Seq. VI New Supplier Entry Procedure Task Force 5/23/2019

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.

Action Item: 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?
    - 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?
- 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.

Why use an equivalence test?

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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 (H_0): The means of the two populations are the same.

- Alternative hypothesis (H_1): 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 (H_0): The difference between the means is outside your equivalence interval. The means are not equivalent.

- Alternative hypothesis (H_1): 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

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

Seq. VI New Supplier Entry Procedure ATTENDANCE 20190516

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Sequence VIF Pairs

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Data Set

- Data is included for all engines with 2 operationally valid reference test since 2018. This includes validity codes "AC" and "OC".

- Data compares 2nd run Yi to first run Yi (58 pairs). In cases where a 3rd run was conduced, 3rd run Yi is compared to 2nd run Yi (10 pairs).

Yi's by Run Number

The table below shows that even with no fuel change, the average difference between successive runs is about ¾ of a standard deviation.

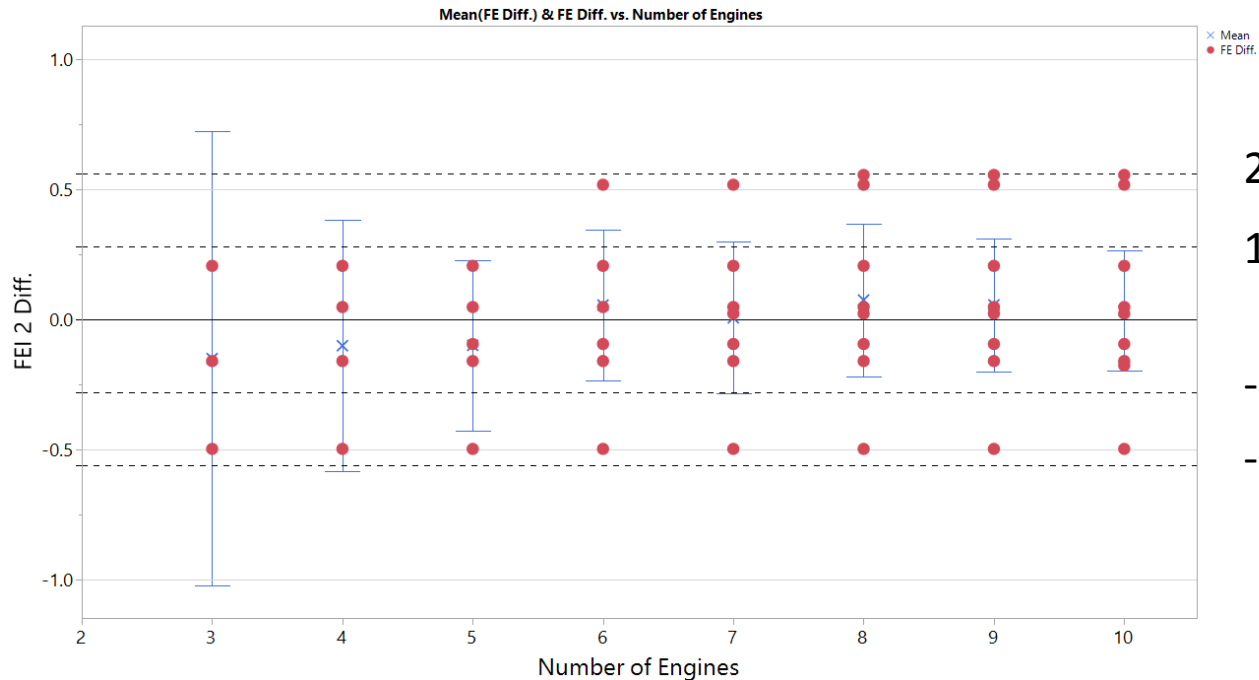Mean(FEI1yi) & FEI1yi & Mean(FEI2yi) & FEI2yi vs. ENRUN
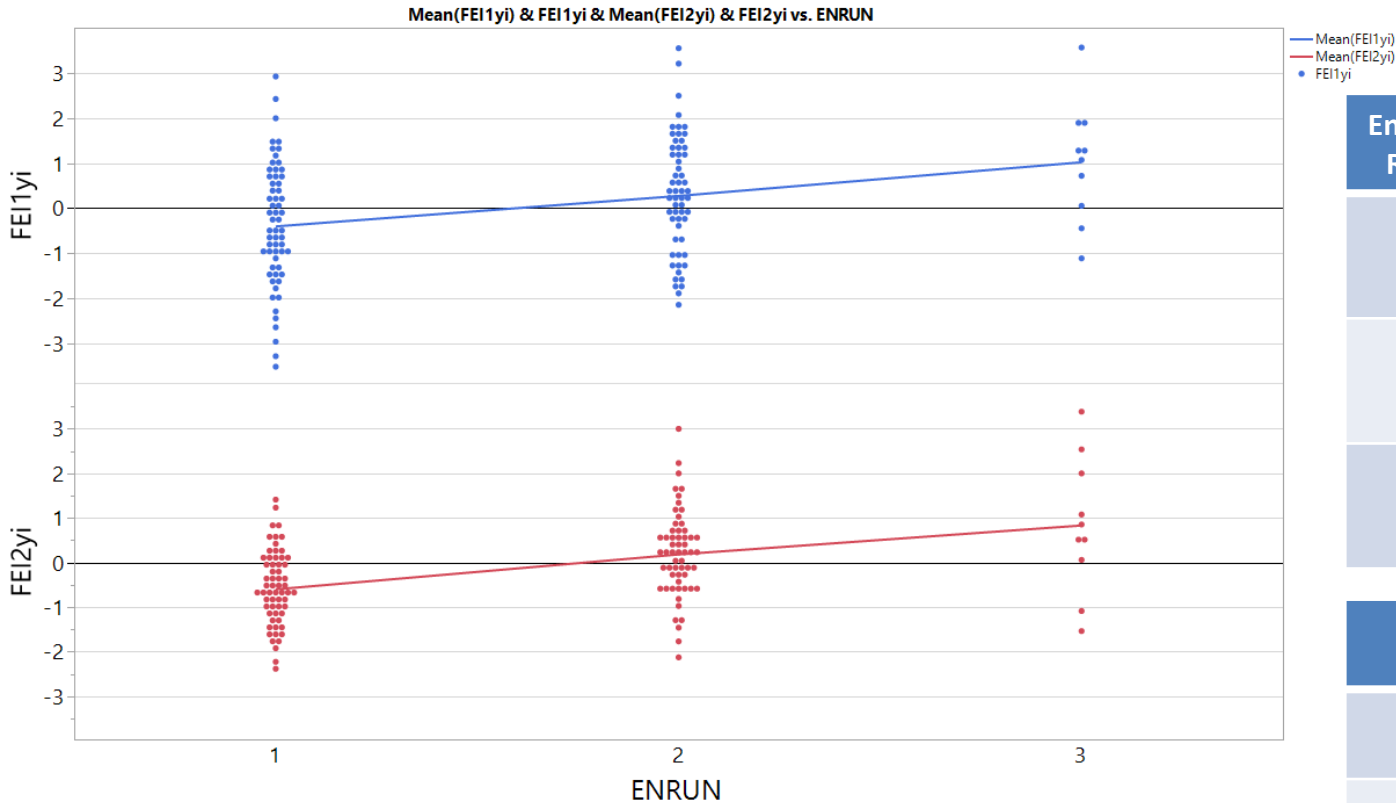
Engine Run	N size	Avg. FEI 1 Yi	Avg. FEI2 Yi
1	58	-0.40	-0.60
2	58	0.28	0.18
3	10	1.02	0.83

