AP-D177

RULES GOVERNING HOW PRODUCT MANUFACTURERS PARTICIPATE IN APAS®

1 SCOPE

a) This document provides advice to Clients (product manufacturers and Toll / Contract Manufacturers) on how APAS operates and how to become a Recognised Manufacturing Unit (RMU) of APAS Certified Products to Members of the Certification Scheme.
b) This document is prepared in a manner compliant with the requirements of AS/NZS ISO /IEC 17065.
c) A Client can be deemed as:
   i. Producing their own products within their own organisations manufacturing facility(s), and / or
   ii. Having products produced for them under contractual agreement with an existing RMU(s) as Toll / Contract Manufactured product
d) APAS® is a trademark registered with IP Australia, 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 and for ensuring compliance to the requirements of this document.

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) **Member:** An organisation that makes use of the services APAS and its Secretariat provides. These services enable the organisation to call up APAS approvals in tender documents and painting specifications or other internal documentation.
e) **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.
f) **Scheme Owner:** The organisation responsible for developing and maintaining the certification scheme. CSIRO is the APAS Scheme Owner.
g) **Secretariat:** The organisation that provides administrative support and other resources necessary to keep the Certification Scheme functioning. The Secretariat is vested in CSIRO.
h) **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
APLAC	Asia Pacific Laboratory Accreditation Cooperation
ARA	Aspects Requiring Attention
ATAP	APAS Technical Advisory Panel
CSIRO	Commonwealth Scientific and Industrial Research Organisation
EO	Executive Officer – APAS
IAV	Initial Assessment Visit
QC	Quality Control
PT	Proficiency Testing
R&D	Research and Development
RMU	Recognised Manufacturing Unit
VSA	Verification Services Agreement
WHS	Workplace Health and Safety

4 REFERENCED DOCUMENTS

a) The following standards are referenced in this document:
   i. **AS/NZS 1580** – Paint and related materials – Methods of Test
   ii. **AS/NZS ISO 9001** - Quality Management Systems - Requirements
   iii. **AS ISO/IEC 17025** – General requirements for the competence of testing and calibration laboratories
   iv. **ISO/IEC 17043** - Conformity Assessment - General Requirements for Proficiency Testing
   v. **AS/NZS ISO/IEC 17065** - Conformity assessment: Requirements for bodies certifying products, processes and services

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These documents may be purchased through the Reference Standards Australia website: https://www.standards.org.au/

b) The following APAS documents are referenced in this document:

i. AP-C001 Certificate of APAS Accreditation
ii. AP-D001 Rules Governing How APAS® Operates
iii. AP-D003 APAS® Schedule of Fees
iv. AP-D004 Rules Governing Appeals and Complaint Handling
v. AP-D112 APAS® Terms of Reference for the Certification Scheme
vi. AP-D114 Rules Governing APAS® Recognition as a Testing Authority
vii. AP-D150 Rules Governing How Specifying Organisations become Members of APAS®
viii. AP-D174 APAS® Conformance Requirements
ix. AP-D178 Rules Governing Proficiency Testing Providers
x. AP-D183 Guidelines for Changes to Formulation of Approved Products
xi. AP-D192 Rules Governing the APAS® Product Certification Scheme
xii. AP-D194 Application for APAS® Signatory Status
xiii. AP-F002 Application for Accreditation as an APAS Recognised Manufacturing Unit

All APAS documents (except AP-C001) are available for download from the APAS web site: https://vs.csiro.au/apas/documents/

5 BACKGROUND

a) To obtain a broad overview of how the Australian Paint Approval Scheme (APAS) operates, refer to APAS document AP-D001.
b) For information about how to become a member of APAS, refer to APAS document AP-D150.
c) To view the associated fees charged by CSIRO for APAS-related services, refer to APAS document AP-D003.

6 PARTICIPATION CRITERIA

a) APAS recognises manufacturing units as complying with APAS requirements for good manufacturing practices and processes. This identifies them as having:
i. The business control systems to consistently manufacture products to a defined quality standard, and
ii. The technical competence to test products routinely and consistently to the same standard, and
iii. A system of technical control that safeguards on-going product quality, and
iv. A manufacturing process that is consistent with good industry practice, and
v. Processes and procedures to ensure an adequate level of workplace health and safety (WHS) and environmental practices are in place.
b) Compliance with these criteria is detailed in clause 7 below.
c) Where the manufacturer is based overseas, and it is deemed preferable to make product certification applications locally in Australia, for example, due to familiarity with AS/NZS 1580 test methods, the requirements of APAS document AP-D114 shall apply to the test authority.
d) The specific conformance requirements for recognition as an APAS RMU are detailed in APAS document AP-D174.

