Scheme Manager (Management Systems)

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1. Introduction

These Scheme Rules have been written in accordance with the requirements of the applicable IAF Member National Accreditation Bodies under Accredited Certification Schemes. **International Associates Limited**, hereafter known as "**International Associates**" also comply with all conditions. These Scheme Regulations form a part of the contract with each client as stated on the quotation.

2. Scope

International Associates provides independent third-party assessment and registration services for companies who have implemented management systems against the following standards: Quality Management Systems (ISO 9001), Medical Devices Quality Management Systems (ISO 13485), Environmental Management Systems (ISO 14001) and Health & Safety Management Systems (ISO 45001).

3. Confidentiality

a) **International Associates** agrees not to disclose any information relating to the client's business or affairs except information, which is in their possession before the date of acceptance of the **International Associates** quotation/contract.

b) Where information is required to be disclosed to a third party either by law or as required under maintenance of certification by an Accreditation Body, the client shall be informed of the information as required by law.

c) For the purposes of registration verification, information contained on all issued certificates can be verified using the registration number shown on the certificate from the certification check on the **International Associates** website which is located at the following URL http://www.ia-uk.com

4. General Conditions

International Associates basic conditions for gaining and maintaining registration with are that all applicants agree to and comply with the following rules:

a) All information deemed necessary by **International Associates** to complete the registration process shall be made available to the applicant company.

b) If **International Associates** are not satisfied that all requirements for registration have been met it shall inform the applicant in writing stating which requirements.

c) When the applicant can demonstrate that effective corrective action has been taken within a specified time limit, then International Associates will arrange only to repeat necessary parts that cannot be verified by the submission of documented evidence.

d) If the applicant fails to take effective corrective action within the time limit, then **International Associates** may repeat the audit in full at additional cost.

e) Identification of conformity shall only apply to the site(s) audited and within the scope of registration as shown on the **International Associates** certificate of registration.

f) All fees must be paid as shown on the individual quotation. No certificate shall be issued for initial assessment or re-assessment until fees have been paid in full. Registration may be suspended if annual fees are not paid in full within the time frame set out in the individual quotation.

g) For the registered company to demonstrate effective management reviews and internal audits, these activities shall be carried out at a frequency of no less than once per year.

h) Failure to return all certificates of registration shall result in legal action being taken against the company for unauthorised use or registration and accreditation marks and on misleading and inaccurate claims of registration.

i) The applicant must allow **International Associates** to conduct on-going surveillance visits at the times stated within the individual quotation.

j) **International Associates** offices which hold national accreditation directly with a national accreditation body or hold "critical location" status are responsible for and retain authority for, decisions relating to accredited certification, including the granting, maintaining, renewing, extending, reducing, suspending and withdrawing of certification.

k) The management representative must be made known to **International Associates** and should there be a change of management representative then **International Associates** shall be informed in writing.

5. Application for Assessment

On receipt of a completed Application for Quotation Form **International Associates** will conduct a pre-contract review of the system and a quotation shall be

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prepared and sent to the prospective client, together with these Scheme Rules.

6. Contract Acceptance

Prior to any arrangement being made for an assessment, the quotation is required to be signed by the Client. Signature on the quotation/contract indicates formal acceptance of these rules as stated within the quotation/contract.

7. Initial Assessment

The initial assessment is conducted in two stages, which are specified below:

a) Stage 1 Visit

Is an audit carried out on-site at the client's premises. The objectives of this visit are as follows:

i. to audit management system documentation.

ii. to evaluate the location, site-specific conditions and to undertake discussions with personnel.

iii. to collect information related to the scope of application and related statutory and regulatory requirements.

iv. to evaluate if management reviews and internal audits are being planned and performed to determine preparedness for the stage 2 audit.

v. to produce a process-based audit plan for the stage 2 visit.

Only when it has been determined that the applicant company is prepared for the stage 2, shall a date be agreed for that visit.

b) Stage 2 Visit

Is an audit carried out on-site at the client's premises to evaluate the effectiveness of implementation and covers:

i. information and objective evidence regarding the standard.

ii. performance monitoring, measuring, reporting and reviewing key performance objectives and targets.

iii. the management system performance regarding legal compliance.

iv. operational control of the management system processes.

v. internal audits and management reviews.

vi. management responsibility for policies.

vii. links between policy and legal requirements, the competence of personnel, operations, procedures and data.

All audits are based upon sampling and therefore not a guarantee of 100% conformity with the standard. Therefore, it is critical that effective internal audits are conducted on an on-going basis by the applicant company.

