INDEX

DOCUMENT OBJECTIVES

The below information addresses commonly asked questions.

This document is also intended to provide guidance and information to assist the successful completion of corrective actions.

I HAVE THE PTP FINAL REPORT, NOW WHAT?

BEFORE DOING ANYTHING ELSE, PLEASE FOLLOW THE BELOW CHART:

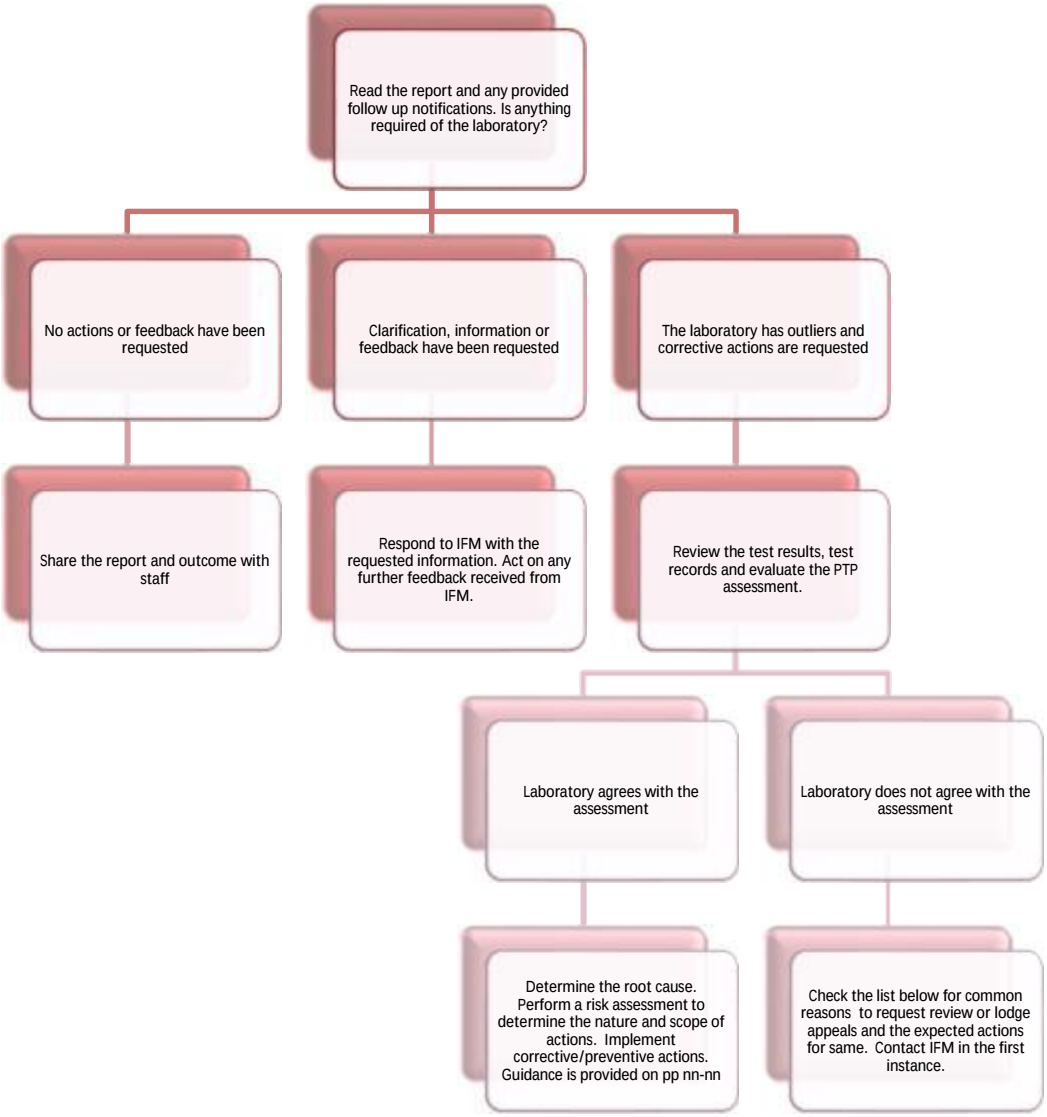

Figure 1: Recommended Evaluation Process for Participant Laboratories

I HAVE A REQUEST FOR FOLLOW UP ACTION. NOW WHAT?

Before starting any action, ensure you have read and understood the final report and all relevant discussion. The follow up system monitors both:

- the progress of corrective actions
- clarification and feedback when requested.