7 COMPLIANCE REQUIREMENTS

7.1 Business Control Systems

a) Applicants shall be able to demonstrate compliance with clause 6 of APAS document AP-D114.

7.2 Technical Competence Systems

a) Applicants shall be able to demonstrate compliance with clauses 7, 8 and 9 inclusive of APAS document AP-D114.

7.3 Manufacturing Competence Systems[1,2,3]

a) All Applicants (Clients) shall participate in an APAS audit of their manufacturing facility, including QC and / or R&D test laboratories, in order to determine compliance to the requirements.
b) Clients that manufacture their own products will have the audit performed on each of their own manufacturing facilities requiring Accreditation (refer to First Tier in clause 1 b) 1. APAS document AP-D174).
c) Clients that have their products manufactured for them under contractual agreement (Toll / Contract manufacturing) with an existing RMU, will have the Toll / Contract Manufacturing facility(s) audited accordingly. This audit will be additional to the existing RMUs standard audit for ongoing Accreditation (refer to Second Tier in clause 1 b) 2. APAS 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.

d) Should an existing RMU acting in a Toll / Contract Manufacturing capacity for the Client have its accreditation Suspended and / or Withdrawn, by extension, the Client utilising this service will also have this accreditation Suspended and / or Withdrawn (refer to clause 10).

8 RECOGNITION PROCESS

8.1 Application

a) Applicants can be either local (Australian) or overseas based organisations. Local organisations must have a current ABN or ACN and not be a Trust.
b) The Applicant can be either a product manufacturer [owned manufacturing facility(s)] and / or a Client that has its products Toll / Contract Manufactured at an existing RMU.
c) If the manufacturer is overseas based, the Applicant may also be the local importer or agent making the application on behalf of the overseas manufacturer.
d) The Applicant shall study and become familiar with this document and all other referenced documents located here https://vs.csiro.au/apas/documents/
a) When satisfied that the Applicant will meet the requirements outlined in this document, the application form AP-F002 (downloadable from the above link) shall be forwarded to the EO via ordinary mail or email:

Executive Officer, APAS
Trudy Lennon-Bowers
CSIRO
Private Bag 10
Clayton South, Victoria, Australia 3169
Or Email: trudy.lennon-bowers@csiro.au

e) Where a local agent is making the Application as per 8.1 c) above, two (2) AP-F002 forms will need to be submitted – one for the overseas based manufacturer and one for the local importer/agent.
f) The EO or their delegate shall review the application(s) to ensure all required data is provided and all pre-conditions have been complied with, for example ISO 9001 and/or ISO 17025 accreditation current and active.
g) Any omissions or errors shall be resolved with the Applicant prior to proceeding with the application.
h) All applications shall, to the maximum extent possible, be processed in order of receipt.
i) Except for situations outlined in 8.3 d) below, there shall be no accelerated advancement up the queue as a result of applicant's size, importance or payment of incentive(s).

8.2 Service Agreement

a) APAS will acknowledge receipt of the application and forward a Verification Service Agreement (VSA) for signing and return (refer to APAS document AP-D112, clause 12.4).
b) The purpose of the VSA is to clearly document:
   i. What the Applicant can expect in the way of CSIRO's APAS services
   ii. What CSIRO expects in return of the Applicant
   iii. The price of those services
   iv. A Certified Trademark Agreement governing how the APAS logo and trademark(s) may be used
c) Once the signed VSA is returned, CSIRO will issue a tax invoice for the Application fee.

8.3 Pre-Audit Activities

a) APAS will acknowledge receipt of the signed VSA and forward a pre-audit questionnaire to obtain basic information regarding the state of adherence to compliance requirements. The purpose of the questionnaire is to determine how ready the Applicant is for an APAS manufacturing audit. An Applicant who is not ready will be wasting their money and everyone's time by submitting to an audit at this stage.
b) APAS will review the completed questionnaire and advise the Applicant of any obvious shortcomings which may impede an immediate audit.
c) Once a prima facie case is established that the Applicant is likely to be ready for an Initial Assessment Visit (IAV), a Lead Auditor will be assigned and, the Lead Auditor and the Applicant will agree on a date for an IAV.
d) Wherever possible, applications will be processed in order of receipt. However, in some instances this may not be optimal for either APAS or the Applicant. APAS tries to maximise the value of audit travel, so wherever possible, more than one audit is scheduled for each trip to a region. Sometimes, for example when there is only one trip per year to that region, and a trip is due soon, the new Applicant may be added to the trip, thereby effectively *jumping the queue*. The alternative will require extra expense for both the Applicant and CSIRO.

