



APAS® CONFORMANCE REQUIREMENTS

1 SCOPE

- a) This document details the conformance requirements for a Client to become an APAS Recognised Manufacturing Unit (RMU) and/or maintain its status as an RMU.
- b) If the RMU produces product that is APAS certified both for themselves and also in a Toll / Contract Manufacturing capacity for another RMU(s), then the RMU must undergo a two tiered audit process:
1. **First Tier¹**: Initial full APAS audit of the RMU as per criteria set out in this document AP-D174, followed by
 2. **Second Tier^{2,3}**: Audit of the same RMU directly related to the Toll / Contract manufactured products produced for another RMU including, but not limited to, all criteria set out in this document AP-D174

NOTE:

¹ The RMU undergoing the First Tier audit (initial full APAS audit) is responsible for all costs associated with this audit.

² The RMU undergoing the Second Tier audit (whose products are made by the First Tier RMU on their behalf under a Toll / Contract Manufacturing arrangement) is responsible for all costs associated with this audit.

³ A senior management representative of the RMU undergoing the Second Tier audit must be present at the time of the audit to be able to answer any and all questions relating to the products Toll / Contract Manufactured for them by the RMU that underwent the first tier audit process.

- c) This document is prepared in a manner compliant with the requirements of AS/NZS ISO /IEC 17065.
- d) APAS® is a registered trademark owned by CSIRO, the Scheme Owner, and protected under applicable laws. Use of the trademark or the Certification Scheme is prohibited unless prior approval in writing is obtained from CSIRO via the APAS Secretariat.

2 AUTHORITY AND RESPONSIBILITY

- a) The Executive Officer (EO) - APAS is responsible for the content of this document.
- b) Conformance to the documented requirements is determined by an APAS Officer at an on-site audit of the organisation's own manufacturing facility and / or an existing RMU acting in a Toll / Contract Manufacturing capacity for the Client under contractual agreement.

3 DEFINITIONS AND ACRONYMS

3.1 Definitions

The definition of terms used in this document and in the Certification Scheme can be found in APAS document AP-D001. In addition, the following definitions within this document shall apply:

- a) **Certification Scheme**: The Certification system related to specified products (Paint and Non-Paint Products) to which the same specified requirements,

specific rules and procedures apply. APAS is the applicable Certification Scheme.

- b) **Client**: The organisation responsible to the Certification Body (APAS) for ensuring that certification requirements, including product requirements, are fulfilled. The Client nominates a person(s) directly responsible (APAS Signatory) within its organisation, and to communicate directly with the Certification Scheme (APAS).
- c) **Contract Manufacture**: An arrangement whereby a contracted third-party uses its own plant, specialised equipment, labour source, organisational model and sourced and supplied raw materials, in conjunction with the Client's intellectual property, to manufacture finished product on behalf of the company, for a fee. A Contract Manufacturer must be a Recognised Manufacturing Unit.
- d) **Recognised Manufacturing Unit (RMU)**: A company voluntarily choosing to participate in the Certification Scheme (APAS) whereby its manufacturing facilities have been assessed in accordance with AP-D177 for supply of products certified to APAS Specifications. The RMU forms part of the Client. Historically referred to as the Supplier.
- e) **Scheme Owner**: The organisation responsible for developing and maintaining the certification scheme. CSIRO is the APAS Scheme Owner.
- f) **Secretariat**: The organisation that provides administrative support and other resources necessary to keep the Certification Scheme functioning. The Secretariat is vested in CSIRO.
- g) **Toll Manufacture**: An arrangement whereby the Client sends its intellectual property and raw materials to a contracted third-party, who supplies the plant, specialised equipment, labour source and organisational model to manufacture finished product on behalf of the company, for a fee. A Toll Manufacturer must be a Recognised Manufacturing Unit.

