

Appendix 9 RULES and REGULATIONS

Terms and Definitions

“Client”.

An applicant for certification or an organisation certified by Assured Origin Ltd. (AO) t/as Print and Media Certification (PMC), or organisation whose certification has been suspended, withdrawn or terminated.

1. Certification Scheme

In order to obtain and retain certification all applicants to the scheme must adhere to the following rules and regulations of the scheme.

All information deemed necessary by AO in order to complete the initial audit programme should be made available by the applicant prior to the assessment. This should include corporate entity, name, address, legal status and relevant human and technical resources, as well as general information concerning the company relevant to the assessment. A description of the system(s) intended to be certified or already certified should be provided and the standards or other normative documents applicable.

The client shall make all the necessary arrangements for the conduct of an assessment, including the examination of documentation, access to all relevant equipment, locations, areas, records, internal audit reports, personnel and subcontractors, and should do so for the purposes of product testing, assessment, surveillance, re-assessment and investigation of complaints. Following initial audit, all audits must be scheduled to occur within a maximum of one year from the date of the previous audit, unless authorised by AO.

AO shall be responsible for all actions of assessment and certification, from the initial audit of the client's system through periodic surveillance visits and re-assessment and monitoring of product conformity for BPIF colour management scheme.

AO shall inform the client of the audit results and if not satisfied that all the requirements for the certification are being met, shall inform the client of those aspects in which the application is deemed non-compliant.

When the client can demonstrate that effective correction/corrective action has been taken to meet all the requirements within the specified time limit, AO will review the correction/corrective action and determine the suitability of awarding or maintaining certification.

For all corrective action requests (CARs) raised at either initial, surveillance or recertification audits, special audits, or at any other time, the client shall respond appropriately to these requests within 30 working days from the date of the request. Mitigating circumstances may apply in exceptional cases.

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All certificate holders will be entitled to provide feedback and suggestions relating to the potential areas for improvement. AO reserves the right to make minor changes and corrections to these Rules & Regulations without prior notification. Clients will be given 1 month notice of any changes that affect their responsibilities or liabilities.

The client shall ensure that the question of responsibility to AO for the system is clearly defined, e.g. by appointing a designated person who is nominated to maintain contact with AO to ensure that the above provisions have been observed.

The client shall permit scheme accreditation representatives all reasonable access for the purpose of observing AO's auditors performing initial, surveillance, re-certification or special audit activities. The client shall permit access for trainee auditors, technical experts and/or observers at initial, surveillance, re-certification or special audit activities.

2. Product Certification-BPIF Colour Management 12647 scheme

The client agrees to comply with the relevant product certification scheme requirements and shall implement any changes to requirements and/or as notified by AO. Clients shall ensure that ongoing production and certified products continue to meet the requirements of the product certification scheme.

In making reference to its product certification, the certified client shall ensure that communication media such as documents, and promotional material comply with the requirements of AO, and the certification scheme.

3. Initial Audit for Certification

Initial audits shall be conducted against the applicant's systems and procedures, and the requirements of international management system standards or other relevant normative requirements, for product certification, according to the certification scheme requirements, and any applicable legislation.

4. Certification

When an initial audit has been completed, and the applicant's systems are deemed to be satisfactory and product conformity has been demonstrated if appropriate, AO shall inform the applicant accordingly and issue a certificate.

Surveillance frequency will be stipulated as either once or twice yearly, but additional visits may be conducted at the discretion of AO, or as a result of changes in client location(s) or other changes, changes to the scope of certification, customer complaints, or follow up audits for suspended clients.

The certificate is valid from the date of issue, subject to successful surveillance, re-assessment every 3 years, and where required by the certification scheme, demonstration of ongoing product conformity.

The certificate will remain the property of AO and shall be returned on request.

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All clients shall maintain a record of all complaints they receive which fall within the scope of the certification, for which a certificate has been awarded. Full records of complaints shall be made available to AO assessment staff or scheme management when requested. Appropriate corrective action with regard to complaints or failures in product conformity shall be taken and recorded. All clients should make available records of measurement data for product conformity, as specified by AO, and records of conformity of relevant product measuring equipment.

Following an initial assessment, surveillance assessment or recertification assessment, the client should respond to any Corrective Action Requests within the timescale specified by the auditor. Delays beyond this date would result in non-issue of a certificate (for Initial Assessment) may result in Certificate suspension (for surveillance assessments) or Certificate expiry (at re-certification stage). In these circumstances, additional, Special Audits may be required.

