



Australian Government

MSL935001 Monitor the quality of test results and data

Release: 1

MSL935001 Monitor the quality of test results and data

Modification History

Release 1. Supersedes and is equivalent to MSL935001A Monitor the quality of test results and data

Application

This unit of competency covers the ability to analyse a series of test results and data to detect potential or actual non-conformances, assess their significance and recommend preventative or corrective actions. The unit assumes personnel will have access to workplace quality assurance procedures based on Australian and/or international standards. This unit of competency does not cover the adaptation or development of test methods or procedures.

This unit of competency is applicable to technical officers, technical specialists and laboratory supervisors in all industry sectors.

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

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 accuracy of data and technical records	1.1	Retrieve and collate all relevant data files and technical records for the specified time interval, tests or product range or project
		1.2	Inspect data records to check the integrity of data entry, alterations, transfers and calculations

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| | | 1.3 | Confirm that technical records contain sufficient information to provide an audit trail for the tests involved |
| 2 | Assess the quality of data/results | 2.1 | Use charts and tables to determine whether data/results are within specified limits |
| | | 2.2 | Analyse data trends and results for blanks, duplicates and/or check samples to detect systematic uncertainties |
| | | 2.3 | Use statistical tests and workplace procedures to check data acceptability |
| | | 2.4 | Check that estimations of uncertainties are reasonable and consistent with test method, client or product specification requirements |
| | | 2.5 | Identify results that cannot be reconciled with technical records and/or expected outcomes |
| 3 | Identify potential causes for unacceptable results | 3.1 | Review user checks and calibration performance records to confirm that equipment or instrument meets test specifications |
| | | 3.2 | Check for obvious sources of interferences that may have occurred during measurements |
| | | 3.3 | Review technical records to identify human or environmental factors that could affect reliability of results |
| | | 3.4 | Review records of sample collection and preparation to confirm chain of custody requirements and adherence to sampling procedures |
| | | 3.5 | Check that any documented deviations from sampling procedures and/or test methods were technically justified and authorised |
| | | 3.6 | Check the condition of sampling equipment and/or stored samples if available/appropriate |
| 4 | Report findings | 4.1 | Summarise the quality of test results and data |

to relevant personnel

- 4.2 Document potential sources or instances of non-conforming work and assess their significance
- 4.3 Recommend appropriate preventative/corrective actions to improve sampling, testing and/or calibration activities
- 4.4 Prepare reports in a format and style consistent with their intended use and workplace guidelines

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 (GUM), quantifying uncertainty in analytical measurement, and sampling and testing methods
- National Association of Testing Authorities (NATA) accreditation program requirements
- 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; and waste minimisation and safe disposal procedures

- customer-specific requirements/standards

Technical records

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

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

Instrument calibration/performance records

Instrument calibration/performance records include, but are not limited to, one or more of:

- checks that equipment/instrument complies with specifications
- dates, results and copies of reports and certificates of calibrations, adjustments, acceptance criteria and due date of next calibration
- maintenance plan and maintenance carried out to date
- damage, malfunction, modification or repairs
- data files and technical records, and laboratory information management system (LIMS)

Charts, tables and statistical analysis tools and techniques

Charts, tables and statistical analysis tools and techniques include one or more of:

- run charts and control charts
- histograms, frequency plots, stem and leaf plots, boxplots and scatter plots
- probability and normal probability plots
- Pareto diagrams, Shewhart control charts and CuSum control charts
- regression methods for calibration, linearity checks and comparing analytical methods

- calculations of means, ranges, standard deviations, confidence limits
- analysis of variance (ANOVA)
- data acceptability tests, such as Q, T and Youden

Sources of interference

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

- spectral interference
- physical interference
- matrix effects
- presence of contaminants
- masking of analytes

Human and environmental factors

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

- lack of operator competence and/or training
- 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

Sample collection and preparation problems

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

- incorrect sample containers
- incorrect sample handling (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
- retesting or recalibration of retained items
- correlation of results for different characteristics of an item
- additional audits and management reviews
- regular quality checks on consumables
- enhanced 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

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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 MSL935001 Monitor the quality of test results and data

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Performance Evidence

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

- analysing at least one (1) series of test results and data to detect potential or actual non-conformances, assessing their significance, identifying potential causes and recommending preventative or corrective actions
- reviewing the accuracy and completeness of at least one (1) set of technical records for sampling or testing activities
- reviewing the accuracy and completeness of at least one (1) set of instrument calibration/performance records
- recognising significant trends in data and/or aberrant results
- using statistical tests to estimate uncertainties and determine data acceptability
- applying effective problem-solving strategies, such as root cause analysis
- following workplace procedures for documenting and reporting information about quality.

Knowledge Evidence

Must provide evidence that demonstrates knowledge of:

- characteristic properties of the materials under investigation
- specifications for samples, tests and/or calibration activities under investigation
- scientific and technical knowledge of the procedures, equipment, materials and instrumentation used to generate the test results and data
- at least three (3) statistical tests used to estimate uncertainties and determine data acceptability
- workplace data quality procedures and/or legal traceability requirements
- relevant hazards, work health and safety (WHS) and environment requirements

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:
 - MSL925001 Analyse data and report results
 - relevant MSL974000 series units of competency
 - relevant MSL975000 series units of competency
- Holistic assessment methods include:
 - review of verified records and reports generated by the candidate
 - feedback from supervisors and peers about the candidate's ability to monitor the quality of test results and data
 - questioning to assess understanding of trends in data, 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:
 - workplace quality assurance procedures based on Australian and/or international standards, and workplace quality manuals and procedures
 - technical records of sampling and testing activities, and instrument calibration/performance records:
 - appropriate software
 - samples, sampling equipment and test equipment, instruments and materials.
- 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.

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