For all high-risk areas where there can be a direct risk to human health, safety and well-being the audit team may be required to take photographs to provide evidence of effective implementation of safety measures. All such photographs shall remain confidential.

8. Certification

a) On completion of the on-site assessment the lead auditor reports back to **International Associates**. The File Reviewer of **International Associates** shall review the report and support information, including the recommendations made by the lead auditor and decide whether to grant certification.

b) For any non-conformities raised, the client shall conduct root cause analysis and send details of corrections, corrective action and preventive action to **International Associates** within 30 days from the last day of the assessment visit. This information shall be reviewed by a qualified lead auditor and the client shall be informed of the result via email and/or have access via the **International Associates** client portal.

c) Upon acceptance of the proposed actions, the File Reviewer shall review the full report and make a decision on certification on behalf of the impartiality committee. Should the File Reviewer not accept the report the impartiality committee shall be informed for the purpose of holding an internal appeal.

d) The certification shall only remain valid based on continued conformity by the registered client. For any non-conformity or other situation that may lead to suspension, the lead auditor shall report to International Associates and the suspension process shall take effect as defined within these rules.

9. Surveillance

a) After the issue of the certificate of registration, surveillance visits shall be carried out at the client's premises. If substantial areas of concern are identified, then extra visits may be scheduled at the discretion of the File Reviewer.

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The client agrees to meet the extra costs relating to such additional surveillance. Should surveillance not take place when required then registration shall be removed and published in the public domain. Surveillance audits shall be conducted at least once a year. The date of the first surveillance audit following initial certification shall not be more than 12 months from the last day of the Stage 2 audit.

b) For any non-conformities raised, the client shall conduct root cause analysis and send details of corrections, corrective action and preventive action to **International Associates** within 30 days from the end of the surveillance visit.

c) The certificate holder shall allow **International Associates** the right of access for the purposes of maintenance of certification.

10. Re-Certification

a) A re-certification audit shall be planned and conducted at the client`s premises to evaluate the continued fulfilment of all the requirements of the relevant management system standard.

b) For any non-conformities raised, the client shall conduct root cause analysis and send details of corrections, corrective action and preventive action to **International Associates** within 30 days from the end of the re-certification visit. In all cases where non-conformities have been raised timescales for corrections and corrective actions to be implemented shall be prior to the expiry of the certificate.

c) Prior to a review being undertaken by the File Reviewer, the details sent by the client shall be reviewed by a qualified lead auditor. The client shall be informed of the results of this review via email and/or the **International Associates** client portal.

d) The File Reviewer shall then review the full file and decide whether to accept the lead auditor's recommendations. Should the File Reviewer accept the actions supplied and the report, then the certification shall be granted. Where the File Reviewer does not accept the report, then the impartiality committee is informed for the purpose of holding an appeal hearing.

e) All re-certification visits shall be carried out prior to the expiry date of the current certificate. Any non-conformity raised at the re-certification visit shall be closed out prior to a new certificate being issued.

f) The decision on whether to grant re-certification shall be based upon the audit results over the period of certification plus complaints from users.

11. Use & Misuse of Certificates, Logos & Certification

Once a Certificate has been issued, then the client has the right to publish the fact and to apply the logo on their stationery and promotional material.
The marks can only be used as specified in clause 23 of these Scheme Rules. Other conditions are as follows related to certification:

a) That no misleading statements are implied or made regarding certification.

b) That no certification document is used in a manner that would mislead clients or registered companies or the public in general.

c) Upon suspension, withdrawal or cancellation cease with immediate effect to use of the marks on advertising, such as brochures, letterheads, business cards, websites, etc, and return the certificate to **International Associates**.

d) Should a scope of registration be reduced, amend all advertising materials where details of the scope have been published. For all reductions or increases in scope the original certificate to be returned to **International Associates**, prior to any updated certificate being issued.

e) That nothing is implied, or an impression is given that certification activities are outside of the scope of certification.

f) Not to use certification in any way as to bring into disrepute the credibility of **International Associates** or of Accredited Certification that could affect public trust and confidence.

12. Suspension, Scope Extension, Scope Reduction & Withdrawal

Following a successful assessment and subsequent Certification of a Client's System to the relevant Management System Standard. Some of the following activities may apply as follows:

a) Suspension

i. as a result of continued misuse of a certificate or logo.

ii. failure to implement corrective action within the specified time scale as a result of concern identified at Assessment, Surveillance or Re-Assessment visits.

iii. any other breach of the **International Associates** quotation and/or Rules of Registration.

iv. when a major non-conformity is raised during any visit, after the original Assessment.

v. under suspension, it is not permitted to use any logos on any advertising materials until the suspension has been lifted.

vi. the File Reviewer of **International Associates** shall write to the registered client outlining the suspension conditions and how the suspension can be lifted.

vii.

