

## 1. Introduction

These Scheme Rules have been formulated in alignment with the requirements of the relevant IAF Member National Accreditation Bodies under Accredited Certification Schemes. **ATC International**, referred to hereafter as "**ATC INTL**" also adhere to all specified conditions. These Regulations within the Scheme constitute an integral component of the agreement with each client, as outlined in the quotation.

## 2. Scope

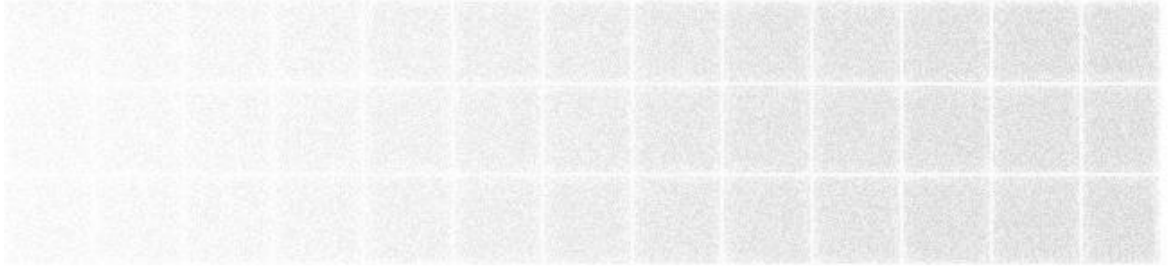
**ATC INTL** provides independent third-party assessment and registration services for companies who have implemented management systems against the following standards/codes of practice:

- Quality Management Systems (ISO 9001)
- Environmental Management Systems (ISO 14001)
- Medical Devices Quality Management Systems (ISO 13485)
- Occupational H & S Management Systems (OHSAS 18001 / ISO 45001)
- Food Safety Management Systems (ISO 22000)
- Energy Management Systems (ISO 50001)
- Information Security Management Systems (ISO 27001)
- Codex Alimentarius (HACCP)
- Good Manufacturing Practice (GMP)
- Anti-bribery management systems (ISO 37001)
- Quality Management – Customer satisfaction – Guidelines for monitoring & measuring (ISO 10004)
- Quality management - Guidelines for training (ISO 10015)
- Quality Management – Customer satisfaction – Guidelines for complaints handling (ISO 10002)
- Health safety and environmental management system (HSE-MS)

## 3. Confidentiality

- a) **ATC INTL** agrees not to expose any information relating to the client's business or affairs except information, which is in their possession before the date of acceptance of the **ATC INTL** contract
- b) Where information is required to be exposed to a third party either by law or as required under maintenance of certification by an Accreditation Body, The client will receive notification of the requisite information in accordance with law
- c) For the purposes of registration verification, details included on all issued certificates can be verified using the registration number displayed on the certificate from the certification check on the **ATC INTL** web site which is located from the subsequent to URL [www.atcintlgroup.com](http://www.atcintlgroup.com)

For ISMS, Prior to the certification audit, **ATC INTL** ask the client to report if any ISMS related information (such as ISMS records or information about design and effectiveness of controls) cannot be provided for review by the audit team due to it containing confidential or sensitive information. Based on these information, **ATC INTL** determine whether the ISMS can be adequately audited in the lack of such information. If the **ATC INTL** concludes that it is not possible to adequately audit the ISMS without reviewing the identified confidential or sensitive information, then the same shall be advised to the client that the certification audit cannot occur until suitable access arrangements are provided.



## 4. General Conditions

**4.1 ATC INTL** basic conditions for gaining and maintaining registration with are that all potential client consent to and comply with the following rules:

- a) All information considered essential by **ATC INTL** in order to complete the registration process will be accessible to the applicant company.
- b) If **ATC INTL** are not convinced that all requirements for registration have been fulfilled it shall inform the applicant in writing stating which requirements.
- c) After the applicant has proven evidence of effective Corrective action within the time frame that has been provided, ATC INTL will arrange only to reiterate essential components that cannot be verified by the submission of documented evidence.
- d) Should the applicant not implement effective corrective action within the time limit, then **ATC INTL** may reattempt the audit in full at additional cost.
- e) All charges must be settled as indicated in the individual quotation. No certificate shall be issued for initial assessment or re-assessment until all fees have been settled in full. Registration may be suspended if annual fees are not settled in its entirety within the specified timeframe outlined in the individual quotation.
- f) Identification of conformity shall only apply to site(s) audited and within the scope of registration as shown on the **ATC INTL** certificate of registration.
- g) For the registered company to illustrate proficient management reviews and internal audits these activities shall be carried out at a frequency of at least once annually.
- h) If the client will not return the certificates of registration then legal action will be taken against the company for unauthorised use of registration and accreditation marks and on misleading and erroneous assertions of registration.
- i) The applicant must grant **ATC INTL** to perform continuous surveillance audit at the specified times outlined in the individual quotation.
- j) **ATC INTL** offices which hold national accreditation directly with a national accreditation body or hold "critical location" status are accountable for, and maintain responsibility for, decision making related to accredited certification, including the granting, maintaining, renewing, extending, reducing, suspending and withdrawing of certification.
- k) The identity of the management representative must be disclosed to **ATC INTL** and In the event of a change in the management representative, **ATC INTL** must be notified in writing.
- l) For ISMS, The Client's shall make all necessary arrangements for the access to internal audit reports and reports of independent reviews of information security. During stage 1 of the certification audit, the client should provide at least the following information:
  - a) general information concerning the ISMS and the activities it covers;

b) a copy of the required ISMS documentation specified in ISO/IEC 27001 and, where required, associated documentation

- m) ISO 13485 mandates that the organization comply with the statutory and regulatory requirements applicable to the safety and performance of the medical devices. It is the responsibility of the client organization to maintain and assess legal compliance. **ATC INTL** is accountable for verifying that the client organization has assessed statutory and regulatory compliance and can demonstrate that appropriate actions have been taken. In cases of non-compliance with relevant legislation and regulations, including the notification to the Regulatory Authority of any incidences that require reporting.
- n) For ISO 13485, **ATC INTL** may release ISO 13485 related audit report information to interested parties/ regulators that recognize ISO 13485 certification.
- o) ATC International accreditation, or any of its reports, in no way, by themselves, constitutes or imply that end product or service is approved by Accreditation bodies

## 5. Application for Assessment

As soon as the receipt of a completed Application form by the client, **ATC INTL** will perform a pre-contract review of the system and a quotation will be drafted and forwarded to the prospective client, along with these Scheme Rules.

## 6. Contract Acceptance

Before any activity are made for planning an audit, the quotation shall be signed by the Client. Signature on the quotation/contract (Form P21/01) signifies formal acceptance of these rules as specified in the quotation/contract.

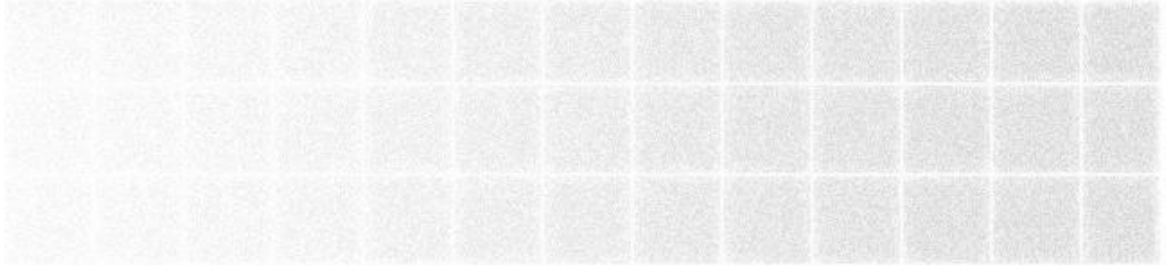
## 7. Initial Assessment

The initial assessment will be carried out in two stages, outlined as follows:

### a) Stage 1 Visit

When the audit is performed on-site at the client's facilities. The objectives of this audit are as follows:

- i. Audit of management system documentation.
- ii. Location evaluation, site specific conditions and to undertake discussions with personnel.
- iii. Gathering information related to the scope of activity and related statutory and regulatory requirements.
- iv. The management reviews and internal audits planned and carried out by the client, are executed to assess preparedness for the stage 2 audit.
- v. Gathering information to plan stage 2 as process based.



Date of stage 2 audit shall be agreed after confirming that the client is adequately prepared for it.