3.2 Acronyms

APAS	Australian Paint Approval Scheme
AS	Australian Standard
CSIRO	Commonwealth Scientific and Industrial Research Organisation
DG	Dangerous Goods
EO	Executive Officer – APAS
IANZ	International Accreditation New Zealand
IEC	International Electrotechnical Commission
ISO	International Standards Organisation
ITE	Inspection and Test Equipment
JAS-ANZ	Joint Accreditation Society of Australia and New Zealand
NATA	National Association of Testing Authorities
NMI	National Measurement Institute
NZS	New Zealand Standard
OHSAS	Occupational Health and Safety Assessment Series
PPE	Personal Protective Equipment
PT	Proficiency Testing
QA	Quality Assurance



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QC	Quality Control
QMS	Quality Management Systems
R&D	Research and Development
RMU	Recognised Manufacturing Unit

- v. AP-D192 Rules Governing the APAS® Product Certification Scheme
- vi. AP-D197 Rules Governing the Use of the APAS® Certified Trademark

4 REFERENCED DOCUMENTS

- a) The following standards are referenced in this document:
- i. **AS/NZS 1580.101.1** - Paints and related materials - Methods of test - Conditions of test - Temperature, humidity and airflow control
 - ii. **AS/NZS 4801** - Occupational health and safety management systems – Specification with guidance for use
 - iii. **AS/NZS ISO 9001** - Quality Management Systems – Requirements
 - iv. **AS/NZS ISO 14001** - Environmental management systems – Requirements with guidance for use
 - v. **AS ISO/IEC 17025** – General requirements for the competence of testing and calibration laboratories
 - vi. **AS/NZS ISO/IEC 17065** - Conformity assessment: Requirements for bodies certifying products, processes and services
 - vii. **AS/NZS ISO 45001** - Occupational health and safety management systems – Requirements with guidance for use (replaces OHSAS 18001)
 - viii. Australian Government National Measurement Institute - Sampling and Test Procedures for Pre-packaged Products
<https://www.industry.gov.au/sites/default/files/2019-04/sampling-and-test-procedures-for-prepackaged-products.pdf>
 - ix. NATA Policy Circular 2 –Proficiency Testing policy
<https://www.nata.com.au/phocadownload/gen-accreditation-criteria/Proficiency-Testing.pdf>
 - x. NATA General Equipment – Calibration and Checks
<https://www.nata.com.au/phocadownload/gen-accreditation-guidance/General-Equipment-Calibration-and-Checks.pdf>
 - xi. NATA Reference equipment – calibration and checks

Unless otherwise specified, these documents may be purchased through the Reference Standards Australia website: <https://www.standards.org.au/> or downloaded from the NATA website: <https://www.nata.com.au> or downloaded from the Australian Government Department of Industry, Science, Energy and Resources website: <https://www.industry.gov.au>, where applicable.

- b) The following APAS documents are referenced in this document:
- i. AP-D001 Rules Governing How APAS® Operates
 - ii. AP-D004 Rules Governing Appeals and Complaint Handling
 - iii. AP-D177 Rules Governing How Product Manufacturers Participate in APAS®
 - iv. AP-D183 Guidelines for Changes to Formulation of Approved Products

All APAS documents are available for download from the APAS website: <https://vs.csiro.au/apas/documents/>

5 COMPLAINTS AND APPEALS

- a) Clients may lodge a complaint or an appeal against a decision made by the Certification Body, Certification Scheme, Scheme Owner or any of its processes or personnel.
- b) Appeals and complaints shall be subject to the process detailed in APAS document AP-D004.



