



Australian Government

MSL935003 Authorise the issue of test results

Release: 1

MSL935003 Authorise the issue of test results

Modification History

Release 1. Supersedes and is equivalent to MSL935003A Authorise the issue of test results

Application

This unit of competency covers the ability to critically assess the accuracy of data and validity of test results prior to formally authorising their release to the client. It involves the statistical analysis of data and information generated during calibration, sampling and testing to determine whether quality and/or process parameters have been achieved. Personnel are required to investigate and, if necessary, rectify results that are not consistent with expected values.

This unit of competency is applicable to laboratory personnel working in all industry sectors who are approved by their organisation to authorise the results obtained for specific test methods. In many instances these personnel are known as ‘signatories’ or ‘delegates’ for the tests involved. The scope of tests authorised in each case will be determined by the specialised knowledge, technical competence and experience of the personnel involved.

While no specific licensing or certification requirements apply to this unit at the time of publication, laboratory operations are governed by relevant legislation, regulations and/or external accreditation requirements. Local requirements should be checked.

Pre-requisite Unit

MSL925001 Analyse data and report results

MSL924001 Process and interpret data

Competency Field

Quality

Unit Sector

Elements and Performance Criteria

Elements describe the essential outcomes.

Performance criteria describe the performance needed to demonstrate achievement of the element.

- | | | | |
|---|------------------------------------|-----|--|
| 1 | Verify the accuracy of data | 1.1 | Access relevant job instructions, data and technical records in laboratory information management system |
|---|------------------------------------|-----|--|

	and technical records		(LIMS)
		1.2	Confirm that technical records provide sufficient information to ensure traceability for the tests involved
		1.3	Compare data with expected values and identify any outliers
		1.4	Inspect data records to check the integrity of data entry, alterations, transfers and calculations
		1.5	Correct and initial any incorrect data records
		1.6	Sign off data records as correct
2	Determine if results are acceptable and within expectation	2.1	Compare results with expected values and identify any significant differences
		2.2	Check the reliability of results by examining data, statistical analysis of data and results from repeat tests or duplicate samples
		2.3	Assess the significance of any documented observations of atypical test conditions or environment and/or sample appearance
		2.4	Check that all calculations are free from error
		2.5	Check that estimates of uncertainty are reasonable and consistent with the test method, client and/or product specification requirements
		2.6	Authorise the issue of results that meet the organisation's quality standards and are consistent with expectations
3	Investigate unexpected or unacceptable results	3.1	Examine records of pre-use checks and calibration performance to ensure that the equipment and/or instruments used meet test specifications and workplace requirements
		3.2	Establish whether human and/or environmental factors could have affected the reliability of results
		3.3	Check for obvious sources of interferences that may have occurred during measurements

- | | | |
|---|--|--|
| | 3.4 | Retrieve stored samples (if available) and assess whether they are atypical or contaminated |
| | 3.5 | Perform control tests using the same, or new, samples to check unexpected results |
| | 3.6 | Authorise the issue of unexpected results that meet the organisation's quality standards |
| | 3.7 | Identify possible root causes of unacceptable results and appropriate preventative/corrective actions |
| | 3.8 | Report investigation outcomes and recommendations for improvements in accordance with workplace procedures |
| 4 | Liaise with clients about results | |
| | 4.1 | Establish whether sampling procedures used by the client could contribute to unexpected/unacceptable results |
| | 4.2 | Arrange for new samples and/or re-testing as necessary |
| | 4.3 | Explain investigation outcomes and confidence level for unexpected test results |

Foundation Skills

This section describes those language, literacy, numeracy and employment skills that are essential to performance.

Foundation skills essential to performance are explicit in the performance criteria of this unit of competency.

Range of Conditions

This field allows for different work environments and conditions that may affect performance. Essential operating conditions that may be present (depending on the work situation, needs of the candidate, accessibility of the item, and local industry and regional contexts) are included.

