Case Study 1

Outlier for unexpected failure to ignite sample on needle flame test in 18e29.

History: The lab is a CBTL.

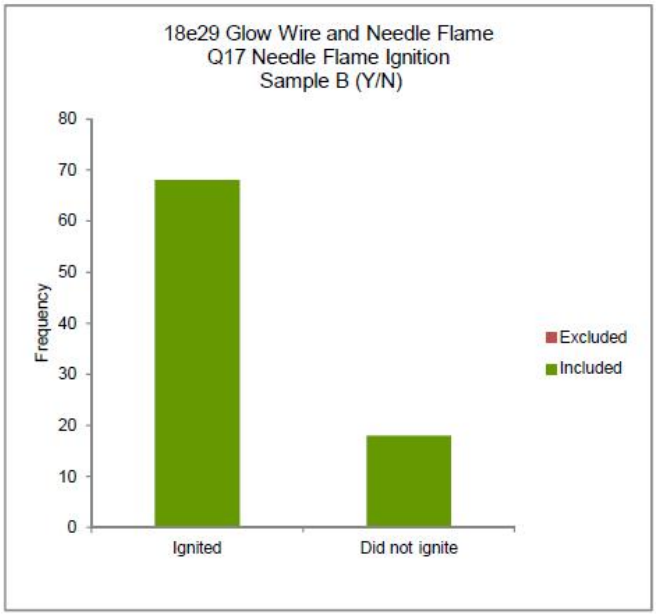
Laboratory has participated in 10 programs in last 3 years.

They received outliers in Creepage and Clearance, Touch current and Needle Flame test.

Results all OK for the remaining 7 PTP rounds.

Previous PTP on "e29 series":

- 15e29 – equipment non-conformity for glow wire test apparatus. No issues on test results.
- 18e29 – outlier for needle flame test, sample B.



PTP instructions were available at the time of enrolment.

http://www.ifmgs.com.au/proficiency/instructions/18e29 Instructions.pdf

Prior to testing work, the lab asked some questions:

"I have several questions about the 18e29, please help clarify.

1. In the instructions it says: "The needle flame shall be applied to the planar surface of the specimen as shown in Figure 1c of the standard. The apparatus shall be perpendicular to the centre of the planar surface of the specimen. DO NOT TEST THE EDGES OF THE SPECIMENS." Please help confirm whether needle flame pic. 1 as attached is the correct position of the test sample.

(pic 1 was sample tested in the middle, pic 2 was sample tested at the edges.)

(IFM Reply: 1. Picture 1.)

2. In the instructions question E09: " Is there a formal needle flame test verification procedure within your laboratory? In the results field, enter “yes” or “no”. (The verification procedure must be separate to formal calibration and confirms the proper function of the needle flame tester.) If yes, outline in the comments field, what this formal procedure entails. "

what does it mean by "what this formal procedure entails"? is it request us to descript our formal verification procedure in details?

(IFM Reply: 2. an outline of your verification procedure is sufficient. (one short sentence summary))

3. In IEC 60695-11-5 it requests to test 3 specimens, in this PT test, do we need to test 3 specimens or only 1 specimen is enough?

(IFM Reply 3. you need to perform sufficient tests to be confident of your answer. Do you ask your customers this question?)

4. In our daily work, we don't do GWIT test of IEC 60695-2-13 then we don't need to do this in this PT test, correct?”

(IFM’s reply 4. correct.)

Originally submitted root cause

In the relevant standards, it says:
IEC 60695-11-5:2004
If not otherwise specified in the relevant specification, the test specimen, the wooden board and the tissue paper shall be conditioned for not less than 24 h in an atmosphere having a temperature between 15 °C and 35 °C and a relative humidity between 45 % and 75 % before starting the test.
In the relevant product standards (such as IEC 60950-1,IEC 60065 and IEC 62368-1), there is no special requirements for temperature and humidity of pre-conditioning, indoor environment of normal temperature and humidity can comply with requirements, so we generally pretreated the sample in normal indoor environment.

However, In the specification of 18e29, it says:
Condition all samples for a minimum of 48 h at 23 °C ± 2 °C and relative humidity between 40 % RH and 60% RH.
We can see that the conditions in the specification are more severe than those in the relevant standards.
During test period, we found the relative humidity of indoor environment is lower than 40% RH, so we placed a basin of water under the sample to keep the humidity within this range, however the sample is hygroscopic resulted in the abnormal results.

Proposed corrective actions

We retested18e29 and also proved that the material can be ignited.

We checked all the completed projects in the past and found no materials were tested in random method. Instead, the materials were required to be certified.

A training course for all testers and project handlers was held in our lab.