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6 REQUIREMENTS

CRITERIA		CONFORMANCE	Conformance Demonstrated Yes / No
1. Quality Management Systems			
1.1	Certification to AS/NZS ISO 9001.	The organisation has current AS/NZS ISO 9001 certification from a JAS-ANZ [^] accredited certifier [^] (or equivalent accreditation society for organisations based outside of Australia or New Zealand).	
1.2	Inclusion of one or more technical function(s) in the organisation's AS/NZS ISO 9001 Scope of Accreditation.	The AS/NZS ISO 9001 Scope of Accreditation needs to make reference to one or more technical function(s) to ensure it is periodically covered by the audit process. Words to be included are similar to design, development, design and development, quality control, research and development (R&D), technical, technical service.	
1.3	Detected non-conformance(s).	There is no conformance / non-conformance requirement. The aim is to identify non-conformance(s) detected during the AS/NZS ISO 9001 audit and determine whether the detected non-conformance(s) will adversely impact the organisation's ability to conform to APAS.	N/A
Technical Competence: Must be either laboratory WITH AS ISO/IEC 17025 Accreditation or laboratory WITHOUT AS ISO/IEC 17025 Accreditation			
2. Technical Competence – Laboratory WITH AS ISO/IEC 17025 Accreditation			
2.1	Certification to AS ISO/IEC 17025.	The organisation has current AS ISO/IEC 17025 certification from NATA [^] (Australian based organisations) or IANZ [^] (New Zealand based organisations) [^] (or equivalent accreditation society for organisations based outside of Australia or New Zealand).	
2.2	The test methods that apply to the organisation's APAS certified products are listed in the organisation's AS ISO/IEC 17025 Scope of Accreditation.	The AS ISO/IEC 17025 Scope of Accreditation covers all test methods that apply to the organisation's APAS certified products.	
2.3	Participation in a Proficiency Testing (PT) program.	* Participation at least once every two (2) years. The PT program shall ensure that every operator is assessed for every test, measurement or related activity undertaken. * PT report(s) exist. * Anomalous result(s), where they exist, are investigated for root cause(s) and corrective action(s) implemented.	
2.4	Detected non-conformance(s).	There is no conformance / non-conformance requirement. The aim is to identify: * non-conformance(s) detected during the AS ISO/IEC 17025 audit and determine whether the detected non-conformance(s) will adversely impact the organisation's ability to conform to APAS and, * anomalous result(s) reported as a result of PT, investigation of anomalous result(s) and corrective action(s) implemented to determine whether the laboratory's technical competence will adversely impact the organisation's ability to conform to APAS.	N/A
3. Technical Competence - Laboratory WITHOUT AS ISO/IEC 17025 accreditation			
3.1	Participation in a Proficiency Testing (PT) program [^] . [^] PT participation may be via an external provider or undertaken in-house.	* Participation in at least two rounds of a PT program per year. The PT program shall ensure that every operator is assessed for every test, measurement or related activity undertaken. * PT report(s) exist. * Anomalous result(s), where they exist, are investigated for root cause(s) and corrective action(s) implemented.	
3.2	Laboratory management is involved in, or aware of, all activities being undertaken in the laboratory.	* Laboratory management has authorised all procedures that govern the operation of the laboratory and all laboratory registers in use.	