Standards, codes, procedures and/or workplace requirements

Standards, codes, procedures and/or workplace requirements include the latest version of one or more of:

- Australian and international standards covering the requirements for the competence of testing and calibration laboratories, quality management systems and plans, measurement management, accuracy of measurement

methods and results, expression of uncertainty of measurement (GUM), quantifying uncertainty in analytical measurement, and sampling and testing methods

- National Association of Testing Authorities (NATA) accreditation program requirements and any supplementary requirements for the relevant field of testing, NATA technical notes, policy circulars and guidelines
- national measurement regulations and guidelines
- specific codes, regulations guidelines, procedures and methods, such as Australia New Zealand Food Standards (ANZFS) Code, Australian code of good manufacturing practice for medicinal products (GMP), principles of good laboratory practice (GLP), National Health and Medical Research Council (NHMRC) Guidelines, and Therapeutic Goods Regulations
- workplace documents, such as standard operating procedures (SOPs); quality and equipment manuals; calibration and maintenance schedules; material safety data sheets (MSDS) and safety procedures; material, production and product specifications; production and laboratory schedules; workplace recording and reporting procedures; waste minimisation and safe disposal procedures; inspection test plans and sampling plans for sites
- customer-specific requirements/standards and customer quality plan

Technical records

Technical records include, but are not limited to, one or more of:

- request forms, service agreements and contracts, clients notes, papers and feedback
- worksheets, work books, check sheets and work notes, original observations, derived data and calculations, and control graphs
- external and internal test reports, and calibration certificates
- listing of data and the personnel responsible for sampling, performance of each test/calibration and checking of results

Statistical tests

Statistical tests include, but are not limited to, one or more of:

- standard deviation, standard deviation of the mean,

histograms and frequency plots

- probability and normal probability plots
- run charts and control charts, such as Shewhart and CuSum
- regression methods for calibration, linearity checks and comparing analytical methods
- analysis of variance (ANOVA)
- data acceptability tests, such as T and F

Estimates of uncertainty

Estimates of uncertainty include, but are not limited to, one or more of:

- calibration uncertainty
- instability or drift in the calibrated instrument
- repeatability of the results
- resolution or readability of the instrument
- environmental influences, such as temperature, air pressure, humidity, vibration, electrical noise and gravity
- reference material uncertainty
- factors arising from using an instrument under a different operating environment or procedures (e.g. orientation of a transducer and immersion depth of a temperature probe)
- reproducibility of quality control data

Human and environmental factors

Human and environmental factors include, but are not limited to, one or more of:

- technician preparing the sample and/or performing the test did not apply the test method correctly
- inadequate attention to detail, fatigue and stress
- inadequate hygiene and sterility
- unacceptable dust, humidity, temperature and illumination levels
- electromagnetic disturbances
- variations to gas, electricity and water supply
- unacceptable sound and vibration levels
-

Sources of interference

Sources of interference include, but are not limited to, one or more of:

- spectral interference
- physical interference
- matrix effects

- presence of contaminants
- masking of analytes

Sample collection and preparation problems

Sample collection and preparation problems include, but are not limited to, one or more of:

- use of incorrect sample containers
- incorrect sample handling, storage or conditioning (filtered/non-filtered, temperature control and preservation), sample disturbance and sample segregation
- incomplete sample preparation
- incorrect particle size
- incorrect matrix
- incomplete digest

Preventative/corrective actions

Preventative/corrective actions include, but are not limited to, one or more of:

- regular use of certified reference materials
- internal quality controls using secondary reference materials
- participation in inter-laboratory comparison or proficiency testing programs
- replicate tests or calibrations using the same or different methods
- re-testing or recalibration of retained items
- correlation of results for different characteristics of an item
- additional audits and management reviews
- regular quality checks on consumables
- increased staff observation, supervision and/or training
- more detailed sample specifications, test methods and procedures

WHS and environmental management requirements

WHS and environmental management requirements include:

- complying with WHS and environmental management requirements at all times, which may be imposed through state/territory or federal legislation. These requirements must not be compromised at any time
- applying standard precautions relating to the potentially hazardous nature of samples
- accessing and applying current industry understanding of infection control issued by the National Health and

Medical Research Council (NHMRC) and State and Territory Departments of Health, where relevant

Unit Mapping Information

Release 1. Supersedes and is equivalent to MSL935003A Authorise the issue of test results

Links

Companion Volume implementation guides are found in VETNet -

<https://vetnet.gov.au/Pages/TrainingDocs.aspx?q=5c63a03b-4a6b-4ae5-9560-1e3c5f462baa>