A REQUEST FOR FOLLOW UP ACTION IS NOT NECESSARILY A REQUIREMENT FOR CORRECTIVE ACTIONS.

If the laboratory has been requested to supply feedback or a comment, the first reply to IFM should be to supply the requested response. Feedback, comments and requests for additional information do NOT necessarily require a root cause analysis or a corrective action. Check what is needed before starting an action.

I AGREE WITH THE LABORATORY'S ASSESSMENT AND NEED TO PERFORM CORRECTIONS, NOW WHAT?

IECEE CB scheme laboratories need to comply with OD5004.

IFM Quality Services will monitor the completion of corrective actions for a period of 3 months from the date of issue of this report. After this time, IFM will refer any remaining open items for CB scheme laboratories to the IECEE secretariat for continuation of this monitoring activity and possible issue of a General Non-Conformity Report. Laboratories not affect ted by the rules for PTP in the IECEE and who have not completed their actions will simply be notified that the response time has expired.

Actions can be closed when:

i. The laboratory has demonstrated via submitted objective evidence that suitable application of quality principles itemized in ISO/IEC 17025:2017 has occurred. These principles include:
   a. A root cause analysis
   b. A risk/impact assessment, and
   c. Development of corrective activities aimed at preventing re-occurrence
ii. Evidence is provided that all required actions have been completed
iii. The PTP Corrective action checklist has been completed and returned. https://proficiency.ifmqs.com.au/dropbox/information/QMT813_Corrective_Action_Checklist.docx

Corrective action forms together with the corrective action checklist are to be submitted via email to support@ifmqs.com.au

Figure 2 on the next page describes the recommended corrective action process.