## b) Stage 2 Visit

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

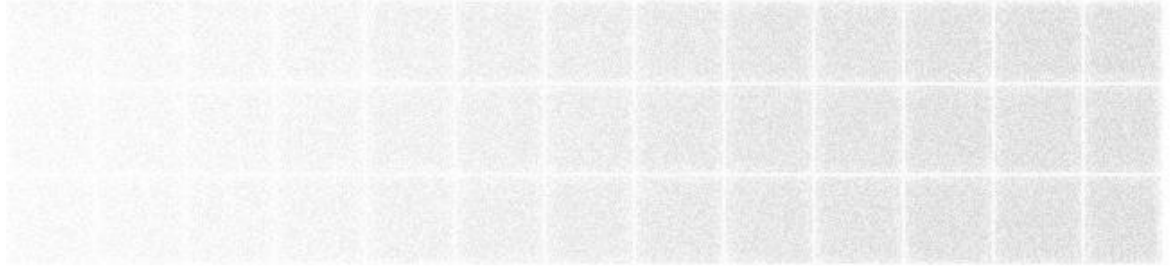
- i. information and objective evidence regarding to the audit criteria
- ii. performance monitoring, measuring, reporting and reviewing key performance objectives and targets.
- iii. the management system performance regarding legal compliance.
- iv. operational control of the management system processes.
- v. internal audits and management reviews.
- vi. management responsibility for policies.
- vii. links between policy and legal requirements, 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) Upon the conclusion of the on-site assessment the lead auditor reports back to **ATC INTL**. The File Reviewer of **ATC INTL** shall review the report and supporting 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 **ATC INTL** within 30 days from the last day of the assessment visit. This information shall be reviewed by a qualified lead auditor and the client will be notified of the outcome either through email.
- c) Upon approval of the proposed actions the Final Reviewer shall review the full report and make a decision on certification.
- d) Certification shall only remain valid on the basis of continued conformity by the registered client. For any non-conformity or other situation that may lead to suspension the lead auditor shall report to ATC INTL and the suspension process will accure as specified within these rules.

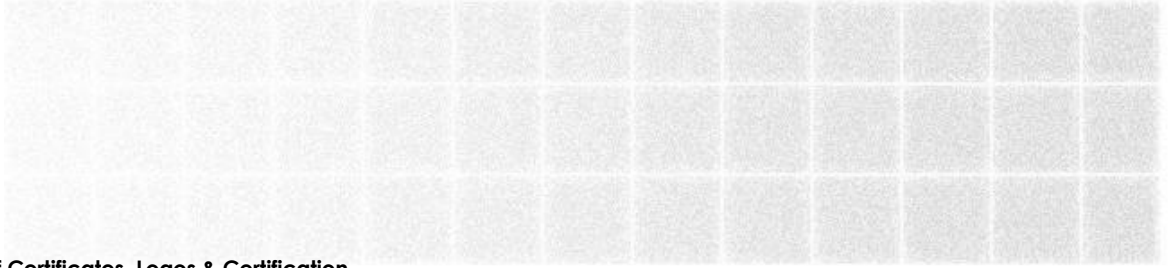


## 9. Surveillance

- a) After the issue of the certificate of registration, surveillance audit shall be performed at the client's premises. If significant areas of concern are identified, extra visits may be scheduled at the discretion of the File Reviewer. The client commits to pay the additional expenses associated with such extra surveillance. Should surveillance not take place when required then registration shall be removed and published in the ATC INTL website. Surveillance audits shall be performed at least annually. 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 **ATC INTL** within 30 days from the end of the surveillance visit.
- c) The certificate holder shall allow **ATC INTL** the right of access for the purposes of maintenance of certification.

## 10. Re-Certification

- a) A re-certification audit shall be scheduled and conducted at the client's premises to assess 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 **ATC INTL** 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 will occur before the certificate's expiration.
- c) Prior to a review being undertaken by the Final 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.
- d) The Final Reviewer shall review the file and determine whether to confirm the lead auditor's recommendation. Should the Final Reviewer accept the actions supplied and the report, then certification shall be granted.
- 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 & Mis-Use 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 with clause 23 of these Scheme Rules. Other conditions are as follows related to certification:

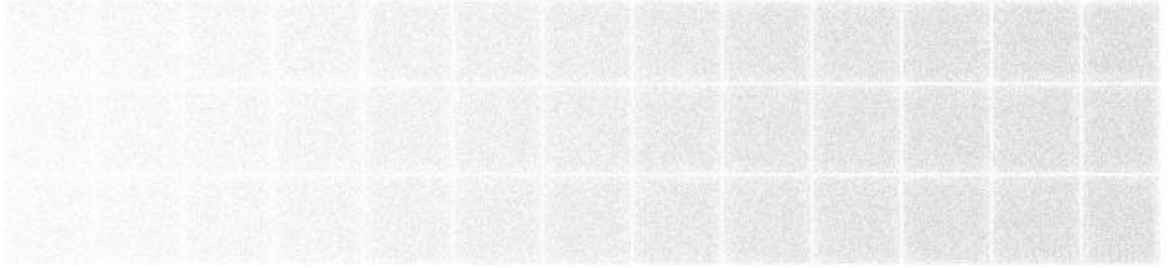
- a) Ensuring that no deceptive statements are suggested or uttered concerning regarding certification.
- b) That no certification document is used in a manner that would mislead clients or registered companies or the public in general.
- c) Upon suspension, withdrawal or cancellation cease with immediate effect to use of the marks on advertising, such as brochures, letterheads, business cards, web sites, etc. and return the certificate to **ATC INTL**.
- 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 **ATC INTL**, 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 manner that might tarnish the credibility of **ATC INTL** 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. due to continued misuse of a certificate or logo.
- ii. failure to implement corrective action within the specified timeframe following concerns identified during Assessment, Surveillance, or Re-Assessment visits.
- iii. any other violation of the **ATC INTL** quotation and/or Rules of Registration.
- iv. when a major non-conformity is identified during any visit after to the original Assessment.
- v. during suspension, the use of logos on advertising materials is prohibited until the suspension is lifted.
- vi. the office admin at **ATC INTL** will communicate in writing to the registered client, outlining the suspension conditions and providing guidance on how the suspension can be lifted.



**b) Scope Extension**

For all scope extensions the registered client has to make a request to **ATC INTL** in writing. The request shall be reviewed and a new quotation sent out. Upon acceptance **ATC INTL** 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 within the assessment report. Should a reduction in scope be recommended by a **ATC INTL** Lead Auditor at a surveillance or re-assessment visit this has to be noted in the report and the File Reviewer informed.

**d) Withdrawal**

Such withdrawals could occur due to:

- i. neglect to respond within the specified time frames to requests made by ATC INTL after the certification suspension.
- ii. failure of a client to settle an account with ATC INTL within one month of formal notification regarding an unsettled account.
- iii. voluntary withdrawal; in such cases, ATC INTL requires written notification.
- iv. the certificate of registration must be returned to ATC INTL upon confirmation by ATC INTL that the withdrawal process is complete. No copies of certificates shall be utilized, and logos shall not be displayed after the withdrawal has been finalized.

**13. Appeals**

If the client does not agree with the Lead Auditor's recommendation after an Assessment, Surveillance or Re-Assessment then they are at liberty to lodge an appeal with the Standard Manager and CEO of **ATC INTL**. The Client shall support his reasons by objective evidence.

All appeals will be heard by a Sub-Committee of the **ATC INTL** 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 **ATC INTL**. Neither party shall be permitted to make any counterclaim. No costs, for whatever reason, will be allowed for either party because of an appeal.





In case of any appeal, information related to handling of appeals can be found at (<https://www.atcintlgroup.com> )

## 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 **ATC INTL** Staff upon request.

### b) Complaints from Clients Regarding Auditors

If a client has a complaint about the conduct of any **ATC INTL** Auditor, then this should be sent "by Form P12/03 that is available in [www.atcintlgroup.com](http://www.atcintlgroup.com)" to the **ATC INTL** Standard Manager or CEO. If the complaint involves the Standard Manager or Final Reviewer, then the complaint is to be addressed to the Chairman of the Impartiality Committee of **ATC INTL**. In other cases, it will be checked by CEO and someone shall be selected to follow the complaint based on Procedure 12.

### c) Complaints from Users of Clients Products & Services

For complaints received from users of client's 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 then, it will be checked by CEO and someone shall be selected to follow the complaint based on Procedure 12.

