SMR

RCA Form

TRACKING NUMBER: 683989 **Critical NC ☒** **Noncritical NC ☐**

CALIBRATING TECHNICIAN: **Kevin Miller** **Technician Risk Rating: 2**

DATE OF REVIEW 02-Dec-21	**QAT** Darryl Hewitt		**TYPE OF REVIEW** **Targeted QR**
LABEL NUMBER **M145410**	**PART NUMBER** **IQ-610**		**JCN** **20211116PA2020**
NOMENCLATURE **INDOOR AIR QUALITY MONITOR**	**Equip Reliability %** **60**	**Equip Risk Rating** **5**	**K-PROCEDURE** **33K6-4-3421-1**

QNC/PNC Code Selected

A04 : The item does not meet calibration tolerances/uncertainties for all parameters certified.

Nonconformity (State the NC; be clear and concise): Item indicated OOT for Carbon Dioxide (CO2). The Standard Gas is rated at 375 ppm. The TI returned a reading of 347 ppm. The corrected TI indication was 273 ppm; 347 ppm - 74 ppm (Zero Gas) = 273 ppm. AFCAV lists the accuracy for CO2 as: ±(3.0% I.V. +50 ppmv), which equates to ±61.25 ppmv (3% x 375 + 50 = 61.25). TI is required to indicate between 313.75 ppm and 436.25 ppm. Ref: 33K6-4-3421-1 step 4.1.6 and 4.1.11

Background *(optional -if needed to describe the situation leading up to NC):* Originally the item selected by PAMS for calibration was the meter (M601169) needed to perform the calibration IAW the calibration procedure 33K6-4-3421-1. However the meter does not have a calibrated, function, range, or accuracy, of its own, listed. And requires an attached probe to facilitate compliance of all steps of the calibration authority. So, this item was selected for a Targeted Quality Review (TQR).

Calibration of Carbon Dioxide (CO2) has its own section for calibration, Section 4.1 (section 4.2 is for all others gases). In Step 4.1 there are two measurements accomplished (two point calibration). The first is at "Zero Gas", a measurement made with a gas that will measure as close to the zero (0) as possible. In our case Nitrogen, with a 99.99% purity rating, is used. The second measurement should be a value at the point of the rated gas cylinder supplied with Unit Under Test (UUT) by the customer. For this TMDE the customer supplied us with two CO2 gas cylinders, one at 375 ppm, the second at 1250 ppm. So two complete runs of step 4.1 were accomplished. The first with "Zero Gas" and 375 ppm CO2. The second with "Zero Gas" and 1250 ppm. This second run (1250) passed the Quality Review.

QAT observations made while observing the suspect process. This is mandatory for every critical NC identified during a QR. Do not divulge the nonconforming condition. During the PR portion of the process the Technician confirmed the OOT condition; 82 ppm for step 4.1.6, 350 ppm for step 4.1.11 (350-82=268 ppm) confirmed the OOT 45.75 ppm below the allowable lower limit. The Trainer also performed the test with similar results 85 at 4.1.6 and 348 at 4.1.11(348-85=263 ppm) OOT by 50.75 ppm.

NC Code Risk Rating: 5

PROCESS/ROOT CAUSE ANALYSIS

RCA meeting will include the Quality Assurance Technician, Lead Technician and Technician who performed the work. Other parties may participate in the RCA if appropriate.

List the root causes possible for this nonconformity:

1. C02 : Calibration technical data in error (qualified technician would not detect).
2. F01 : Component failure caused degradation or hard failure (normal process would not find).
3. H01 : Human error: When all equipment, technical data, training and other factors are adequate. When another
4. T02 : OJT insufficient (trainer does not demonstrate task proficiency).

Identify the most likely root cause from the possible causes and explain why you selected it.

Root Cause Code selected: T02 : OJT insufficient (trainer does not demonstrate task proficiency).

Reason for selection: After the Quality Review a Process Review was accomplished on the Process Owner and the Trainer (also certified in the calibration of Gas Detector's). All three (QAE, Process Owner and Trainer) confirmed the OOT for the CO2 (section 4.1) based on the calibration procedure as presently written. None of us, including the TCM at AFMETCAL, knew of the different calibration/certification required by the manufacturer. It wasn't until the manufacturer directed us to a YouTube video on how to properly perform the user calibration/bump test. We also discovered from the manufacturer that after one year of use and adjustment by the user and/or PMEL from the factory calibration the values shown, no matter how many adjustments are made, will not be reliable. A factory calibration and reset is required to adjust those factory values, so that the calculations in the software will be performed with accuracy and reliability. In conversation between us, the manufacturer and the TCM, it was determined by the TCM that the procedure does not need to be corrected. The TCM is considering to make the item a NOTE 64. For this reason T02 was selected over the C02 possible root cause.