8.4 Initial Assessment Visit

a) The IAV shall only be scheduled once the application fee has been paid.

NOTE: In certain circumstances, for example at the request of the Applicant or if there has been a history of slow payment or other issues, CSIRO may choose to request whole or part payment of the audit fee prior to undertaking the audit.

b) The IAV shall be conducted according to the criteria in clause 7 above and APAS document AP-D174.
c) The IAV shall be conducted by the Lead Auditor and any additional personnel necessary to ensure that any and all gaps in experience or technical knowledge of the Lead Auditor have been covered. Such additional persons shall first be approved by the Applicant prior to the IAV.
d) The IAV Team will pay particular attention during the visit to the *culture* of the organisation – the professionalism, good corporate citizenship and general attitude of employees towards technical and QA issues in particular.
e) At the completion of the IAV, the Assessment Team shall present a final report detailing all aspects requiring attention (non-conformances) as detected during the audit. These are typically graded as Aspects Requiring Attention (ARA), Major Non-Conformances, or Observations. Depending on the complexity of the audit, this report is typically prepared and presented within 1-2 weeks post-audit.

8.5 Post-Audit Activities

a) Corrective actions are made by the Applicant as necessary to the satisfaction of the Lead Auditor.
b) Evidence of corrective actions, including evidence of the actual implementation, shall be supplied. This may in some instances necessitate a further (chargeable) visit depending on the nature of the corrective actions needed. Refer to clause 8.8 below.
c) All evidence shall be supplied to the Lead Auditor within four (4) weeks of the date of despatch of the audit report.
d) Where evidence of corrective actions is not supplied within the required time, extension(s) may be granted if approved by the EO. If the audit is not closed within four (4) months of the audit date, the EO shall advise the Applicant that unless progress is made within the next five (5) working days, the audit and application will be terminated. There shall be no refund of any monies paid to date and any current outstanding invoices shall be immediately due.
e) ARAs require evidence of corrective action taken to be provided to APAS before Recognition can be granted.
f) Observations need to be considered but there is no requirement to immediately report any action taken. However, at the next audit, any Observations not addressed may be upgraded to ARAs.

8.6 Nomination of APAS Signatory

a) Each Applicant organisation shall nominate at least one (1) person who shall act as an APAS Signatory.
b) RMUs may have up to four (4) APAS Signatories.
c) There are two types of APAS Signatory:
    i. **Formulation Signatory:** is typically a member of the R&D department or product development section. The role of this Signatory is principally to oversee the submission of product certification application and to ensure they meet all the requirements of APAS document AP-D192.
    ii. **Production Signatory:** is typically a member of the QC or other technical department. The role of this Signatory is to ensure that certified products are made in accordance with APAS requirements – no Significant formulation changes (refer to APAS document AP-D183), no correction batches to bring a faulty batch into specification and no use away of faulty stock.
d) In smaller organisations, one Signatory may fill both roles.
e) Applications for Signatory status shall be made on the appropriate APAS form AP-D194.
f) Training for a new Signatory may be delivered by either an existing Signatory or, in the case of a new Applicant, by the Lead Auditor during or immediately after the IAV. Records of the training shall be kept.

8.7 Issue of Certificate of Recognition

a) Following a response(s) to all audit ARA's to the satisfaction of the Lead Auditor, a recommendation for Recognition shall be made to the EO who will decide on whether Recognition is warranted.
b) If approved, a Certificate of Recognition, APAS document AP-C001, shall be issued by the Lead Auditor **provided that** all outstanding invoices have been paid.
c) The first Certificate of Recognition shall have an expiry date twelve (12) months from the date of the IAV.
d) Subsequent certificates, assuming there have been no significant issues or lapses detected, shall have an expiry date not more than twenty-four (24) months from the audit date.
e) Once Client Recognition is granted by APAS, products may be submitted against relevant product specifications, refer to APAS document AP-D192.