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CRITERIA		CONFORMANCE	Conformance Demonstrated Yes / No
		<p>* Laboratory management ensures conformance to procedures and the currency of its registers by way of regular internal auditing. The requirements for internal auditing are detailed in Clause 3.5</p> <p>* Laboratory management, and the activities of the laboratory, are always independent of the organisation's other business functions regarding decisions made relating to quality assurance (QA) and quality control (QC).</p> <p>* Laboratory management undertake and document, at least annually, a management review of the laboratory's operations.</p>	
3.3	The laboratory is appropriately sized, clean, safe, tidy and uncluttered.	<p>* The laboratory is appropriately sized.</p> <p>* Visual inspection of the laboratory demonstrates that good housekeeping practices are in place.</p> <p>* Documented records of housekeeping activities may exist.</p>	
3.4	The laboratory environment is controlled to the extent that consistent and reproducible test results are achievable.	<p>* The laboratory, or dedicated test room, is temperature controlled. Other environment controls such as relative humidity, lighting, air speed (in the immediate vicinity of the test area) and air purity, conforming to AS/NZS 1580.101.1, may also exist. Laboratory environment conditions for temperature and relative humidity are always recorded whenever testing occurs.</p> <p>* Laboratory test(s) that specify control(s) for temperature, relative humidity, air flow or lighting, are documented to ensure that testing only occurs when the control(s) for the specified parameter(s) is met. The specified test control(s) conditions are always recorded whenever testing occurs.</p>	
3.5	The AS/NZS ISO 9001 internal audit program covers laboratory activities.	<p>* Documented evidence of internal audits being done shall exist.</p> <p>* Corrective action(s) have been applied to non-conformance(s) arising from internal audits.</p>	
3.6	A register of laboratory inspection and test equipment (ITE) exists.	All ITE is listed on a register that defines what the ITE is, where the ITE is, how the ITE is calibrated/checked, the frequency of calibration/checking and calibration/checking pass-fail criteria. The ITE register is always current.	
3.7	ITE is calibrated/checked.	<p>* All ITE is calibrated/checked according to a schedule. All calibrations/checks are current.</p> <p>* ITE that is out of calibration or damaged is isolated to prevent its use.</p> <p>* The frequency of calibrations/checks may be set in accordance with the NATA publication General Accreditation Guidance – General Equipment - Calibration and Checks, General Equipment Table, January 2018.</p>	
4. Other External Accreditations (optional)			
4.1	Certification to: <ul style="list-style-type: none"> AS/NZS ISO 14001 AS/NZS 4801 AS/NZS ISO 45001 (formerly OHSAS 18001) 	Conformance / non-conformance is not an issue as these accreditations are not a mandatory requirement for APAS accreditation.	N/A
4.2	Detected non-conformance(s)	There is no conformance / non-conformance requirement. The aim is to identify non-conformance(s) detected during the audit(s) and determine whether the detected non-conformance(s) will adversely impact the organisation's ability to conform to APAS.	N/A
5. Personnel			
5.1	Effective management of the quality management systems (QMS).	<p>* The organisation has assigned accountability for the QMS to personnel that are knowledgeable and competent to effectively administer/manage the QMS.</p> <p>* The organisation provides sufficient resourcing (e.g., labour, time) to effectively manage the QMS.</p>	
6. Raw Material Storage			
6.1	Environmental deterioration and mechanical damage of raw materials is prevented.	Raw materials storage, both liquid and powder, prevents deterioration due to environmental conditions (e.g., weather, water ingress) and/or mechanical damage (e.g., forklift).	



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6.2	The raw material store is appropriately sized, clean, compliant to local regulation, safe, tidy and uncluttered.	<ul style="list-style-type: none"> * The store is appropriately sized. * Raw material storage complies with local regulation (e.g., placarding, DG limits). * Visual inspection of the raw material store demonstrates that good housekeeping practices are in place. * Documented records of housekeeping activities may exist. 	
6.3	Cross-contamination of raw materials is prevented.	<ul style="list-style-type: none"> * Coloured pigments are always stored away from white pigments and/or extender pigments. * Raw material packaging is always sealed upon storage. * Incompatible raw materials are always segregated in accordance with local regulation. 	
6.4	Identification of raw materials is easy.	All raw materials in the store are identifiable with a clear and legible printed raw material code (if used) or name. Part-bags of powder raw materials, part-containers of raw materials, as well as part-pallets of raw materials are always identifiable.	
6.5	Storage of empty finished goods containers prevents dirt/dust collection.	Empty finished goods containers are stored either with top layer upside down or, with a cardboard/plastic sheet across the top layer of containers or, covered with a plastic lining to prevent dirt/dust depositing inside the empty containers.	
6.6	Identification of raw material hazards and personal protective equipment (PPE) requirements is easy. PPE is available, accessible and appropriate.	<ul style="list-style-type: none"> * All operators handling raw materials can always, readily and fully identify the handling hazards and PPE requirements of all raw materials on-site (e.g., use of a coding system for raw materials that identifies the hazardous nature of raw materials. A "decoder" then identifies the appropriate PPE to be worn). Alternative effective systems will also be considered. (e.g., colour coded labelling, pictograms, or use of a single PPE regime that applies for the handling of all raw materials). * PPE must always be available, always be accessible and always be appropriate for the safe handling of all raw materials on site. 	
6.7	For organisations that conduct raw material pre-weigh in the raw material store; calibrated and clean scale(s) are in use.	<ul style="list-style-type: none"> * Calibration report(s) and certificate(s) from a third-party metrology provider demonstrates that the scale(s) are working to the manufacturer's working specification and have currency of calibration. The calibration report(s) and certificate(s) must be checked and initialled. * Visual inspection of the scale(s) demonstrates that the scale(s) are well maintained; free of raw material deposits. 	
6.8	For organisations that use underground bulk tank(s) storage; routine and effective monitoring occurs.	Documented evidence of routine and effective monitoring of underground bulk tank(s) storage occurs (e.g., raw material is not leaking out of any tank; groundwater is not entering into any tank).	
6.9	For organisations that undertake raw material(s) testing; the process is effective in avoiding the manufacture of non-conforming product.	A current listing of all raw material(s) that need to be tested exists; testing is always done by someone competent to do the task and, acceptance/rejection determination is done by an authorised person.	
7. Manufacturing			
7.1	Only the current formulation for a product can be manufactured.	System controls are in place to ensure that only the current formulation for all products can be raised for manufacture.	
7.2	A unique batch number is assigned to every manufactured/re-packaged batch of product.	System controls are in place to ensure that a unique batch number is assigned to every manufactured/re-packaged batch of product.	
7.3	Process instructions on the manufacturing batch card are comprehensive, legible and unambiguous.	The process instructions on the manufacturing batch card are comprehensive, legible, and unambiguous to the extent that the manufacture process is easily understood by operators.	



