proposal for the introduction of new fuel/supplier:

The following test plan eliminates concerns about engine, stand, and lab severity differences by obtaining direct A/B paired comparisons.

New engine
Break in and 542 ref on alternate fuel
Switch to Haltermann Solutions fuel, run 542 reference oil again (2nd run).
Engine can be used for two candidates

- New engine Break in and 1010 ref on Haltermann Solutions fuel Switch to alternate fuel, run 1010 reference oil again (2nd run) Engine can be used for two candidates

New Engine
Break in and 544 ref on alternate fuel,
Switch to Haltermann Solutions fuel, run 544 reference oil again (2nd run)
Engine can be used for two candidates

The above gives 3 direct comparison points. Statistical power can be calculated for n = 3, 4, 5, etc. and determine the appropriate number of tests needed to detect differences of size 0.5 sigma, 1.0 sigma, etc.

<u>Action Item</u>: All members to review the above proposal and review the procedures to introduce new hardware and new batches of BL, compare those to the proposal above and be prepared to discuss next time.

Meeting adjourned. 5/2/2019

- Develop a procedure containing the requirements a new supplier shall fulfill before becoming a viable supplier.
 - Could different fuels age the engines differently?
 - o What is the difference between different suppliers vs. different batches?

Prasad: I would like to add the following:

- 1. Changing fuel batches involve no change in raw material blend component source, generally speaking.
- 2. Each supplier has different raw material source.
- 3. C of A does not adequately describe the fuel fully well particularly in reference to Deposit (IVD) behavior.
- 4. Not all additives work equally on various components of the fuel.
- 5. Deposits do cause fuel economy degradation that need to be tested
- 6. Fuels with same C of A can produce very different deposit quantities.

My point here is that extensive testing is required before we establish equivalency particularly regarding performance degradation measurements from lab to lab and run to run.

- How often large batches for other test types adjusted to stay in compliance?
- o Statistically, what is the most efficient way to evaluate equivalency for new suppliers?
- Based on previous input, should it be different than introducing a new batch?
- Outline cost responsibilities for introducing a new supplier.

Please refer to the attached power point presentation from SwRI presented by Travis. The comments to follow refer to the presentation.

Most of the group favored option 2 is a good starting point of discussion for next call. Option 2 or a modified version of it, could test for equivalency but will not provide data for engine aging effect. There were comments about running option 2 as ABA or running BA instead so that if the stand calibrates it would be with the currently approved fuel. The discussion will continue next call. An option was presented to determine engine aging effect by analyzing the baseline fuel consumption, this will further discuss next call as well.

Meeting adjourned. 5/10/2019

Article presented by Prasad:

Why use an equivalence test?

Learn more about Minitab 18 [minitab.com]

You can use an equivalence test to determine whether the means for product measurements or process measurements are close enough to be considered equivalent. Equivalence tests differ from standard t-tests in two important ways.

The burden of proof is placed on proving equivalence

In a standard t-test of the means, the null hypothesis assumes that the population mean is the same as a target value or another population mean. Thus, the burden of proof falls on proving that the mean differs from a target or another population mean. In equivalence testing, the null hypothesis is that the population mean differs from a target value or other population mean. Thus, the burden of proof is placed on proving that the mean is the same as a target or another population mean.

For example, consider the difference between a 2-sample t-test and a 2-sample equivalence test. You use a 2-sample t-test to test whether the means of two populations are *different*. The hypotheses for the test are as follows:

- Null hypothesis (H₀): The means of the two populations are the same.
- Alternative hypothesis (H₁): The means of the two populations are different.
 If the p-value for the test is less than alpha (α), then you reject the null hypothesis and conclude that the means are different.

In contrast, you use a 2-sample equivalence test to test whether the means of two populations are *equivalent*. Equivalence for the test is defined by a range of values that you specify (also called the equivalence interval). The hypotheses for the test are as follows:

- Null hypothesis (H₀): The difference between the means is outside your equivalence interval. The means are not equivalent.
- Alternative hypothesis (H₁): The difference between the means is inside your equivalence interval. The means are equivalent.
 If the p-value for the test is less than α, then you reject the null hypothesis and conclude that the means are equivalent.