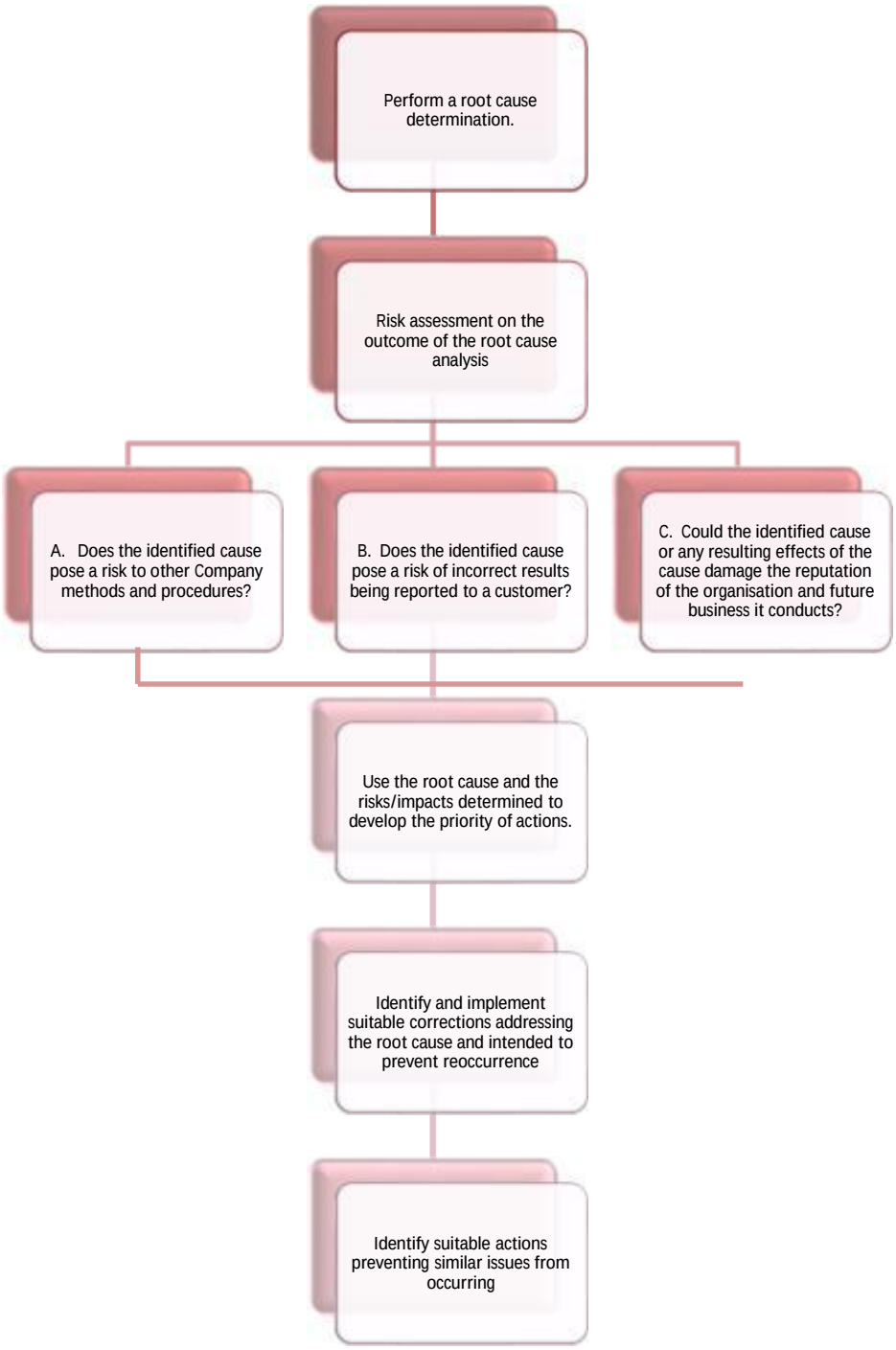

Figure 2: Recommended Considerations for Corrective Action Process

WHY MUST WE PERFORM A ROOT CAUSE ANALYSIS (RCA)?

In the context of the entire laboratory system, things can go wrong which may not necessarily require a root cause analysis. The quality management requirements in ISO/IEC 17025:2017 allow staff to formulate actions with degrees of activity, expense, detail and urgency appropriate to the issue at hand. The broader context of this standard therefore could allow for improvements to be made without the need for a root cause analysis. These clauses in ISO/IEC 17025 apply to the laboratory as a whole, including issues not related to testing.

However, PTP test outliers are:

- incorrect test results
- that have been reported outside the laboratory and
- testing staff are unaware that they are in error.

PTP determined equipment deficiencies are evidence of non-compliant or faulty equipment that negates ALL testing results generated by that equipment since the last time it was known the equipment was compliant.

PTP testing outliers and equipment deficiencies classify as non-conforming work and ISO/IEC 17025:2017 clauses 8.7.1 and 8.7.2 apply.

AN RCA IS REQUIRED FOR EVERY PTP DEFICIENCY

MY ERROR IS SMALL AND POTENTIAL IMPACT TO CUSTOMERS IS MINOR.
I BELIEVE NO RCA OR CORRECTIONS ARE REQUIRED, WHAT NOW?

The magnitude of an error is not necessarily an indication of the magnitude of a problem. Therefore, the term "minor" is meaningless unless the reason for the outlier is known.

For example, an incorrect measurement may have the following direct causes, some of these have potentially dire risks, while others have associated risks that may be minor. Until the root cause has been established, any decisions to avoid corrective actions are indefensible:

i. sloppy technique
   - Further causes might include
     - The quality of management supervision – potentially affects all areas of testing
     - Inappropriate training - potentially big ramifications, especially if training lack covers many areas,
     - Inability to apply time management - impacts are affected on the reason time management is poor and how global this problem is,

ii. the wrong measurement was made
   - Further causes might include
     - Inadequate contract review,
     - Inadequate communication,
     - Poor general adherence to instructions and procedures,
     - Poor supervision,
     - Poor review process

iii. unfamiliarity with an instrument
   - Further causes might include
     - Inadequate training detail list for instrument
     - Inadequate training detail list for all instruments
     - Inadequate management authorization to perform tests or use equipment

iv. instrument not in calibration
   - Further causes might include
     - Inadequate quality procedures relating to this equipment
     - Inadequate quality procedures relating to all equipment
     - Poor staff adherence to quality procedures in this department
     - Poor staff adherence to quality procedures in all departments
     - Inadequate verification procedures for this equipment/tests
     - Inadequate verification procedures for all equipment/tests

v. instrument faulty, but test staff unaware
   - Further causes might include
     - Poor verification procedures for this equipment
     - Poor verification procedures for all equipment
     - Poor implementation of test controls for this test
     - Poor implementation of test controls for any tests, etc.,

vi. instrument faulty, test staff aware but used anyway
   - Further causes might include
     - Inadequate staff supervision
     - Inadequate policies,
     - Policies adequate but not enforced
     - Policy adhered to, e.g., a known fault applies outside a measurement range but equipment OK within a range. The bounds of use and subsequent reporting practices are not correctly applied.

vii. inappropriate instrument choice
   - Further causes might include

- Lack of basic technical knowledge for this test
- Lack of basic technical knowledge generally
- Lack of training for this test
- Lack of training for many tests
- Inadequate procedure for this test
- Inadequate procedures for many tests
- Procedures not enforced for this or many tests

viii. instrument is of lower, but acceptable, accuracy according to OD5014
   - This could be acceptable if established as the true root cause.