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7.4	Change(s) to the manufacturing batch card are done in a controlled manner.	* A documented record exists noting how changes to formulae are managed; detailing who has the authority to amend a manufacturing batch card and to what extent (e.g., change raw materials, change quantities, add rework). * Change(s) to manufacturing batch cards are always made by authorised personnel only and always in accordance with the authority limits noted.	
7.5	The manufacturing area is appropriately sized, clean, safe, tidy and uncluttered.	* The manufacturing area is appropriately sized. * Visual inspection of the manufacturing area shows that good housekeeping practices are in place. * Documented records of housekeeping activities may exist.	
7.6	Identification of raw material hazards and personal protective equipment (PPE) requirements is easy. PPE is available, accessible and appropriate.	* All operators handling raw materials can always, readily and fully identify the handling hazards and PPE requirements of all raw materials on-site (e.g., use of a coding system for raw materials that identifies the hazardous nature of raw materials. A "decoder" then identifies the appropriate PPE to be worn). Alternative effective systems will also be considered. (e.g., colour coded labelling, pictograms, or use of a single PPE regime that applies for the handling of all raw materials). * PPE must always be available, always be accessible and always be appropriate for the safe handling of all raw materials on site.	
7.7	Calibrated and clean scale(s) are in use.	* Calibration report(s) and certificate(s) from a third-party metrology provider demonstrates that the scale(s) are working to the manufacturer's working specification and have currency of calibration. The calibration report(s) and certificate(s) must be checked and initialled. * Visual inspection of the scale(s) demonstrates that the scale(s) are well maintained; free of raw material deposits.	
7.8	Manufacturing batch card control – raw materials and quantities added to a production batch are recorded.	Manufacturing batch cards always show that the prescribed raw materials and associated quantities have been added to a production batch; typically, with a tick or with the operator initials.	
7.9	Manufacturing batch card control - batch/lot numbers of key raw materials added to a production batch are recorded.	* Operators record batch/lot numbers of raw materials onto the manufacturing batch card as required; can be all raw materials or selected raw material types or specific raw material(s).	
7.10	Identification of tank contents is easy.	Visual inspection of the manufacturing plant shows that process mixers/tanks are labelled so as to readily identify the contents inside the mixer/tank.	
7.11	Process plant and equipment is clean and maintained in good condition.	* Visual inspection of the manufacturing plant shows that not-in-use process mixers/tanks are either cleaned back to bare metal or, if process mixers/tanks are dedicated to a limited range of product(s), sufficiently clean so as to prevent paint skins falling off the mixer/tank wall into manufactured product. * A documented works schedule detailing process mixers/tanks cleaning and maintenance activities may exist.	
7.12	For organisations that use bulk storage for raw material(s); identification of bulk storage tank(s) content(s) and associated transfer lines is easy.	Bulk storage tank(s) and associated transfer lines must be clearly and legibly labelled with the raw material being handled. The requirement to label transfer lines to process tanks may be relaxed where a computerised process is used to transfer more than one raw material to a process tank via a single transfer line.	
8. Quality Control (QC)			
8.1	The laboratory area is appropriately sized, clean, safe, tidy and uncluttered.	* The laboratory area is appropriately sized. * Visual inspection of the manufacturing area shows that good housekeeping practices are in place. * Documented records of housekeeping activities may exist.	
8.2	A defined QC test schedule exists for all product(s).	* All products have a QC test schedule. * Products are always tested to the QC schedule in full.	