The user defines a range of acceptable values for the difference

Small differences between products are not always functionally or practically important. For example, a difference of 1 mg in a 200 mg dose of a drug is unlikely to have any practical effect. When you use an equivalence test, you must enter equivalence limits that indicate how large the difference must be to be considered important. Smaller differences, which are within your equivalence limits, are considered unimportant. In this way, an equivalence test evaluates both the practical significance and statistical significance of a difference from the population mean.

To choose between an equivalence test and a standard t-test, consider what you hope to prove or demonstrate. If you want to prove that two means are equal, or that a mean equals a target value, and if you can define exactly what size difference is important in your field, you may want to use an equivalence test instead of a standard t-test.

Dr. Prasad Tumati

Group agreed to accept the risk of assuming there will be no engine hour correction change/effect by introducing new fuel.

The group agreed to accept option 2, run order BA (A is the known Haltermann fuel, B the new supplier fuel).

Next call the group will concentrate in discussing the limits, how many tests are needed to have confidence there is enough data. Also, there must be a review on whether the data analysis should focus on FEI 1 and 2 or only 2.

Meeting adjourned. 5/16/2019

Refer to SwRI presentation "VIFPairsAnalysis" for the notes below:

After reviewing the 5 potential paths forward to test for equivalency presented by Travis, option 5 was the preferred path. There will be further discussions about option 5 during next call.

- What reference oil will be used
- Metric to determine if the method is effective for equivalency testing.

Meeting adjourned. 5/23/2019

From SwRI "AlternateFuelSupplierTesting" Presentation (in blue font):

The questions below should be answered in order to properly develop option #5: 1.Will a single supplier ultimately be chosen, or will the fuel be interchangeable? What is the objective?

Discussion around this question landed on; given the importance of having a true understanding of the interchangeability of the fuel and being cautious not to have a barrier to entry that will discourage new suppliers, the two following options were presented:

1. define the barrier to entry from the beginning and once a supplier successfully completes the process if the data shows acceptability, then, the fuel will be considered interchangeable. This option will most likely require a much larger number of tests and therefore larger cost/higher barrier to entry.

2. define a lower barrier to entry, then continue to collect data until there is enough to determine whether the fuels are interchangeable.

For either option, labs will be required to introduce a new supplier's fuel with references. All engine/stands at a specific lab regardless of engine hours or calibration status at the time of transition most calibrate on the new fuel and will not be allowed to mix fuels.

Most of the group preferred option 2 (results of the survey listed on the attendance sheet). There will be more discussion on option 2 next call and proceed to questions 2 and 3 below if time allows.

2.Based on the answer to question #1, what is the maximum acceptable difference between the fuels?

-If the goal is to use these fuels interchangeably, this should require more testing and a smaller tolerance limit for the difference between fuels. On the other hand, if only a single fuel is allowable, one might feel comfortable with a larger potential difference which could be handled by severity adjustments.

3. How many reference oils? How many labs or stands?

-Limiting the testing to a single reference oil on the most current technology (1010-1) should provide insight into any differences between fuels in the fewest number of tests, but requires assuming the conclusion applies equally to all other oils.

-Does the group feel the testing should require at least 2 labs? At least 2 stands?

Meeting adjourned. 6/6/2019

Further discussion of option 2.

Steps previously discussed to introduce the new supplier:

Step 1. Run a set number of tests before the fuel is considered acceptable. Determine the difference between the fuels.

Step 2. If the fuel is acceptable, then calibrate stands and run candidates. Enough reference data must be generated to determine step 3.

Step 3. Determine interchangeability.

What happens if fuels are determined not interchangeable?

As long as the candidates are tested on a engine/stand that successfully calibrated then the tests are valid and acceptable.

2.Based on the answer to question #1, what is the maximum acceptable difference between the fuels?

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Questions 2 above: Next call Travis will present an analysis on existing/historical data to help the decision-making process for question 2.

Question 3 above:

Select 1 RO, preferably 1010-1 since it is the most current technology of the 3 RO. A concern about running only one reference oil was presented and after discussing the subject the following plan was proposed:

- Check the lower performing oil and better performing oil:
 - Sense check; run 544 on a new engine and review results, if the result is "expected/acceptable", then continue to run 1010-1 on the same engine as well as a new engine to complete the designed matrix (matrix design TBD).
- If the result of the matrix is acceptable, then the supplier is approved to use, calibrate engines, run candidates and continue to generate reference data to later determine if the fuels are interchangeable.

