Australian Government

Department of Education, Employment and Workplace Relations

MSL935001A Monitor the quality of test results and data

Revision Number: 1

MSL935001A Monitor the quality of test results and data

Modification History

Not applicable.

Unit Descriptor

Unit descriptor	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 enterprise 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.

Application of the Unit

Application of the unit	This unit of competency is applicable to technical officers, technical specialists and laboratory supervisors in all industry sectors. Industry representatives have provided case studies to illustrate the practical application of this unit of competency and to show its relevance in a workplace setting. These can be found at the end of this unit of competency under the section 'This competency in practice'.

Licensing/Regulatory Information

Not applicable.

Pre-Requisites

Prerequisite units		
	MSL924001A	*Process and interpret data*

Employability Skills Information

Employability skills	This unit contains employability skills.

Elements and Performance Criteria Pre-Content

Elements describe the essential outcomes of a unit of competency.	Performance criteria describe the performance needed to demonstrate achievement of the element. Where bold italicised text is used, further information is detailed in the required skills and knowledge section and the range statement. Assessment of performance is to be consistent with the evidence guide.

Elements and Performance Criteria

ELEMENT	PERFORMANCE CRITERIA
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 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 enterprise 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/ 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 to relevant personnel	4.1. Summarise the quality of test results and data 4.2. Document potential sources or instances of non-conforming work and assess their significance 4.3. Recommend appropriate preventative/corrective

ELEMENT	PERFORMANCE CRITERIA
	actions to improve sampling, testing and/or calibration activities 4.4. Prepare reports in a format and style consistent with their intended use and enterprise guidelines

Required Skills and Knowledge

REQUIRED SKILLS AND KNOWLEDGE
This section describes the skills and knowledge required for this unit.
Required skills
Required skills include: • verifying the accuracy and completeness of data, results and technical records • recognising significant trends in data and/or aberrant results • using statistical tests to estimate uncertainties and determine data acceptability • analysing sampling, sample preparation testing and/or calibration activities to identify potential causes of unacceptable data/results • applying effective problem solving strategies • recommending appropriate preventative/corrective actions to control potential/actual non-conforming work • following enterprise procedures for documenting and reporting information about quality
Required knowledge
Required knowledge includes: • characteristic properties of the materials in question • 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 • methods for statistical analysis of data (means, ranges, standard deviations, confidence limits and data acceptability) and sampling procedures • problem solving techniques androot cause analysis • enterprise and/or legal traceability requirements • relevant health, safety and environment requirements

Evidence Guide

EVIDENCE GUIDE	
The Evidence Guide provides advice on assessment and must be read in conjunction with the performance criteria, required skills and knowledge, range statement and the Assessment Guidelines for the Training Package.	
Overview of assessment	
Critical aspects for assessment and evidence required to demonstrate competency in this unit	Assessors should ensure that candidates can: • verify the accuracy and completeness of data, results and technical records • recognise significant trends in data and/or aberrant results • use statistical tests to estimate uncertainties and determine data acceptability • analyse sampling, sample preparation testing and/or calibration activities to identify potential causes of unacceptable data/results • apply effective problem solving strategies • recommend appropriate preventative/corrective actions to control potential/actual non-conforming work • follow enterprise procedures for documenting and reporting information about quality.
Context of and specific resources for assessment	This unit of competency is to be assessed in the workplace or simulated workplace environment. This unit of competency may be assessed with: • *MSL925001A Analyse data and report results* • *relevant MSL974000 series units of competency* • *relevant MSL975000 series units of competency*. Resources may include: • data files and technical records, and laboratory information management system (LIMS) • appropriate software • enterprise quality manual and procedures • access to samples, sampling equipment and test equipment/instruments/materials.
Method of assessment	The following assessment methods are suggested: • review of verified records and reports generated by the candidate • feedback from supervisors and peers about the

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	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. In all cases, practical assessment should be supported by questions to assess underpinning knowledge and those aspects of competency which are difficult to assess directly. Where applicable, reasonable adjustment must be made to work environments and training situations to accommodate ethnicity, age, gender, demographics and disability. Access must be provided to appropriate learning and/or assessment support when required. The language, literacy and numeracy demands of assessment should not be greater than those required to undertake the unit of competency in a work like environment.
This competency in practice	Industry representatives have provided the case studies below to illustrate the practical application of this unit of competency and to show their relevance in a workplace setting. **Manufacturing** The person conducting final quality assurance activities is responsible for ensuring that the results of each calibration or test carried out by the laboratory are reported accurately, unambiguously, clearly and objectively in accordance with specific instructions in the test or calibration method. Test reports and calibration certificates are checked for mistakes, including the correct transfer of data from original worksheets and to ensure all relevant information is documented and is the result of valid measurements. Quality inspectors are also ultimately responsible to their clients for the quality of work produced by outsourced subcontractors. **Environmental** A laboratory regularly collects carbon monoxide (CO) data as part of an air monitoring program. The laboratory operates several remote air sampling sites that take CO samples every three seconds using standard methods. The measurements are stored in data loggers and