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8.3	QC test records exist.	<ul style="list-style-type: none"> * QC test results are always recorded. * Good laboratory practice is always followed; white out is never used, a single line is always made through an incorrect data entry, the operator initials/signs an erroneous data entry. 	
8.4	Routine QC approval of product is controlled to the extent that approval to fill a production batch is clear and is granted only by authorised person(s).	<ul style="list-style-type: none"> * The process for routine QC approval of production batches is always followed. * Inspection of the QC test schedule demonstrates that all QC tests have test results recorded, that the test results are within minimum/maximum tolerances and that approval to fill has been granted by an authorised person and evidenced by way of signature/initials on the QC test schedule. 	
8.5	Concessional QC approval of product is controlled to the extent that approval to fill a production batch is clear, assessed and granted only by authorised person(s).	<ul style="list-style-type: none"> * The process for concessional approval of production batches is always followed. * Inspection of the QC test schedule demonstrates that all QC tests have test results recorded, that the out-of-spec test result has been approved by an authorised person and that approval to fill has been granted by an authorised person by way of signature/initials on the QC test schedule. 	
8.6	Production formulae are monitored and amended to correct repeated and/or excessive adjustments.	QC test results of production batch formulae are monitored. Where there is consistent and/or excessive adjustments, production formulae are amended to correct the situation.	
8.7	Competency and proficiency of operators that undertake laboratory testing is documented.	<ul style="list-style-type: none"> * Documented training records exist detailing how operators are accredited as competent re. the laboratory tests that they perform. * Documented competency records exist detailing how operators maintain accreditation as competent for laboratory tests that are performed infrequently. Competency is demonstrated by operators performing all laboratory tests for which they are accredited at least once per year. * Documented proficiency records exist detailing how operators demonstrate proficiency for the laboratory tests that they perform via PT. Conformance requirements for PT are detailed in Clause 2.3 and 3.1 	
8.8	Calibrated and clean laboratory equipment is in use.	<ul style="list-style-type: none"> * Calibration report(s) and certificate(s) from a third-party provider demonstrates that the laboratory equipment is working to the manufacturer's working specification and have currency of calibration. The calibration report(s) and certificate(s) must be checked and initialled. If equipment is maintained internally, records of calibration must be provided. * Visual inspection of the equipment demonstrates that the equipment is well maintained; free of raw material deposits. 	
9. Filling			
9.1	The filling area is appropriately sized, clean, safe, tidy and uncluttered.	<ul style="list-style-type: none"> * The filling area is appropriately sized. * Visual inspection of the manufacturing area shows that good housekeeping practices are in place. * Documented records of housekeeping activities may exist. 	
9.2	Filling of production batches into finished goods containers is controlled to the extent that only production batches approved to fill by QC are filled into finished goods containers.	<ul style="list-style-type: none"> * Inspection of a manufacturing batch card always gives a clear indication (e.g., signature of an authorised person or stamp) that a production batch has been approved to fill. * Only production batches that are approved to fill by QC are filled into finished goods containers. 	
9.3	Production batches are subject to cleanliness checking and/or filtration whilst being filled into finished goods containers.	<ul style="list-style-type: none"> * Cleanliness testing for products is specified; including pass/fail criteria and the timing/frequency of cleanliness testing. Cleanliness testing is always performed on production batches where there is a stated requirement to do so and/or, * The filter sizing for products is specified. Production batches are always filtered through a filter medium of the specified sizing where there is a stated requirement to do so. 	