Amol presented a concern regarding the current fuel contract. No alternate fuel/supplier can be introduced for regular testing until the HF2003 batch number GI2021NX10 is depleted. The expectation is the fuel will last approximately one year. This topic will be further discussed in the seq. VI Surveillance

Panel once a recommendation from this task force is provided for what the process should be to introduce a new fuel supplier.

Meeting adjourned. 6/14/2019

Travis:

I had an action item last meeting to write out the steps we have discussed for approving a potential alternative fuel supplier so we can try to all be on the same page. Below are the steps as I understand them.

<u>Please note, the purpose of this is so that we all agree on the 3 steps, not the details within the steps</u> <u>yet</u>. Those are for us to continue developing. Many of the details within the steps have been made up by me for illustration purposes only, and have not been discussed or agreed upon, so please try not to get hung up on the numbers I have used.

We have currently been developing the test design for Step 1, and have not yet gotten into the statistical stopping criteria for this step.

Finally, at the last call there was brief discussion about adding 544 testing to the mix. However, it might be good to discuss this more and get everybody's opinions and thoughts on whether to include it. 544 is the bad performing oil, not the good performing oil, as I think might have been suggested on the call. 1010-1 was originally suggested because it is the most current technology and is thought to be most likely to perform similar to candidates. Adding 544 into the testing requirements adds additional variability and additional complexity to the test design. If we just run a sense check run or two on 544, we are back into the discussion of "what happens to those engines?" If we require a full engine of 4 tests on 544, we have run number considerations to think about again. Therefore, maybe we can have some more discussion on this and get input from more of the group members after they have had some time to think about this, and we can poll the group on whether or not to include this reference oil.

Step 1 – Qualification Procedure (No Candidate Testing)

This step outlines the requirements that must be met in order for a potential fuel supplier to be qualified for consideration to be purchased by a test lab.

Test Design

Test using reference oil 1010-1 on a minimum of two engines, using the first four runs of an engine's life, alternating between fuels as follows:

Current Fuel = "Fuel A"

Potential Alternative Supplier Fuel = "Fuel B"

Run Order #1, Engine #1 – Break in with Fuel A, then test Fuel A – Fuel B – Fuel A – Fuel B

Run Order #2, Engine #2 – Break in with Fuel B, then test Fuel B – Fuel A – Fuel B – Fuel A

If the stopping criteria has not been met after Engine #2, continue testing on additional engines, alternating between run order #1, and run order #2, until the stopping criteria has been met.

There are concerns regarding new fuel affecting the performance of different R.O. with new fuel and selecting a single R.O. for the matrix. The chemistry of the fuel can be different even if the fuel meets the CoA requirements. How different if a new fuel from a new batch of fuel? That is an unknown and a risk to be considered, however, the fuel will be tested in a matrix using an existing R.O. with historical performance available.

Action Item: Todd will review historical CoA for changes throughout the years as we change batches.

Adding one run with a R.O. different than the R.O. to be used for most of the matrix will take the most meaningful run from that engine and will reduce the total number of data points on the primary R.O. The purpose of the matrix is to determine if the fuel is acceptable to use, if yes, then more data will be required to determine interchangeability. After determining the fuel is acceptable; engines will be required to calibrate prior to run candidates and the R.O. assignments will be random. At that point the performance of other R.O. different than the one used in the matrix will be available for review.

Motion: Ben Maddock, Second: Andrew Stevens

The Task Force agrees to proceed to design the matrix using a single reference oil, 1010-1.

Approved: 6 (4 labs, 2 non-labs), Waive: 6 (1 lab, 5 non-labs), Do not Approve: 0

The TF agrees to use a design of minimum of 1 stand, two engines on the same stand. The result of the 1st test will be reviewed to determine whether it would have been a passing result, yet, this will not be a stopping point for the matrix. If the result is "alarmingly off" then the result will be analyzed in detail.

Next call we will review Todd's CoA findings and discuss the stopping point as stated below.