Parameter	Avg. Yi Diff.
FEI 1	0.69
FEI 2	0.69

Example of Stopping Conditions

- Minimum 3 tests (1 per oil)
- Mean difference C.I. overlaps zero.
- No part of 95% C.I. is outside +/- 2 sigma

2 sigma = 0.562

1 sigma = 0.281

-1 sigma = -0.281

-2 sigma = -0.562

VIF Probability of Pass

Below tables show the probability of passing after "X" pairs using randomly simulated VIF pairs under some hypothetical criteria.

95% C.I. within sigma limit

Conf. Int. Limit	3 Pairs	4 Pairs	5 Pairs	6 Pairs	7 Pairs	8 Pairs	9 Pairs	10 Pairs
+/- 2 sigma	28%	50%	66%	78%	85%	90%	92%	94%
+/- 1.5 sigma	16%	30%	43%	56%	63%	69%	73%	78%
+/- 1 sigma	5%	11%	19%	29%	33%	40%	43%	46%

95% C.I. within sigma limit AND C.I. overlaps zero

Conf. Int. Limit	3 Pairs	4 Pairs	5 Pairs	6 Pairs	7 Pairs	8 Pairs	9 Pairs	10 Pairs
+/- 2 sigma	23%	41%	47%	49%	41%	35%	31%	25%
+/- 1.5 sigma	12%	25%	33%	40%	39%	35%	31%	25%
+/- 1 sigma	4%	9%	15%	24%	27%	30%	29%	25%

Some Potential Paths Forward

B = Potential Alternate Supplier
A = Haltermann Fuel

1. Ignore the potential run number impact and proceed with choosing a limit for B-A testing on engine runs 1 & 2

2. Balance out B-A testing on engine runs 1 & 2 with A-B testing also on runs 1 & 2.

3. Run B-A testing on runs 1 & 2 but compare "B" results to historical "A" results.

4. Run B only testing on run 1, set engine aside, awaiting potential approval. This would require break in also be done on B fuel. Engine is scrapped if B fuel does not get approved, and becomes usable otherwise.

5. Run testing for the full engine life on a minimum of 2 engines. Unless the number of engines becomes large (likely > 4), we will likely still not be able to detect anything but very large engine hour effect differences. Thus we would still mainly be focusing on overall average differences seen between the fuels. Example:

   - Engine #1 A-B-A-B

   - Engine #2 B-A-B-A

   - …