8.8 Subsequent Audits

a) Following the IAV, the first subsequent audit shall take place approximately twelve (12) months after the IAV or at such a date acceptable to both parties.
b) ARAs from the IAV that have not been adequately corrected or fully implemented into the manufacturing system, shall be upgraded to Major Non-Conformances and their resolution to the satisfaction of the EO shall be a condition of continuing Recognition. The determination of the acceptability of the corrective action(s) may require a Mini Audit (chargeable) in order to verify satisfactory implementation.
c) Where a first audit report after the IAV lists more than four (4) Major Non-Conformances, the EO shall

Suspend the application pending consideration by the ATAP on whether the application should be terminated.

d) The satisfactory resolution of the first audit subsequent to the IAV shall result in the RMU going onto a two-yearly audit cycle.
e) Depending on future audit performances, the EO may increase but not decrease the audit frequency so that APAS Member confidence in manufacturers is maintained.

9 POST-RECOGNITION REQUIREMENTS

9.1 System Changes

a) It is the responsibility of the management of the RMU and/or the APAS Signatory to inform APAS of any changes to:
   i. The range of APAS-certified products manufactured
   ii. The organisation, its ownership or management
   iii. The quality control system including technical personnel or responsibilities in the quality assurance function
b) Failure to do so may result in clause 10 below being implemented.

9.2 Surveillance Visits

a) Continuing compliance to APAS requirements is ensured through a system of ongoing audits or surveillance visits. The initial post-Recognition surveillance visit will take place typically twelve (12) months after Recognition. Subsequent surveillance visits will typically occur at twenty-four (24)-month intervals, assuming a satisfactory surveillance outcome previously.
b) The EO may decide that a more frequent surveillance program is warranted where there have been lapses in the system or breaches of compliance requirements deemed to be of a serious nature.

9.3 Proficiency Testing Program

a) In order to provide APAS Members with confidence that the technical aspects of the RMU's operations continue to be under a level of control sufficient to ensure continuing consistent product quality, a program of Proficiency Testing (PT) has been established for all laboratories that do not hold AS ISO/IEC 17025 accreditation.
b) APAS requires that laboratories **without** AS ISO/IEC 17025 accreditation participate in at least two (2) PT programs of four (4) tests per calendar year, at their own expense.
c) APAS requires that laboratories **with** AS ISO/IEC 17025 accreditation participate in one (1) PT program of four (4) tests every (2) two years, at their own expense, as per the requirements of maintaining their ongoing AS ISO/IEC 17025 accreditation once achieved.
d) Proficiency testing programs shall be conducted by agencies formally recognised as competent in conducting such services in accordance with the requirements of APAS document AP-D178.

9.4 Certification of Products

a) Once the Client's manufacturing facility has achieved RMU status, product(s) can then be submitted requesting certification to defined APAS specifications. Refer to APAS document AP-D192 for further instruction on the application process.
b) The timeframe between the attainment of RMU recognition and initial product submissions by the RMU is set at two (2) years maximum.
c) Should the RMU have extenuating circumstances and be unable to submit within this timeframe, the EO must be contacted, and their needs discussed on a case by case basis.
d) There may be manufacturing facilities that choose to obtain RMU status in order to produce products in a Toll / Contract manufacturing capacity (refer to clause 3.1 for definitions of Contract Manufacture and Toll Manufacture). If this is the case, these facilities must be considered on a case by case basis and a suitable timeframe between RMU attainment and product certification be determined by the EO in conjunction with the manufacturer.

10 WITHDRAWAL OF (RMU) RECOGNITION

10.1 General

a) When certain issues have been breached, the EO may withdraw Recognition from a Client. This withdrawal is a two-stage process: Suspension followed by Withdrawal.
b) Typical issues initiating such action are:
   i. Where the Client or any of its key members have been convicted of fraudulent or other criminal activity
   ii. Where in a civil case the Client, its products or any of its employees have been found to be wholly or partly responsible for any loss or damage due to a failure of a coating(s)
   iii. Where the Client has been placed in liquidation
   iv. Where the actions of the Client or any of its employees have brought the reputation of APAS or CSIRO into disrepute
   v. Where the Client has failed to comply with the basic principles under which APAS is established:
      - Any external accreditation such as AS/NZS ISO 9001 or AS ISO/IEC 17025 has been withdrawn; or
      - Failure to participate in proficiency testing; or
      - Failure to embrace the principles of continuous improvement.

vi. Where the Client persistently refrains from implementing lawful actions issued by the EO, for example audit corrective actions, continuous improvement actions, non-payment of accounts.
vii. Where the Client has more than one manufacturing site, all of which operate under a single corporate management system and where one or more sites have satisfied the condition(s) for Suspension of RMU status, production of APAS certified products at the offending RMU shall cease until the detected issue(s) is rectified (and the Suspension Notice is withdrawn).

c) Should the Suspension Notice be upheld and RMU status be Withdrawn, either:
   i. No further manufacture of APAS certified products shall occur at the offending site (but may continue at other site(s) or
   ii. APAS certification for all products continuing to be made at the offending site (and other sites) shall be withdrawn.
d) Under 10.1 c) above, RMU management or the former APAS Signatory shall promptly advise APAS as to the direction the Client intends to take with respect to manufacture of APAS certified products affected by the Withdrawal of RMU status.