Meeting adjourned. 7/03/2019

Statistical Stopping Criteria – Example only, as this has not been discussed

At the completion of each engine after Engine #2, an ANOVA model will be constructed using the engine hour corrected results. Factors to include are "Engine", with levels Engine1, Engine2, ..., Engine N, and "Fuel", with levels Fuel A and Fuel B. To be qualified, the following must be true of the ANOVA model results:

- The absolute difference in the least squares mean for Fuel A and the least squares mean for Fuel B is less than 1 standard deviation, using the 1010-1 standard deviation (0.199 for FEI1 and 0.327 for FEI2).
 - \circ $\;$ This criteria requires the qualifying fuel be close to the current fuel.
- The least squares mean estimate for Fuel B are within 1.5 standard deviations from the 1010-1 target, and the upper and lower limit of a 95% confidence interval on the least squares mean for Fuel B are not outside of the +/- 2 standard deviation range of the 1010-1 target, using the 1010-1 standard deviation.
 - This criteria requires the qualifying fuel be close to the target mean, regardless of where the current fuel lies.

Step 2 – Limited Fuel Interchangeability for Candidate Testing

Any fuel supplier who has met the above testing requirements will become a "qualified" supplier in addition to the current fuel supplier. Providing that there are no contractual obligations with the current supplier, each individual lab has the freedom to purchase fuel from either the current fuel supplier or any other qualified supplier. Limited interchangeability allows labs to change between qualified fuel suppliers if desired, but requires that all candidate testing be conducted on the same fuel as the reference test(s) which generated the severity adjustment for that engine-stand combination. Tanks should be depleted less than 10% before adding a new fuel.

Step 3 – Complete Fuel Interchangeability for Candidate Testing

If one or more labs choose to purchase fuel from one of the newly qualified suppliers, it is possible that in the future, enough reference data may be obtained such that new statistical analysis may confidently state that the difference between fuels is so small that the Sequence VI Surveillance Panel considers the fuels equivalent enough to be interchanged completely, even within a reference period for an enginestand. Tank depletion requirements for mixing these two fuels could be removed as well.

• Submit TF recommendation to the Seq. VI Surveillance Panel.

Name	email	Organization	Attendance
Adrian Alfonso	adrian.alfonso@intertek.com	IAR	Voting x A
Bill Buscher	william.buscher@intertek.com	IAR	
Rich Grundza	reg@astmtmc.cmu.edu	ТМС	Voting x A
Hap Thompson	hapjthom@aol.com	TMC/Consultant	

Seq. VI New Supplier Entry Procedure ATTENDANCE 20190703

Travis G. Kostan	travis.kostan@swri.org	SwRI	x
Dan Worcester	dan.worcester@swri.org	SwRI	Voting x A
Michael Lochte	michael.lochte@swri.org	SwRI	х
Pat Lang	plang@swri.org	SwRI	х
Daniel Engstrom	daniel.engstrom@swri.org	SwRI	х
Charlie Leverett	charlie.leverett@yahoo.com	Infineum	Voting
Tracey King	TKing@h-c-s-group.com	Haltermann	Voting x W
Prasad Tumati	ptumati@jhaltermann.com	Haltermann	Voting x W
Dr. Jens Schaak	JSchaak@h-c-s-group.com	Haltermann	
Matthew Bowden	mjbowden@ohtech.com	OHT	х
Jason Bowden	jhbowden@ohtech.com	OHT	Voting x A
Andrew Stevens	Andrew.Stevens@Lubrizol.com	Lubrizol	ХА
Phil Scinto	Phil.Scinto@Lubrizol.com	Lubrizol	
Robert Stockwell	Robert.Stockwell@chevron.com	Chevron	Voting x A
Jo Martinez	JoMartinez@chevron.com	Chevron	х
Jonathan VanScoyoc	VANSCJ@cpchem.com	Chevron Phillips	Voting x W
Jeff Hsu	J.hsu@shell.com	Shell	Voting
Ben Maddock	Ben.Maddock@AftonChemical.com	Afton	Voting x A
Bob Campbell	Bob.Campbell@AftonChemical.com	Afton	
Todd Dvorak	Todd.Dvorak@AftonChemical.com	Afton	х
Amol Savant	ACSavant@valvoline.com	Valvoline	Voting x W
Jim Carter	jcarter@gageproducts.com	Gage	х
Bob Patzelt	bpatzelt@gageproducts.com	Gage	Voting x W
Aleise Gauer	aleise.gauer@gm.com	GM	Voting

Timothy Cushing	timothy.cushing@gm.com	GM	
Scott Stap	<pre>scott.stap@tgidirect.com</pre>	TGI Direct	