Special Audits may be conducted by AO in the following circumstances:

- Extension to scope (see clause 5 below)
- In the event that there are Corrective Action Requests that require an on-site visit to verify the corrective action/s
- In the event that a certification has expired and that an on site visit is necessary to verify the corrective action/s. Delays in closing Corrective Action Requests beyond a 6 month time period for an expired certificate will require an initial re-assessment.
- Non-response by the client to Corrective Action Requests 6 months beyond the date raised.

5. Extending Certification

A client wishing to extend its certification scope to cover additional processes, presses, services or sites shall apply to AO in writing. AO shall review the nature of extension and decide on the necessary audits to be performed.

6. Publicity by Certificate Holders

A certified client has the right to publish that a member of AO has audited the process, service and organisation and apply a AO mark to promotional materials for which the certificate applies. The instructions governing the use of certification marks and accreditation symbols will be supplied by AO either via AO's Internal Management system (IMS) before downloading the AO/PMC Certificate/Certification Marks/UKAS Accreditation Symbols artwork.

Each client has to agree and accept the Instructions (via IMS) or sign the instructions and return to AO upon, and prior to any use of the AO/PMC marks or UKAS symbols. The client agrees to comply with these instructions, and any licensing agreement with AO for the use of any certification marks or symbols. The instructions and any licensing are available for applicants on request from AO. For product certification, the client shall make the relevant and appropriate product conformity claims as required by the relevant standard's or other normative document's requirements.

In every case, the client shall take sufficient care of its publications and promotional material so that no confusion arises between certified and non-certified product, presses, processes, and/or services, as appropriate.

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The client shall only make claims consistent with the scope of the certification and shall not make any incorrect, misleading or unauthorised claims or statements regarding its certification, or claims or statements which could indicate that a product, process, production method, equipment, service, or site is included in the scope of the certification, when in fact it is not.

In the event of a reduction in the scope of certification, the client will amend all promotional material referring to the certification accordingly

In the event of suspension, withdrawal or termination of certification, the client shall discontinue its use of all promotional material that contains reference to its certification, and take action required by the certification scheme and any other measure required by AO.

The client shall not use its certification in such a manner that would bring AO and/or its certification system into disrepute or to lose public trust.

7. Confidentiality

AO shall endeavour to ensure that its employees and agents maintain as confidential, all information with which they become acquainted as a result of their contact with the client.

The client allows AO to verify with the issuing organisation any certificate or other conformity document (issued or claimed to be issued) that is presented to AO as evidence of conformity. Such contact will be confined to validation of any conformity document. No information obtained following this verification will be placed in the public domain.

If AO is required by law to release confidential information, then AO will inform the client in advance, including notification of the information to be provided. Client information will be made available to UKAS for accreditation purposes and is subject to a confidentiality agreement between UKAS and AO.

8. Use of Certificates

AO shall take all reasonable precautions to control the use of its certificates. Incorrect references to certifications, product conformity or misleading use of certificates found in promotional material, advertisements, catalogues, etc. shall be dealt with by suitable actions, which could include legal or corrective action or publicising the transgression. Clients are invited to report to AO any misuse of AO/PMC's marks that comes to their attention. The source of all information received will be treated in confidence.

If the client provides copies of certification documents to other third parties, then the certification documents shall be reproduced in their entirety or as specified by the certification scheme

9. Suspension of Certification

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The certificate applicable to a specific process, press, service, site or organisation may be suspended for a limited period, for example in the following cases:

- if the surveillance or re-audit shows non-compliance with the requirements which are of such a nature that immediate withdrawal is not necessary
- if there is a minor or isolated failure of product conformity
- if a case of improper use of the certificate, e.g. misleading prints or advertising, is not solved by suitable retractions or other appropriate remedial measures by the client
- if there has been any other contravention of these rules and regulations
- if corrective action requests (CAR's) have not been implemented within specified time scales
- if the surveillance or re-certification audit is delayed by more than 1 month beyond due date
- if the client voluntarily requests suspension
- if the client fails to comply with the due settlement of its financial obligation to AO or its agents

The client shall not claim as certified any product, process production method, equipment, service, or site, for which a suspended certificate applies.