10.2 Withdrawal Process

a) Where the EO believes that one or more of the issues in clause 10.1 above have been breached, a written Notice of Suspension shall be provided to the Client. The manufacturer shall have ten (10) working days to provide the EO with a case for closing the Notice of Suspension.
b) After ten (10) working days, the EO shall prepare a case for consideration by the ATAP detailing the circumstances of detection and issue(s) which caused the Notice of Suspension to be raised. The EO shall attach to the submission all documentation received from the manufacturer. The submission to the ATAP shall be distributed by the most expedient means.
c) The ATAP may request clarification or additional information, but within one (1) calendar month of receipt of the submission, the ATAP shall provide the EO with a recommendation for action. This shall comprise either:
   i. Uphold the Notice of Suspension
   ii. Reject the Notice of Suspension
d) The EO may vary the timing requirements (in clause 10.2 b) and c) above) depending on the calendar situation, for example Easter, Christmas etc.
e) All proceedings up to this stage shall be between the EO and ATAP only and shall be treated as Commercial-in-Confidence.

10.3 Withdrawal of Recognition

a) If the Notice is upheld, the EO shall advise the Client in writing and publish the Withdrawal of Recognition on the APAS website and to APAS Members.
b) Withdrawal shall be for a minimum of six (6) months.
c) Withdrawal shall simultaneously involve the retraction of all product approval certifications.
d) Should an existing RMU acting in a Toll / Contract Manufacturing capacity for the Client have its accreditation Suspended and / or Withdrawn, by extension, the Client utilising this service will also have this accreditation Suspended and / or Withdrawn.

10.4 Reinstatement of Recognition

a) Reinstatement shall only be considered at the conclusion of the period of Suspension.
b) Reinstatement shall be considered as a new application for Recognition and shall be initiated by the Client.

11 COMPLAINTS AND APPEALS

a) Clients may lodge a complaint or an appeal against a decision made by the APAS 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.

12 APPENDIX A

Document History

Status: Current
Version: 16
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Document Version No.:	Date Published:	Summary of Changes:
16	15-02-2022	• Updated contact information, references to other APAS documents, document links, timeframe for receipt of an audit report post-audit and requirements of PT relating to labs with ISO 17025 accreditation (in line with APAS document AP-D114)
15	03-08-2021	• Update of clause 7.3 regarding 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-D174
14	11-06-2021	• Updated APAS website details within document • Further defined clause 1 b) Scope • Replaced OH&S reference with WHS in clauses 3.2 and 6 a) v. • General formatting changes
13	04-02-2021	• Addition of clause 9.4 (timeframe between RMU status acquisition and the certification of product approvals) and general format changes
12	22-10-2020	• Addition of Appendix A Document History and removal of the Editorial Note previously used in document versions • Minor formatting changes • Updated clause 11 to reflect other APAS documents
11	25-09-2020	• Name change from *How Paint Manufacturers Participate in APAS®* to *Rules Governing How Product Manufacturers Participate in APAS®* • Document brought in line with requirements of AS/NZS ISO/IEC 17065 • Updated document to the current format • Incorporation of definitions and acronyms • Minor editorial changes • Addition of “People + Product = Protection” to Footer
10	03-05-2016	• Undergone a major revision in line with ISO 17065 requirements
9	10-05-2013	• Corrects references in section 7
8	06-01-2009	• New document format • Incorporates changes to section 7 as agreed at APAS66
7	08-11-2005	• Clarifies Recognition requirements in clause 1 • Corrects contact fax number.
6	06-06-2005	• Reflects the new Scheme Ownership by CSIRO
5	30-09-1999	• Changes aimed at removing duplication of auditing quality systems between APAS, NATA and ISO9000 auditors as it already is a part of ISO9000 • References to Quality Manuals etc have been deleted • References to Product Approvals have been moved to a new document (D192) • Improved explanation of how APAS operates