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		Note: this requirement is waived for those products where a cleanliness check and/or filtration is of no value (e.g., coarse texture coatings).	
9.4	Use of calibrated scale(s).	* Calibration report(s) and certificate(s) from a third-party metrology provider demonstrates that the scale(s) are working to the manufacturer's working specification and have currency of calibration. The calibration report(s) and certificate(s) must be checked and initialled. * Visual inspection of the scale(s) demonstrates that the scale(s) are well maintained; free of paint deposits.	
9.5	Filling of finished goods containers is controlled to the extent that the correct mass/volume is inside the containers.	Where filling of liquid paints into finished goods containers is done by mass, there needs to be documented evidence demonstrating that the actual density of the batch is always determined, that the operator doing the density determination is competent to do so, that the density cup being used for density determinations is calibrated, that the person noting the fill weights onto the filling card is authorised to do so and, that calibrated scales are always used for filling operations. Intermittent checking and recording of fill weights is undertaken. Where filling of powder/thermoplastic coatings occurs, there needs to be documented evidence demonstrating that calibrated scales are used for filling operations. Intermittent checking and recording of fill weights is undertaken. Where filling of liquid paints into finished goods containers is done by volume, there needs to be documented evidence demonstrating that a calibrated stylus (or like implement) is used for filling operations. Intermittent checking and recording of fill volume are undertaken.	
9.6	Finished goods have a batch number noted on the product packaging.	The correct production batch number is always clearly and legibly noted onto all finished goods containers (e.g., direct to the can or using an adhesive sticker or written onto a label using permanent marker).	
9.7	A retain sample is taken of every production batch of finished goods.	* A retain sample, representative of what is being filled into the finished goods containers, of minimum volume of 2 x 500 millilitres (1 litre total volume), is always taken from the filling line. * Retain samples are labelled for positive identification, for quick and easy access, stored to prevent environmental deterioration and prevent mechanical damage and are kept for a minimum of two years.	
9.8	The fill yield is measured, the fill yield variance is determined against the theoretical yield and the batch fill is investigated when the fill yield variance is over/under the defined limit.	* The fill yield minimum and maximum tolerances are defined. * Records exist demonstrating that the fill yield of finished goods production batches is always measured and is always assessed against the theoretical yield. * A documented record, typically in the form of a non-conformance report, exists demonstrating that when the fill yield is outside the defined minimum/maximum tolerance limits, the fill was investigated to determine the root cause(s) and corrective action(s) implemented.	
9.9	Product fills are checked for accuracy against the stated fill quantity for finished goods manufactured in Australia or being exported to Australia.	Product fills are assessed on a monthly basis in accordance with the Australian Government National Measurement Institute (NMI) Sampling and Test Procedures for Pre-packaged Products publication.	
9.10	For organisations that fill production batches prior to the completion of QC testing, such batches are subject to quarantine controls.	Quarantine controls are always enacted; prohibiting the release to market for production batches that are filled into finished goods containers prior to the completion of all QC testing.	
10. Finished Goods Storage			
10.1	Environmental deterioration and mechanical damage of raw materials is prevented.	* Finished goods storage, both liquid and powder, prevents deterioration due to environmental conditions (e.g., weather, water ingress) and/or mechanical damage (e.g., forklift).	