### d) Serious incidents and breach of legal requirements

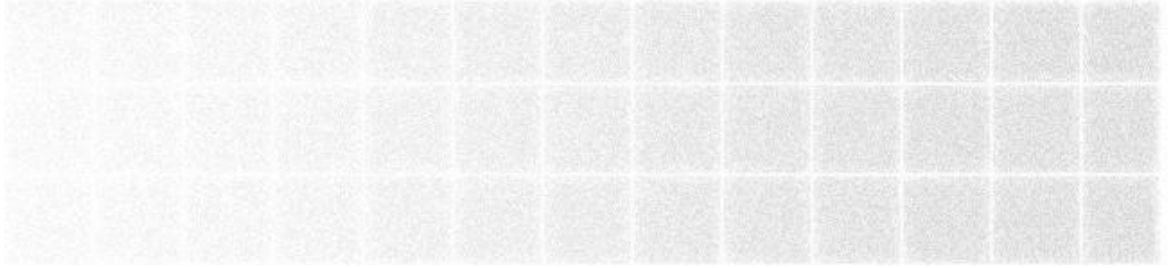
The client must inform, without delay, **ATC INTL** of any occurrence of a serious incident or breach of regulation necessitating the involvement of the competent regulatory authority.

If **ATC INTL** becomes aware of a nonconformance relating to the client being in breach of a relevant regulatory requirement, it shall notify the client without delay.

In such circumstances, **ATC INTL** may deem it necessary to conduct a special audit focusing on the incident or breach and to determine that the management system has not been compromised.

In case of any Complaint, information related to handling of complaints can be found at (<https://www.atcintlgroup.com>)





## 15. Witnessed Visits

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

## 16. Short Notice Audits

For clients that have been suspended or where **ATC INTL** has received complaints then a short notice audit maybe required for follow-up and verification/validation of the implementation of corrective and preventive measures. In such cases the client commits to cooperate with ATC INTL 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:

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

significant safety related information becoming known to **ATC INTL**.

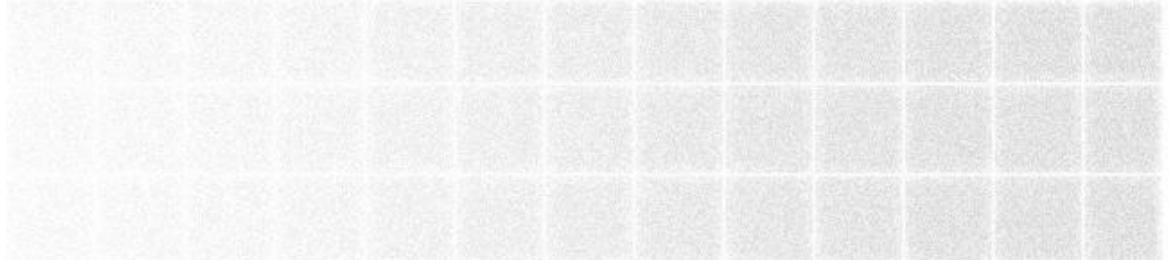
significant changes occur which have been submitted as required by the regulations or become known to **ATC INTL** and which could affect the decision on the client's state of compliance with the regulatory requirements.

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

automatically trigger a special audit:

i) QMS – impact and changes:

- new ownership
- extension to manufacturing and/or design control
- new facility, site change

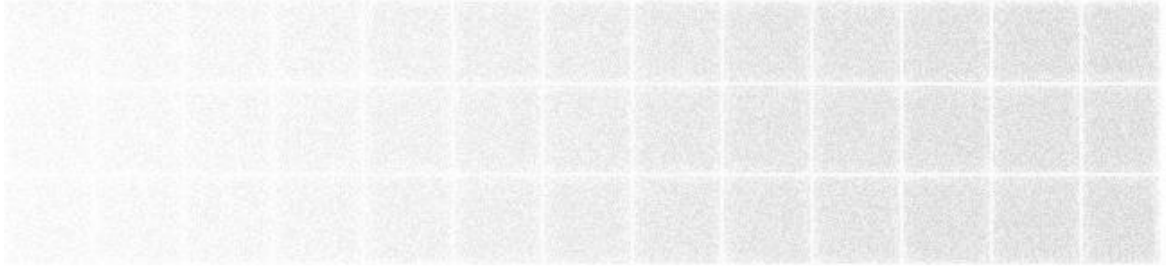


- modification of the site operation involved in the manufacturing activity (e.g. relocation of the manufacturing operation to a new site or centralising the design and/or development functions for several manufacturing sites).
- new processes, process changes
- significant modifications to special processes (e.g. change in production from sterilization through a supplier to an on site facility or a change in the method of sterilization).
  - QM management, personnel.
- modifications to the defined authority of the management representative that impact quality management system effectiveness or regulatory compliance.
- the capability and authority to assure that only safe and effective medical devices are released.
  - ii) Product related changes:
    - new products, categories
    - addition of a new device category to the manufacturing scope within the quality management system (e.g. addition of sterile single use dialysis sets to an existing scope limited to haemodialysis equipment, or the addition of magnetic resonance imaging to an existing scope limited to ultrasound equipment).
  - lii) QMS & Product related changes:
    - Changes in standards, regulations.
    - Post market surveillance, vigilance

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

## 17. Terms of Payment

Payment will be conducted in adherence to the specific invoice and the terms outlined in the quotation/contract document or based on agreement with the Branch/partner if it is allowed.