Once the root cause is known, further decisions will be better informed and actions taken are more likely to avoid reoccurrence.

MY ROOT CAUSE EVALUATION WAS NOT ACCEPTED BY IFM. WHAT NOW?

IFM needs to take care to ensure that all assessments of causes and corrective actions are objective and based on the provided evidence. If the submission does not provide objective evidence as to the nature of the root cause, or how a conclusion was reached, then it is difficult to accept.

OBJECTIVE EVIDENCE MUST BE PROVIDED

If t true root cause is not identified, then the chances a situation will recur are much higher. Below are common DIRECT causes and some possible further investigations a laboratory could conduct.

COMMON DIRECT CAUSE 1: INADEQUATE STAFF TRAINING OR UNDERSTANDING

WHY THE STATED CAUSE IS NOT A ROOT CAUSE

If the laboratory states the staff members responsible were not adequately trained, it may mean a factor in the relevant ISO/IEC 17025 clauses was not properly carried out, e.g. inappropriate training goals, training procedure lacking, manner of determining what training needs exist, training was not fully relevant or lacked focus, effectiveness of training was not adequately assessed, ongoing evaluations of competence were missing, supervision of 'trained" staff was inappropriate.

FREQUENTLY OFFERED SOLUTIONS:

The staff members were provided with training.

WHY THE OFFERED SOLUTION IS INSUFFICIENT:

The solution does not address the root cause. Addressing the training defect in the current staff and relating to the current test only assists to repair the condition for the exact current situation. It does not prevent the problem from reoccurring, nor does it cater for future staff situations. If one of the above mentioned issues is applicable, then there is a systems deficiency that needs to be rectified for present and future staff as well as the current and OTHER tests.

COMMON DIRECT CAUSE 2: STAFF DID NOT UNDERSTAND THE PTP INSTRUCTIONS OR PERFORMED THE WRONG TEST

WHY THE STATED CAUSE IS NOT A ROOT CAUSE

If the test proceeded without clarifying the requirements, then there may be a problem with the application of the contract review section of ISO/IEC 17025 and/or the type of supervision/instructions provided to the staff when asked to follow a customer requirement. There may also be an issue with staff supervision or review of test results.

FREQUENTLY OFFERED SOLUTIONS:

The staff was provided with an explanation and/or the test was repeated. Another common solution is that a staff meeting will be held in future before running any PTP.

WHY THE OFFERED SOLUTION IS INSUFFICIENT:

The solutions do not address the root cause.

Providing an explanation or repeating the test for the current staff and relating to the current test only assists to repair the condition for the exact current situation. It does not prevent the problem from reoccurring, nor does it cater for future staff situations nor does it ensure other customer requirements are met.

A PTP should be reflective of real life testing, so introducing a meeting prior to PTP does not address possible issues conducting client tests. (PTP tests should considered as though IFM is the customer.)

The level of supervision and instruction given to staff for running PTP should be the same as when a customer test is involved. If it is necessary to introduce steps to clarify the PTP requirements, then affected staff should be afforded the same support for all testing.

COMMON DIRECT CAUSE 3: EQUIPMENT WAS NOT CALIBRATED

WHY THE STATED CAUSE IS NOT A ROOT CAUSE

The laboratory needs to explore why non-calibrated equipment was used.

FREQUENTLY OFFERED SOLUTIONS:

The equipment is calibrated and test repeated.

WHY THE OFFERED SOLUTION IS INSUFFICIENT:

The solution does not address the root cause. The solution does not prevent the problem from reoccurring.

Calibration of the equipment may be required. However, the specific reasons why the result was reported from non-calibrated equipment must be determined. This would normally require a quality system solution in addition to a calibration activity.

The laboratory is also advised to check whether calibration is actually required for the parameter in question. The problem may not be related to the calibration program at all, but rather to staff knowledge of equipment limitations. (It is possible the more cost effective solution includes communication with personnel about checking equipment limitations and ensuring no results are reported when the limitations are exceeded.)