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	downloaded to the laboratory's computer every 24 hours. Using a standard software package, the laboratory technician generates 1 hour and 24 hour averages for each site. They then graph the results over a one year period and use the appropriate Australian Air Quality Standard to determine exceedances for the 1 hour and 24 hour averages. To ensure that any exceedances are genuine, the technician carefully checks factors, such as equipment calibration procedures, seasonal variations in data, artefacts, equipment downtime and maintenance of monitoring equipment over the past year. The verified data and exceedances are reported and compared with previous years' exceedances to determine long term trends in air quality at the sampling sites.

Range Statement

RANGE STATEMENT	
The range statement relates to the unit of competency as a whole. It allows for different work environments and situations that may affect performance. Bold italicised wording, if used in the performance criteria, is detailed below. Essential operating conditions that may be present with training and assessment (depending on the work situation, needs of the candidate, accessibility of the item, and local industry and regional contexts) may also be included.	
Codes of practice	Where reference is made to industry codes of practice, and/or Australian/international standards, it is expected the latest version will be used

Standards, **codes**, **procedures and/or enterprise requirements**	Standards, codes, procedures and/or enterprise requirements may include:
	• Australian and international standards, such as:
	  • AS ISO 1000-1998 The international system of units (SI) and its application
	  • AS ISO 17025-2005 General requirements for the competence of testing and calibration laboratories
	  • AS/NZS ISO 10005:2006 Quality management systems - Guidelines for quality plans
	  • AS/NZS ISO 10012:2004 Measurement management systems - Requirements for measurement processes and measuring equipment
	  • AS/NZS ISO 9000 Set:2008 Quality management systems set
	  • AS/NZS ISO 9001:2008 Quality management systems - Requirements
	  • ISO 5725 Accuracy (trueness and precision) of measurement methods and results
	  • ISO/IEC Guide 98-3:2008 Uncertainty of measurement - Part 3 Guide to the expression of uncertainty in measurement (GUM)
	• Eurachem/CITAC Guide CG4 Quantifying uncertainty in analytical measurement
	• national measurement regulations and

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	guidelines • Australian code of good manufacturing practice for medicinal products (GMP) • enterprise recording and reporting procedures • equipment startup, operation and shutdown procedures • material safety data sheets (MSDS) • National Association of Testing Authorities (NATA) Accreditation programs requirements • principles of good laboratory practice (GLP) • production and laboratory schedules • quality manuals, equipment and procedures manuals • standard operating procedures (SOPs) and published preparation methods
Technical records	Technical records consist of data and information generated during sampling, testing and/or calibrations which indicate whether quality or process parameters have been achieved. They may include: • request forms, service agreements and contracts • worksheets, work books, check sheets and work notes • original observations, derived data and calculations • control graphs • external, internal test reports and calibration certificates • clients notes, papers and feedback • listing of data and the personnel responsible for sampling, performance of each test/calibration and checking of results
Charts, **tables and statistical tests**	Charts, tables and statistical tests may include: • run charts and control charts • histograms, frequency plots, stem and leaf plots, boxplots and scatter plots • probability and normal probability plots • Pareto diagrams, Stewhart control charts and CuSum control charts

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	• regression methods for calibration, linearity checks and comparing analytical methods • analysis of variance (ANOVA) • data acceptability tests, such as Q, T and Youden
Instrument calibration/ performance records	Instrument calibration/performance records may include: • 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, maintenance carried out to date • damage, malfunction, modification or repairs
Sources of interferences	Sources of interferences may include: • spectral interference (e.g. in inductively coupled plasma) • physical interference (e.g. in atomic absorption spectroscopy) • matrix effects • presence of contaminants • masking of analytes
Human and environmental factors	Human and environmental factors may include: • 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 preparation problems	Sample preparation problems could result from: • incomplete preparation • segregation • sample disturbance • incorrect sample containers

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	• incorrect sample handling (filtered/non-filtered, temperature control and preservation) • incorrect particle size • incorrect matrix • incomplete digest
Preventative/corrective actions	Preventative/corrective actions could include: • 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 • feedback from clients on improving quality system, testing and calibration activities
Occupational health and safety (OHS) and environmental management requirements	OHS and environmental management requirements: • all operations must comply with enterprise OHS and environmental management requirements, which may be imposed through state/territory or federal legislation - these requirements must not be compromised at any time • all operations assume the potentially hazardous nature of samples and require standard precautions to be applied • where relevant, users should access and apply current industry understanding of infection control issued by the National Health and Medical Research Council (NHMRC) and State and Territory Departments of Health

Unit Sector(s)

Unit sector	Maintenance

Competency field

Competency field	

Co-requisite units

Co-requisite units		