Assessment Requirements for MSL935003 Authorise the issue of test results

Modification History

Release 1. Supersedes and is equivalent to MSL935003A Authorise the issue of test results

Performance Evidence

Evidence of competence in this unit must satisfy all of the requirements of the elements and performance criteria, and include demonstration of:

- verifying the accuracy and completeness of at least one (1) set of data, results and technical records for specified tests
- issuing at least one (1) set of specified test results in accordance with authorisation and workplace procedures
- reviewing at least one (1) set of records of sampling, sample preparation, testing and/or calibration activities to identify potential causes of unacceptable data/results
- using statistical tests to estimate uncertainties and determine data acceptability
- recognising unexpected or unacceptable data and results and then investigating the occurrence in a logical and efficient manner using effective problem-solving strategies
- rectifying results that are not consistent with expected values
- recommending appropriate preventative/corrective actions to control potential/actual non-conforming work
- explaining technical details of sampling, test methods and results to clients
- maintaining a professional approach and positive company/organisation image, including maintaining independence and an ability to resist improper influences.

Knowledge Evidence

Must provide evidence that demonstrates knowledge of:

- workplace procedures for authorising the issue of specified test results
- relevant reporting requirements, such as the *ISO Guide to the Expression of Uncertainty in Measurement*, National Association of Testing Authorities (NATA) and/or test methods
- the confidence level required according to the National Measurement Act 1960 (e.g. 95% for most applications, but it may be higher)
- scientific and technical knowledge of the samples, procedures, equipment, materials and instrumentation used to generate the specified test results and data
- at least three (3) statistical tests used to estimate uncertainties and determine data acceptability
- expected values for data and results and the uncertainty components for specified test methods
- common sources of interference, human and environmental factors, sample preparation problems and relevant preventative/corrective actions associated with specified test results
- confidentiality requirements relevant to job role

- work health and safety (WHS) and environmental management requirements relevant to job role.

Assessment Conditions

- Judgement of competence must be based on holistic assessment of the evidence. Assessment methods must confirm consistency of performance over time, rather than a single assessment event.
- This unit of competency is to be assessed in the workplace or a simulated workplace environment. A simulated workplace environment must reflect realistic operational workplace conditions that cover all aspects of workplace performance, including the environment, task skills, task management skills, contingency management skills and job role environment skills.
- Foundation skills are integral to competent performance of the unit and should not be assessed separately.
- Assessment processes and techniques must be appropriate to the language, literacy and numeracy requirements of the work being performed and the needs of the candidate.
- Knowledge evidence may be collected concurrently with performance evidence or through an independent process, such as workbooks, written assessments or interviews (provided a record is kept in each case).
- This unit of competency may be assessed with:
 - MSL935001 Monitor the quality of test results and data
 - relevant MSL974000 and MSL975000 series units of competency that cover the ability to perform the tests involved, relevant data analysis and quality assurance procedures.
- Holistic assessment methods include:
 - review of records and test results verified and issued by the candidate
 - feedback from supervisors and clients regarding the candidate's ability to issue authorised test results
 - review of recommendations and reports prepared by the candidate
 - questions to assess understanding of procedures governing the authorised issue of test results, acceptability of data/results, sources of uncertainty and preventative/corrective actions.
- Access is required to instruments, equipment, materials, workplace documentation, procedures and specifications associated with this unit, including, but not limited to:
 - sampling and test methods, description of test set-up, data sets, results and technical records
 - calculator
 - spreadsheets and databases
 - computer, relevant software or laboratory information system
 - workplace quality procedures.
- Assessors must satisfy the assessor competency requirements that are in place at the time of the assessment as set by the VET regulator.
- The assessor must demonstrate both technical competence and currency.

- Technical competence can be demonstrated through:
 - relevant VET or other qualification/Statement of Attainment AND/OR
 - relevant workplace experience.
- Currency can be demonstrated through:
 - performing the competency being assessed as part of current employment OR
 - having consulted with a laboratory about performing the competency being assessed within the last twelve months.

Links

Companion Volume implementation guides are found in VETNet -

<https://vetnet.gov.au/Pages/TrainingDocs.aspx?q=5c63a03b-4a6b-4ae5-9560-1e3c5f462baa>