COMMON DIRECT CAUSE 4: EQUIPMENT CHOICE, SETTING, USE, PARAMETERS OF EQUIPMENT, OR INTERPRETATION OF OUTPUTS FROM EQUIPMENT.

WHY THE STATED CAUSE IS NOT A ROOT CAUSE

If the laboratory states their equipment was inappropriately used or selected, a systems requirement has failed. The root cause will be found after investigating exactly which section(s) of the quality system failed and why.

If the laboratory states the results were incorrectly interpreted or reported (e.g. reported result was “noise”), then it would seem the test staff require deeper knowledge of the scope of valid operations of the equipment and/or limitations of equipment.

In the case of noise, laboratory staff should remember that their customers request results related to the items undergoing tests, not the ambient environment. Therefore, the root cause would address why noise was not distinguished from valid technical results.

FREQUENTLY OFFERED SOLUTIONS:

The test is repeated to prove the results would have been acceptable, if they had selected the correct equipment or settings.

WHY THE OFFERED SOLUTION IS INSUFFICIENT:

The solution does not address the root cause. The solution does not prevent the problem from reoccurring.

Proving the equipment would have provided the correct results if it had been selected or used properly does not negate the fact that incorrect results were reported. The preferred solution will be proactive and systems related, not retrospective.

COMMON DIRECT CAUSE 5: STAFF MADE A TYPOGRAPHICAL ERROR (TYPO) ON THEIR SUBMISSION

WHY THE STATED CAUSE IS NOT A ROOT CAUSE

The root cause will address why the typo was not prevented, or not detected prior to the report being issued.

FREQUENTLY OFFERED SOLUTIONS:

The test report is amended and proof is provided usually by means of raw data that the original measurement was correct.

Another common solution is to introduce another checking step.

WHY THE OFFERED SOLUTION IS INSUFFICIENT:

The solution does not address the root cause. The solution does not prevent the problem from reoccurring.

Proving the correct data was generated does not address the fact an incorrect result was originally reported.

Without analysis of the data collection and reporting process to determine which part of the process failed it is unlikely that the introduction of additional checking steps will prevent the problem from reoccurring.

ADDITIONAL CHECKING STEPS HOPE TO DETECT MISTAKES THAT ALREADY OCCURRED. A BETTER SOLUTION IS TO PREVENT MISTAKES FROM OCCURRING IN THE FIRST PLACE.

COMMON DIRECT CAUSE 6: THE LABORATORY REPORTED RESULTS FOR TESTS IT IS NOT SET UP TO PERFORM, OR TESTS NOT REGULARLY PERFORMED

TESTS OUT OF SCOPE:

The laboratory may still perform the test and participate in PTP. It is also encouraged that laboratories working towards an expansion in scope should participate in PTP as part of the verification process for the test. To meet the requirements of ISO/IEC 17025, it is necessary to have verified or validated that the laboratory can successfully conduct the tests, has trained their staff, confirmed the staff competence and has a quality plan in place to ensure ongoing appropriate conduct of these tests. Testing and officially reporting results for something the laboratory has not yet properly implemented must be done in such a way that recipients of the test results are fully aware of the credence that can be given to such activities.

However, when the test is not in scope, the laboratory must not report the result to a customer without any qualification. (In this context, qualification means providing information to indicate the laboratory's lack of expertise, e.g., to indicate the method is under development, training exercise, etc.)

Reporting results without such kinds of qualification implies to the customer that there has been a third party assessment of the conduct of the test and the laboratory's processes were accepted, (which usually is not true if it is out of scope). Consequently, "out of scope" claims are not accepted without a proper root cause analysis.

The root cause report should include:

- (when relevant), the reasons results are reported for out of scope tests without qualification,
- the reasons for the outlying results (failure to report a technically correct result)

THE TEST IS NOT FREQUENTLY PERFORMED:

If the test is in scope, the laboratory must maintain sufficient expertise in its execution to support its ongoing acceptance. Therefore stating infrequent performance of tests is not acceptable and an appropriate root cause analysis is required.

WHY THE STATED CAUSE IS NOT A ROOT CAUSE

The root cause will address why tests were conducted and reported without having maintained competence and / or why it was not declared in the report that the test was not part of the laboratory's scope.

FREQUENTLY OFFERED SOLUTIONS:

Frequently, no solution is offered, but to dismiss the matter as not relevant.