AO will confirm an official suspension of the certificate to the client and indicate under which conditions the suspension shall be removed.

At the end of the suspension period, an investigation will be carried out to determine whether the indicated conditions for reinstating the certificate have been fulfilled. On fulfilment of these conditions the suspension shall be removed by notifying the client that the certification has been reinstated.

If the conditions are not fulfilled, the certificate shall be withdrawn.

All costs incurred by AO, in the suspending and reinstating of certificates will be charged to the client. Time will be charged at assessment fee rates (pro rata).

10. Withdrawal/Termination of Certificate/ Reduction in scope of certification

A certificate may be withdrawn in the following cases:

- if the surveillance or re-audit, or other assessment activity, shows that the non-compliance or failure of product conformity is of a serious and persistent nature
- if the surveillance or re-certification audit is overdue for specified time scales
- if the client fails to comply with the due settlement of its financial obligation to AO or its agents
- if inadequate measures are taken by the client in case of suspension
- if any actions are taken by the client which would bring the AO's scheme into disrepute

In the above cases AO has the right to withdraw the certificate and inform the client and the Impartiality Team.

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AO may reduce the scope of certification to exclude parts not meeting certification requirements, where the client has persistently or seriously failed to meet the requirements for those parts being excluded.

The client shall have the right to appeal.

Certificates will be cancelled in the following cases: -

- if the client does not wish to continue to maintain certification to the scheme.
- if the product, process or service is no longer offered
- if the client ceases trading for whatever reason

11. Corrective Actions

When AO receives a report of certificate misuse the report shall be investigated. If misuse is substantiated, the certificate holder shall pay the cost of the investigation. Investigation costs will be charged at assessment fee rates (pro rata).

AO will determine the scope of misuse and the type of corrective action to be undertaken.

12. Complaints against AO

Should a client have cause to complain regarding the conduct of AO's staff, the complaint should be made in writing and addressed to the Director of AO. Should the complaint be made against the Director, the letter of complaint should be addressed to the Colour/Certification Manager.

13. Appeals Procedure

Notification of failure to comply with the requirements of certification may be given for, but not limited to, the following:

- deficiencies in management systems or, if appropriate, lack of product conformity observed during initial audit, or surveillance visits, or at any other time, revealing non-conformity with certification requirements.
- misrepresentation or misuse of certification
- misrepresentation or misuse of the UKAS Accreditation symbols or AO certification marks

The client has the right to appeal against any notification given.

Notification of an organisation's intention to appeal must be made in writing and must be received by a Director of AO within fourteen days of notification of failure to comply with the certification requirements.

All appeals shall be submitted to the Impartiality Team. AO will submit evidence to the Impartiality Team regarding any decision to issue a notice of suspension or withdrawal.

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The client has the right to object to involvement of particular members of the Impartiality Team in the appeals procedure if evidence can be provided that their impartiality is compromised. The appellants also have the right to present their case in person at their own expense.

The decision of the Impartiality Team shall be final and binding on both the organisation and AO. Once the Impartiality Team has made a decision regarding an appeal, no counter claim by either party in dispute can be made to amend or change this decision. Decisions on appeals will be made within 3 months of receipt of the appeal.

In instances where the appeal has been successful and the award made or reinstated, reimbursement of costs of appeals will only be made at the discretion of the Impartiality Team.

14. Changes to Systems, Organisation, Production Methods, Product Specification/Technical Files (13485) and processes. (See also clause 17)

All clients are required to keep their system documentation up-to-date and to notify AO without delay, of any changes that may affect the capability of the management system to fulfil the requirements of the standard or other normative requirements, or to maintain product conformity. This includes changes to the organisation's systems, technical files, products, product specifications, materials, processes, production methods and equipment, contact addresses, site locations, structure, status or ownership. In particular any changes which may affect the scope of certification or which result in a new appointment to the position of Management Representative must be reported. AO must be notified of all major changes made to the management system.

15. Disputes

Any disputes subject to legal proceedings will be settled in accordance with English Law.

16. Fees

Commercial arrangements are also detailed in contracts or other agreements between AO, or its agent, and the applicants or clients. AO shall be entitled to charge fees at a level to be determined from time to time having regard to its operations, administration and other costs. The monthly charged fee or annual fees are non-refundable. Clients will be notified in advance of any change in fees.

