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 Performance criteria describe the performance needed to

essential outcomes.		demonstrate achievement of the element.	
1	**Verify the accuracy of data and technical records**	1.1	Access relevant job instructions, data and technical records in laboratory information management system (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	Standards, codes, procedures and/or workplace requirements include the latest version of one or more of:

workplace requirements

- 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.education.gov.au/Pages/TrainingDocs.aspx?q=5c63a03b-4a6b-4ae5-9560-1e3c5f462baa