IFM staff reply

Thank you for your email regarding the 18e29 corrective actions.
A deeper root cause analysis is required to close the action, this includes corrective and preventive actions. Providing training to your current staff will not prevent new/future staff from coming across a similar scenario.
This document may help you to establish a root cause: http://www.ifmqs.com.au/proficiency/references/QRD003-02_From_Direct_to_Root_Cause.pdf

Revised root cause

I have updated the root cause and corrective actions, please confirm the below contents is ok or not. If the contents is OK, i will send a formal correction report to you.
Thanks a lot.

Non-conformity description:
In the Proficiency testing 18e29 Glow Wire and Needle Flame organized by IFM, our lab got an off-limit result as listed below:
Part01: 1 result assessed as outlying (Q17 Needle Flame Ignition).
Part02: 1 result assessed as outlying (Q17 Needle Flame Ignition).
See attached result report for more details. (Participant Id: 168324 /168325, Ref: 5/T5-4/01/2019)
For Q17: The satisfactory result is that the plastic can be ignited by NF tester, but our lab attained result is that the plastic did not ignite.

Root cause:
In the IEC 60695-11-5:2004,it says: "If not otherwise specified in the relevant specification, the test specimen, the wooden board and the tissue paper shall be conditioned for not less than 24 h in an atmosphere having a temperature between 15 °C and 35 °C and a relative humidity between 45 % and 75 % before starting the test".
In the relevant product standards (such as IEC 60950-1, IEC 60065 and IEC 62368-1), there are no special requirements for temperature and humidity of pre-conditioning.
We followed the requirements of IEC 60695-11-5 in past.
Although our laboratory has a constant temperature and humidity chamber, but its temperature and humidity cannot be maintained at 21-25 degrees, 40-60% RH due to the limitation of its function, so we usually only use it for 30 or 40 degree C, 93%RH humidity testing.
We usually place the sample in normal indoor environment and using air conditioner, if applicable. The indoor environment usually meets the requirements of IEC 60695-11-5.
However, in the specification of 18e29, it says: "Condition all samples for a minimum of 48 h at 23 °C ± 2 °C and relative humidity between 40 % RH and 60% RH."

We can see that the conditions in the specification are more severe than those in the relevant standards.
We can only place the samples in the indoor environment and turn on air conditioner, unless we seek a manufacturer to refit the chamber or purchase a new chamber for this PTP project.
Before the pre-conditioning of this PTP's samples, we found the humidity of indoor environment is higher than 60% RH, thus we turned on the air conditioner to dehumidify, then we found the relative humidity of indoor environment was turned lower than 40% RH, and then we placed a basin of water under the sample to keep the humidity within 40%-60%RH, but this pre-conditioning way is improper.

Proposed Corrective action(s):
We retested18e29 and also proved that the material can be ignited.
We checked all the completed projects in the past and found no materials were tested in random method. Instead, the materials were required to be certified.
A training course for all testers and project handlers was held in our lab.
We have asked the manufacturer to refit the chamber, then the humidity can be maintained this range. We will put all samples into this chamber to do pre-conditioning in future.
We will retest the saved sample B one time every year until the next same comparison of ability is approved.

IFM sent the above information to the technical advisers. IFM informed the lab of outcome, as follows:

The technical advisers are in agreement that the lab has not yet found a root cause, nor devised an appropriate action relating to the root cause.

Comment 1:
It took me a few reads but based on the analysis I would suppose we could sum up the problem statement as "did not follow instructions". With that said, I am having a hard time finding a root cause in the explanation the specifically addresses that. Based on the one corrective action ("A training course for all testers and

project handlers was held in our lab.") I guess I could assume they are citing it as a training issue. But since that is not mentioned anywhere in the root cause it's hard to quantify if "more training" is the proper solution. If the problem statement is more along the lines of "we don't have the proper conditioning chamber/room but it is not necessary the testing we perform under our Scope", then it gets more confusing by the solution to "refit the chamber".

A lot of information in that reply. I am just trying to connect it all. Maybe one of the others can see it more clearly than me.

Comment 2
in my opinion this falls into the contract review requirement of ISO/IEC/EN 17025:2005 (cl. 4.4.1). I am pretty sure that IFM has sent out the instructions with the ordering of the PTPs, so, it should not have been a surprise that they do not have the proper environment.
What I see is only a direct cause, but not a root cause. Training is not sufficient in this case, as it seems to be that they do not know what they can do, or not. For this PTP the chamber eventually can be refurbished, but this does not avoid in general the contract review understanding.

So, I would propose not to close the issue.

Questions for workshop:

1. Please compare the items that were raised as concerns prior to commencing test work with the cause analysis that was submitted. In overview is the lab proactive or reactive in its approach to test?

2. The technical advisers have pointed to contract review as being at least part of the reasons the lab had problems. What are the elements of contract review that should be attended to when deciding to take on laboratory work?

3. What is your opinion about adjusting the humidity with a basin of water?
    a. Can this process be controlled?
    b. Which clause(s) of ISO/IEC 17025 is/are applicable to this activity?

4. In general – what advice for improvements could you suggest to the laboratory?