

Johnson Matthey Supplier Management System Clean Air

Part 2: Global Supplier Manual
Appendix E – Analytical Change Approval Process

Valid from: April 2021

The latest version of all documents associated with the Global Supplier Manual can be found at the following address:

<https://matthey.com/en/enhancing-life/sustainability-governance/clean-air-global-supplier-manual>

The English version of this document is the master version. Although translations are provided by Johnson Matthey, should there be any ambiguity in the translation, then the English language text will prevail.

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1 Introduction

This appendix details the requirements for the approval of analytical changes that impact product delivered to Johnson Matthey (JM).

2 Validation of an Analytical Change

The supplier shall complete and submit a JM Analytical Change Submission Warrant (see Section 3) for all analytical changes, which require notification to JM (see Appendix D). All JM Analytical Change Submission Warrants should be submitted to the appropriate JM Technology Site (JMTS).

In addition, the supplier shall produce and submit an 'Equivalence Report', which shall contain, at a minimum, the following information:

- details of the analytical change that is being proposed;
- the reason for the change;
- data to support the change;
- details of statistical analyses employed to prove equivalence, including justification of sample size.


In the case of a change to the level of a laboratory's accreditation (*e.g.* gaining or losing ISO/IEC 17025 accreditation), neither a JM Analytical Change Submission Warrant nor an Equivalence Report is required, however, the supplier shall notify the appropriate JM Technology Site and supply copies of any relevant certificates.

If the JM Technology Site gives only interim approval of a JM Analytical Change Submission Warrant, the supplier shall address the reasons for full approval not being given, and complete a further JM Submission Warrant in order to gain full approval.

Analytical changes may lead to the requirement for a change to a JM specification.

3 Johnson Matthey Analytical Change Submission Template (SMS-017)

Analytical Change Approval



Supplier name: supplier

Supplier Test location(s) impacted: Test locations (include town and country)

Reason for submission:

Procedure/method change
 Instrument change/addition
 Test location change
 Other

Details:

Click or tap here to enter text.

JM Materials impacted (include all materials impacted and the COA characteristics potentially impacted):

Click or tap here to enter text.

Supporting documentation:

MSA studies completed:
 Stability
 Bias
 Linearity
 Repeatability and Reproducibility
 None

Comments: Click or tap here to enter text.

Equivalence data summary (include sample size and raw material codes used for demonstrating equivalency):

Click or tap here to enter text.

Supporting data attached?
 yes
 no

Test method attached?
 yes
 no

If no, explain why not: Click or tap here to enter text.

Declaration:

I confirm that the data represented by this warrant are representative of our analysis, have been generated by the specified equipment with regular analytical processes. I also certify that documented evidence of such compliance is on file and available for review.

Signature: _____ Date: Click or tap here to enter text.

Name (print): Click or tap here to enter text. Email: Click or tap here to enter text.

Job Title: Click or tap here to enter text.

For Johnson Matthey Use Only

Submission and warrant decision:
 Approved
 Interim Approval
 Rejected

Comments: Click or tap here to enter text.

Analytical Specialty:
 XRF
 ICP
 Particle size
 XRD
 Other Specialty: _____

Specialist Technical Lead Supplier Quality

Signature: _____

Printed Name: _____

Region: _____

Date: _____

Date that previous condition becomes obsolete: Click or tap