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b) Scope Extension

For all extensions, to scope, the registered client must make a request to **International Associates** in writing. The request shall be reviewed, and a new quotation sent out. Upon acceptance, **International Associates** shall decide the action required to verify and validate the scope extension.

c) Scope Reduction

Reductions to scope could be a result of an initial assessment, which shall be confirmed by the assessment report. Should a reduction in scope be recommended by an **International Associates** Lead Auditor at a surveillance or re-assessment visit this must be noted in the report and the File Reviewer informed.

d) Withdrawal

Such withdrawals could be as a result of:

i. failure to respond to requests/time scales made by **International Associates** after suspension of Certification.

ii. failure of a client to settle an account with **International Associates** within 1 month of formal notification of a failure to settle an account.

iii. voluntary withdrawal, in such a case **International Associates** require this in writing.

iv. the certificate of registration shall be returned to **International Associates** when **International Associates** has informed the client that withdrawal has been completed. No copies of certificates shall be used, or logos displayed after withdrawal has taken place.

13. Appeals

If the client is not in agreement with the Lead Auditor's recommendation after an Assessment, Surveillance or Re-Assessment then they are at liberty to lodge an appeal with the Quality Manager of **International Associates**. The Client shall support his reasons by objective evidence.

All appeals will be heard by a Sub-Committee of the **International Associates** Impartiality Committee. The Sub-Committee may hear evidence from the client's representative and the Lead Auditor. The decision of the Sub-Committee is final and binding on both the Client and **International Associates**. No counterclaim will be allowed by either party. No costs, for whatever reason, will be allowed to either party as a result of an appeal.

14. Complaints

a) General Requirements

All clients are required to maintain a log of all customer complaints raised against them. This log must be available for review during all Assessment and Surveillance Visits. This log shall also be available to **International Associates** Staff upon request.

b) Complaints from Clients Regarding Auditors

If a client has a complaint about the conduct of any **International Associates** Auditor, then this should be sent in writing to the **International Associates** Quality Manager. If the complaint involves the Quality Manager or File Reviewer, then the complaint is to be addressed to the Chairman of the Impartiality Committee of **International Associates**.

c) Complaints from Users of Clients Products & Services

For complaints received from users of clients' products and/or services shall be lodged and then acknowledged to the complainant. Follow-up shall then be taken with the registered company in question.

15. Witnessed Visits

As part of the on-going surveillance of **International Associates**, the client agrees to allow representatives from national accreditation bodies the right to witness **International Associates** conducting their audit duties. The fact that an Accreditation Body representative attends an audit will not affect the audit. Also, from time to time **International Associates** may have to have trainee auditors or internal audits on an assessment team.

16. Short Notice Audits

For clients that have been suspended or where **International Associates** has received complaints then a short notice audit may be required for follow-up and verification/validation of the implementation of corrective and preventive measures. In such cases, the client agrees to co-operate with International Associates audit team members and allow the required access.

For ISO 13485 short notice audits may take place for the following reasons:

a) external factors apply such as:

i. available post-market surveillance data known to **International Associates** on the subject devices indicate a possible significant deficiency in the quality management system.

ii. significant safety-related information becoming known to **International Associates**.

iii. significant changes occur which have been submitted as required by the regulations or become known to **International Associates** and which could affect the decision on the client's state of compliance with the regulatory requirements.

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The following are examples of such changes which could be significant and relevant to **International Associates** when considering that a special audit is required, although none of these changes should automatically trigger a special audit:

i) Impact and changes:

- new ownership
- extension to manufacturing and/or design control
- a new facility, site change
- modification of the site operation involved in the manufacturing activity (e.g. relocation of the manufacturing operation to a new site or centralising the design and/or development functions for several manufacturing sites).
- new processes, process changes
- significant modifications to special processes (e.g. change in production from sterilisation through a supplier to an on-site facility or a change in the method of sterilisation).
- Key management personnel.
- modifications to the defined authority of the management representative that impact quality management system effectiveness or regulatory compliance.

ii) Products/Service categories:

- new products/service categories
- addition of a new device category to the manufacturing scope within the management system.