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10.2	The finished goods store is appropriately sized, clean, compliant to local regulation, safe, tidy and uncluttered.	<ul style="list-style-type: none"> * The store is appropriately sized. * Finished goods storage complies with local regulation (e.g., placarding, DG limits). * Visual inspection of the finished goods store demonstrates that good housekeeping practices are in place. * Documented records of housekeeping activities may exist. 	
10.3	Labelling of finished goods is unambiguous, legible and denotes a batch number.	Visual inspection of the labelling of various finished goods is always unambiguous, always legible and always denotes a batch number.	
10.4	APAS designations of conformity on finished goods packaging is correct.	Where APAS conformity is noted on the product labelling, such labelling always conforms to the relevant requirements of APAS documents AP-D192 and AP-D197.	
10.5	Separation of saleable product from non-saleable is in place.	Visual inspection of the finished goods store demonstrates that non-saleable product is identifiable and segregated from saleable product.	
11. Product Development (where applicable)			
11.1	Revisions of master formulae are controlled.	The organisation has a process in place that effectively and continually controls the integrity of master formulae; who can access the master formulae depository, who can change/approve edits to master formulae and the use of a unique identifier to provide full traceability to the different versions of master formulae that exist.	
11.2	Details of changes to product master formulae are recorded.	When master formulae are changed, the following records always exist: <ul style="list-style-type: none"> * What change(s) was implemented and, * Why the change(s) was implemented and, * Activation date of the current formulation and, * Master copy of the superseded formulation noting the date it was archived. 	
11.3	Significant change to the master formulation of APAS certified product(s) is managed in accordance with APAS document AP-D183	For all APAS certified product(s): <ul style="list-style-type: none"> * The active master formulation does not have any significant change compared to the master formulation that was active at the time of certification/re-certification and, * Where an active master formulation has a significant change compared to the master formulation that was active at the time of certification/re-certification, evidence exists that significant change is always communicated to APAS. 	
11.4	For organisations that undertake product development; AS/NZS ISO 9001 accreditation covers product development activities.	<ul style="list-style-type: none"> * The organisation's AS/NZS ISO9001 accreditation includes product development. * Documented evidence of internal and external audit(s) exists. 	
11.5	For organisations that utilise their own atmospheric exposure facility for demonstrating conformance to APAS Specifications; the facility has AS ISO/IEC 17025 accreditation.	The organisation's atmospheric exposure facility has AS ISO/IEC 17025 accreditation.	

**APAS® CONFORMANCE REQUIREMENTS****7 APPENDIX A****Document History**

Status: Current
 Version: 10
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Document Version No.:	Date Published:	Summary of Changes:
10	03-08-2021	<ul style="list-style-type: none"> Updated clause 1 Scope relating to the requirements of the audit process and responsibilities for RMUs that produce / receive products in a Toll / Contract Manufacturing capacity, to reflect APAS document AP-D177
9	11-06-2021	<ul style="list-style-type: none"> Updated APAS website details within document Further defined clause 1 b) Scope General formatting changes
8	17-02-2021	<ul style="list-style-type: none"> Amendments: 1. Clause 2.3 addressing the required timeframe for holders of ISO/IEC 17025 accreditation for Proficiency Testing participation (at least once every two (2) years); 2. Clause 6.7, 7.7 and 9.4 for the inclusion of certificates as means of ensuring calibration of scales and 3. Clause 9.7 updated to reflect requirement of 2 x 500mL retention samples required for every production batch of finished goods (in line with APAS document AP-D192) Addition of clause 8.8: requirement for laboratory equipment calibration certificates and reports
7	22-10-2020	<ul style="list-style-type: none"> Addition of Appendix A Document History and removal of the Editorial Note previously used in document versions Minor formatting changes Updated clause 5 to reflect other APAS documents
6	25-09-2020	<ul style="list-style-type: none"> Document brought in line with requirements of AS/NZS ISO/IEC 17065 Updated document to the current format (portrait format) Incorporation of definitions and acronyms Includes updated website details Minor editorial changes Addition of "People + Product = Protection" to Footer
5	19-10-2018	<ul style="list-style-type: none"> Re-write clause 3.7 to reference the current NATA publication for calibration and checking of laboratory equipment
4	09-07-2018	<ul style="list-style-type: none"> Replaces the word 'guidelines' with 'requirements' for emphasis that manufacturing organisations need to meet the criteria tabled in clause 6 for APAS certification
3	24-11-2017	<ul style="list-style-type: none"> New document format (landscape format), including the new APAS logo Adds sections 1. to 5., deletes the 'NON-CONFORMANCE' column, re-writes the 'CONFORMANCE' requirements
2	21-06-2016	<ul style="list-style-type: none"> Updated criteria, compliance and non-compliance requirements
1	26-07-2011	<ul style="list-style-type: none"> Updated criteria, compliance and non-compliance requirements
0	30-07-2002	<ul style="list-style-type: none"> Original document version