RC Code Risk Rating: 5

Explain why you eliminated the other root causes <u>if there was more than one possibility</u>:

1. C02 : Calibration technical data in error (qualified technician would not detect). For this Part Number/Manufacturer a "Zero Gas" measurement should not be used for the low point (zero gas) measurement. The resulting "Zero Gas" measurement recorded in 4.1.6, which will be subtracted from the recorded gas cylinder measurement recorded in step 4.1.11, will result in an erroneous final/corrected value. According to the manufacturer (see attached email thread) their "Advanced Sense Pro" system is designed for indoor air quality. This CO2 sensor range, for fresh air indoors, is between 300 and 400 ppm. That is the reason a gas cylinder with a rating of 375 ppm is supplied with the TI. Any measurement made below 300 ppm will result in improper calculations made by the software resulting in erroneous displayed values on the TI. This means that all of section 4.1 will not allow compliance of calibration of CO2 for this Model. A Reason for Change (RC) would be required to correct the calibration authority. Considered as a significant possibility. But not selected.

2. F01 : Component failure caused degradation or hard failure (normal process would not find). Based on the comments made by the certifying technician (process owner) during the post interview. We were concerned that there may be an issue with the eProm that stores the correct values during the adjustment procedure. The technician indicated that during the as-received calibration the item indicated OOT. He made several software adjustments back and forth between the adjustment for the 375 ppm and 1250 ppm to get an in-tolerance indication for both measurements. This turned out not be the case after further discussion with the manufacturer (see attached email thread), they indicated that was not the cause. That each time the technician made a software adjustment the software would recalculate the attempted zero reading giving a bad indication. It was just by luck that he was able to get an in-tolerance indication once. Not slected.

3. H01 : Human error: When all equipment, technical data, training and other factors are adequate. When another Always considered, as a last resort. In this case, there seems to be at least two other Root Cause Codes that would be better suited for the true root cause. Not selected.

Cite your corrective action/solution <u>for the nonconformity</u> and explain why you selected it: Item will be re-calibrated for CO2 based on the commercial data. The Special Block will read; "CO2 calibrated IAW Commercial Data. Due to an error in the calibration authority". Or, something along those lines.

Was the corrective action fully accomplished? Yes ☒ No ☐

If no, was follow-up action added to the QSL under the follow-up tab? Yes ☐ No ☐

Additional Info:

Overall Nonconformity Risk Assessment: 17

<u>Preventive Action:</u>

☐ Preventive Action required, Explain why:

☒ Preventive Action not required, Explain why: The TCM has indicated that further research is required on his part. Either Section 4.1 will be changed, or AFCAV corrected to have the item certified by the manufacturer (Note 64), or both. In either case there is nothing we can do here to prevent this re-occurrence except what is described in the corrective action above IAW with 00-20-14 section 5.4.2.3.2

Was the Preventive Action fully accomplished? Yes ☐ No ☐

If no, was follow-up action added to the QSL under the follow-up tab? Yes ☐ No ☐

Additional Info:

Recall Determination:

☐ Recall required, Explain why:

☒ Not required, Explain why: There are only two items in the Air Force inventory with this part number. This one, and one at Elmendorf AFB.

If recall is required was the follow-up action added to the QSL under the follow-up tab? Yes ☐ No ☐

Signatories:

12/20/2021

X

Kevin Miller
Process Owner
Signed by: MILLER.KEVIN.DOUGLAS.1208505935
1/3/2022

12/19/2021

X

Darryl Hewitt
Quality Assurance Technician
Signed by: HEWITT.DARRYL.L.1027279186

X Peter Newlun

Peter Newlun
Technologist/Lead Technician
Signed by: NEWLUN.PETER.L.JR.1089347382

Site Manager

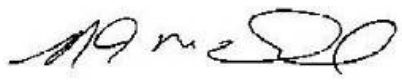
Measurement Area Assessment:

Did critical nonconformity increase the Risk Level of the Measurement Area? Yes ☐ No ☒

Explain:

Other PMEL Manager Comments: This NC, in my opinion, is an anomaly as the calibration is performed differently than almost every other gas monitor. So much so that not even the TCM was aware that this was accomplished differently. This is truly a training deficiency all around.

1/3/2022

X 

Brian MacDonald
Patrick SFB PMEL Manager
Signed by: MACDONALD.BRIAN.W.1039515128