Iii) Management system & related changes:

- Changes in standards, regulations.
- Post-market surveillance, vigilance

An unannounced or short-notice audit may also be necessary if **International Associates** has justifiable concerns about implementation of corrective actions or compliance with standard and regulatory requirements.

17. Terms of Payment

Payment shall be made in accordance with the individual invoice and the quotation/contract document.

18. Indemnification

In respect of any claim, loss, damage or expense however arising, **International Associates'** liability to the client shall in no circumstances exceed the amount of **International Associates**' fees paid by the client. Under no circumstance shall **International Associates** be liable for any consequential loss.

19. Impartiality

International Associates or any **International Associates** representative shall **NOT**:

a) provide management system consultancy which includes preparation or production of manuals or procedures, or give specific advice, instructions or solutions towards the development, structure and implementation of a quality management system, environmental management systems and food safety management system.

b) allocate auditor(s) for a client in where provided internal audit, hazard analysis, or other related management system consultancy on the management system, within two years following the end of the consultancy.

c) certify a management system on which it provides any consultancy or offer certification when relationships that threaten impartiality cannot be eliminated or minimised.

d) certify another certification body for management systems.

e) certify a client when a relationship with a management systems consultancy poses an unacceptable threat to impartiality. Provide an internal audit service to any certified clients.

f) outsource any audits to a management consultancy company involved in management systems as described with the scope of these scheme rules.

g) have within any marketing materials any linkage to management system consultancy.

For any threats to impartiality that are discovered or reported, then the impartiality committee shall be informed, and responses shall be made and communicated.

20. Intellectual Property

The ownership of all issued audit reports remains the property of **International Associates**.

21. Organisational & Management System Changes

Should there be any significant changes to the client organisation such as change of address, ownership, scope or management representative then **International Associates** should be informed as soon as it is practical to do so.

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Such changes will be reviewed and may require follow-up at the next scheduled surveillance visit.

22. Amendments to Scheme Rules

a) The Impartiality Committee of **International Associates** reserves the right to amend these Scheme Rules without prior notification. Should the Scheme Rules be updated the latest version shall be put on the website and all clients informed.

b) The client should record the Scheme Rules as an "external document" within their management system for document control.

23. Use of Certification Marks

Only **International Associates** certificated clients are authorised to use the certification marks, whilst registration is active, under the following conditions:

a) Holders of certificates issued by **International Associates** may use the appropriate logo in accordance with the requirements of these scheme rules on stationery and publicity material or other items relevant to the certificate of registration.

b) That when accredited, the client shows the logo issued by International Associates, that is, the IA logo on the left and the UKAS logo & accreditation number below it, and both are enclosed in rectangle. (See Figure 1)

c) Embossed, relief or die-stamped versions may be used. The marks may also be produced as water marks if clarity is maintained. Electronic reproduction of the marks is permitted provided that the organisation's certificate number is shown for traceability and verification purposes and that the logo only relates to information on the certificate of registration.

d) Reversed image versions of the accreditation marks are allowed. When the marks are printed on an advertising or stationery the marks shall be no less than 20mm in height, however, regardless of the minimum height restriction all logos shall be legible.

e) The marks must always be shown next to the **International Associates** logo. The accreditation body logos are not permitted to be displayed on their own without the **International Associates** logo both inside the outer box.

f) The logo is not permitted to be used on any product as this could be misleading and give the impression that the product has been approved under a product certification scheme.

g) The national accreditation marks shall not be used on vehicles and flags. No **International Associates** certificates are to be scanned and/or put on any website for reasons of brand integrity management. If additional certificates are required, then the client should request this in writing from **International Associates**.

h) Should certification be withdrawn or cancelled then the original certificate(s) must be returned to **International Associates**. From the date of cancellation, no websites can display the logo nor stationery be issued displaying the logo which could mislead clients and potential clients regarding the registration status. In cases of scope reduction or increase the certificate(s) shall be returned to **International Associates** for re-issue.

i) At all times certificate(s) remain the property of **International Associates Limited** and can be recalled upon request.

j) The certification marks shall not be used on laboratory test reports, calibration certificates and inspection reports.

24. Responsibility

The client shall be responsible for evaluation and legal compliance to be verified by **International Associates** and in cases of non-compliance the client shall show the appropriate action has been taken including notification to the Regulatory Authority. All complaints sent from the Regulator and received by Certified Clients shall be sent to **International Associates Limited** within 7 days of receipt

25. Openness

To increase confidence International Associates shall release client audit reports to Regulators and interested parties that recognise management system standard certification.

Figure 1: Logo example

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