Annual Fees will be invoiced in advance upon receipt of application for initial assessment or up to 60 days in advance of the annual surveillance/recertification audit. Annual fees are due prior to audit in order to confirm the audit dates.

For the monthly option, payments must begin in the month of initial assessment and must be paid each month thereafter. We require that standing orders should be set up without an expiry to avoid a lapse in payments.

AO also reserves the right to charge interest at 1.5% per month on unpaid bills. Prices will be reviewed annually in January each year and will be increased based on the RPI (RPI figure used is the December annual RPI index figure as defined by the office of national statistics, rounded up or down the nearest £10).

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Cancellation fees are charged as follows:

For cancellation of more than 1 month’s notice-No charge of assessment fees

For cancellation of less than 1 month’s notice-100% of assessment fees

Reimbursement of any expenses already incurred (e.g. overnight accommodation/flights/rail tickets etc., that are already booked and cannot be refunded) will be charged to the client in full.

All additional work undertaken arising from non-conformances being identified, e.g. unscheduled special audit/s will incur additional costs at the current quoted rates plus expenses (necessary accommodation/subsistence and mileage charged at 45p/mile and other travel expenses at cost) and shall be invoiced separately. Costs are based on the charged fee rate applicable at the time of submitting the proposal.

The Client agrees that for the monthly payment option any cancellation or lapse of the standing order is subject to an administration fee of £30 for each month or part month where payment has not been received and for each month thereafter until the standing order is re-established. Back payment of missing monthly instalments will still be due.

The Client agrees that when certification ceases for any reason they are required to cease using AO certification marks and UKAS accreditation symbols within one calendar month of notification. AO will monitor websites/other uses monthly and any client found to still be using the AO certification marks and UKAS accreditation symbols will be informed by email and be liable for an administration fee of £75 for each instance reported to the client.

In the event of suspension or withdrawal of certification for a client paying on a monthly basis the client will settle the outstanding sum for the remainder of the annual fees and expenses.

Other charges specific to a particular certification scheme will be defined in the proposal terms and conditions.

17. Additional Contractual Requirements for Medical Devices

The below are not exclusive lists and these requirements are designed to cover any adverse, significant or risk-based changes, development of its products or product family. It is not intended that minor changes be communicated in every instance. Communications shall be timely and in writing.

The client agrees to:

- Inform AO of any active/interested parties of which it is associated or becomes aware. These may include manufacturers or manufacturer associations, non-governmental organisations (NGOs), Regulatory Authorities or other organisations and users/user groups
- Inform AO of any reports, concerns or feedback of which it is or becomes aware relating to the efficacy or safety of its products including advisory notices, post market surveillance, recall or similar
- Inform AO of any notification to the Regulatory Authority of any incidences that require reporting or other interested party
- Inform AO of any adverse clinical or performance evaluation

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- Accept unannounced or short announcement audits consequent to communications received from Regulatory Authorities, from the client itself, other interested parties
- Assured Origin, where required, shall provide information about certifications granted, suspended or withdrawn to the appropriate Regulatory Authority
- Accept costs and expenses consequent of any necessary investigation or additional audit activities

Further, the client agrees to inform AO of any changes to its:

- Raw materials, components, products, packaging, their specification/s or variations or supply base changes
- New products or developments involving changes to product categories, technical areas or risk class of medical devices, materials, components or subassemblies
- Operations including changes to processes, manufacturing equipment, work environment, outsource operations, significant expansion or contraction of business activity, sites involved in manufacturing or storage
- Company ownership, legal status, management structure, employee competence/s, changes to Compliance management staff, management representative

The client commits to meeting all applicable legal compliance in the market/s in which it operates and to inform AO of any breach of legislation or material and significant “near miss”.

18. Signatories

I HEREBY ACKNOWLEDGE RECEIPT OF THE RULES AND REGULATIONS AND AGREE TO BE BOUND BY THEM. CERTIFICATION WILL ONLY BE ISSUED WHEN THIS DOCUMENT HAS BEEN SIGNED AND RETURNED TO ASSURED ORIGIN LTD.

SIGNED (authorised representative)	
POSITION	
NAME	
ORGANISATION	
DATE	

Please return signed Rules and Regulations to:
 Client Services Manager,
 Assured Origin Ltd.
 84 Main Road,
 Wigginton,
 Tamworth B79 9DZ