WHY THE OFFERED SOLUTION IS INSUFFICIENT:

The solution does not address the root cause. The solution does not prevent the problem from reoccurring.

COMMON DIRECT CAUSE 7: HUMAN ERROR

WHY THE STATED CAUSE IS NOT A ROOT CAUSE

While human error is never completely preventable, a root cause cited as “human error” will only be accepted with evidence that possible reasons for such an error have been investigated. Frequently a corrective action can be implemented to reduce occurrences of human error. Refer to IEC 62740 and references cited by this document.

FREQUENTLY OFFERED SOLUTIONS:

Frequently, no solution is offered, but to dismiss the matter as impossible to change.

WHY THE OFFERED SOLUTION IS INSUFFICIENT:

The solution does not address the root cause.

The solution does not prevent the problem from reoccurring.

SUGGESTED LINES OF INVESTIGATION:

In case of staff incorrectly following the procedure: was the procedure adequate, was the correct procedure chosen, was a decision making process flawed, was suitable guidance provided?

In case of a violation in protocol: is protocol violation part of the accepted culture in the organisation or due to another factor, was communication adequate, were adequate tools, resources and time provided to do the job properly?

In cases of a lapse in judgment: was communication about the project requirements adequate, were there distractions affecting concentration, are there issues of environment, preconditions (as stated in IEC 62740) or supervision that contributed to the outcome?

I DO NOT AGREE WITH MY LABORATORY'S ASSESSMENT, WHAT NOW?

It is understandable that participants with outlier results would be disappointed with their assessments.

DISPUTES AND APPEALS

Before proceeding with any form of appeal, participants are urged to consider that:

- EVERY report is reviewed by the appointed technical advisers and WG2 prior to issue.
- During this review, these 3rd parties consider the assessment criteria and the parameters against which outliers are determined.
- While there is an acknowledged possibility that certain factors may not have been considered during the evaluation and reporting process, participants appealing their assessments need to be aware that several experts have already considered the final report and the assessment of participants.

An appeal, therefore, should be considered as a last resort in a desperate situation where all items shown in Figure 1 have failed to yield satisfaction.

Common grounds for appeal:

THE ASSESSMENT IS TOO HARSH

Participants are advised to write to IFM stating their case and why it is believed the assessment is too harsh. IFM will review and as relevant, provide a clarification.

If, after receiving this clarification, the participant wishes to lodge a formal appeal, it should be lodged in writing to the appropriate channels.

- CB scheme laboratories follow OD5004, lodging the appeal in writing to the IECEE secretariat with copy to IFM.
- Non-CB scheme laboratories appeal directly to IFM.

MY RESULTS *ARE CORRECT FOR TECHNICAL REASONS*

Participants are advised to write to IFM stating their case and why it is believed the laboratory is correct. IFM will respond with any relevant background information or clarifications. If, after receiving this clarification, the participant wishes to lodge a formal appeal, it should be lodged in writing to the appropriate channels.

- CB scheme laboratories follow OD5004, lodging the appeal in writing to the IECEE secretariat with copy to IFM.
- Non-CB scheme laboratories appeal directly to IFM.

MY RESULTS ARE CORRECT FOR NON-TECHNICAL REASONS

- I think the sample was damaged or malfunctioning
- The instructions were incorrect or unclear.

The instructions are approved by technical advisers prior to their release. The integrity of the samples is thoroughly checked prior to sample release for a PTP program.

Participants are advised to provide their evidence and reasoning to IFM, who will review and provide clarification. If necessary the information is forwarded to the IECEE secretariat for further action.

THE SUBMITTED RESULT WAS MISINTERPRETED BY IFM

This is not grounds for "appeal". Participants are advised to contact IFM, stating their case and requesting the situation be reviewed.

If it is clearly a misinterpretation, IFM will make a note and, if relevant, correct the assessment.

I BELIEVE IFM MADE AN ERROR IN THE ASSESSMENT

This is not grounds for "appeal". Please write to IFM to state your case and request a review. IFM will take the necessary steps to either

- Explain the assessment, or
- Correct the assessment

FEEDBACK

Feedback and suggestions for improvement are always welcome and shared with the technical advisers for the purposes of improving future rounds.

Participants are referred to IFM's website for policies relating to participant appeal of assessments and IFM's role in monitoring corrective actions:
https://proficiency.ifmqs.com.au/dropbox/information/CPL017_Terms_and_Conditions.pdf