## 18. Indemnification

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

## 19. Impartiality

ATC Intl auditor signed confidentiality impartiality statement before start.

**ATC INTL** or any **ATC INTL** 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, FSMS or other related management system consultancy on the management system, within two years following the end of the consultancy.
- c) certify a quality management system, environmental management systems, food safety management system on which it provides any consultancy. offer certification when relationships that threaten impartiality cannot be eliminated or minimized.
- 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.

Besides above, for ISMS, **ATC INTL** shall not provide internal information security reviews of the client's ISMS subject to certification. Furthermore, the **ATC INTL** shall be independent from the body or bodies (including any individuals) which provide the internal ISMS audit. However, following duties may be carried out as without considering as consultancy or potential conflict of interest as below:

- a) arranging and participating as a lecturer in training courses, provided that, where these courses relate to information security management, related management systems or auditing, this must be confined to the provision of generic information and advice which is publicly available, i.e. they shall not provide company-specific advice which contravenes the requirements of b) below;
- b) making available or publishing on request information describing the **ATC INTL's** interpretation of the requirements of the certification audit standards;
- c) Engaging in activities before the audit focused solely on determining readiness for certification, without providing recommendations or advice conflicting with these rules. The certification body must confirm that such activities comply with these requirements and are not used to justify a reduction in the eventual certification audit duration.

- d) performing second and third-party audits according to standards or regulations other than those being part of the scope of accreditation;
- e) adding value during certification audits and surveillance visits, e.g. by identifying opportunities for improvement, as they become evident during the audit, without recommending specific solutions.

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 **ATC INTL**.

## 21. Organizational & Management System Changes

The client shall inform **ATC INTL** any significant changes with the client organization such as change of address, ownership, scope or management rep. Such changes will be reviewed and may require follow-up at the next scheduled surveillance visit.

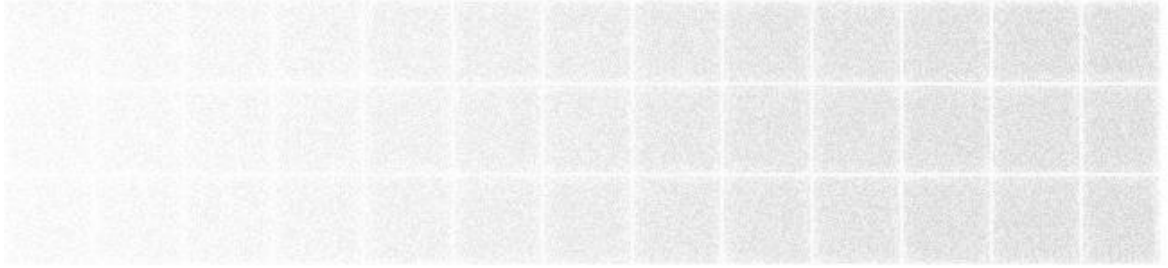
## 22. Amendments to Scheme Rules

- a) **ATC INTL** 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 web site and all ASB / ASPs and clients informed.
- b) Client should record the Scheme Rules as an "external document" within their management system for document control.

## 23. Use of Certification Marks

Only **ATC INTL** certificated clients are authorized to use the certification marks, whilst registration is active, under the following conditions:

- a) Certificate holders issued by ATC INTL are authorized to use the appropriate logo following the requirements outlined in these scheme rules on stationery, publicity material, or other items relevant to the certificate of registration.
- b) That the registration number as shown on the certificate of registration is displayed underneath the outside of the outer box, in the centre.
- c) Embossed, relief, or die-stamped versions may be used. The marks may also be produced as water marks as long as 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) Accreditation logo can be used but requirements of mark and logo use of AB should be satisfied.



- e) The marks must always be shown next to the **ATC INTL** logo. The accreditation body logos are not permitted to be displayed on their own without the **ATC INTL** logo both inside the outer box.
- f) The logo is not allowed 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 accreditation marks shall not be used on vehicles and flags. If additional certificates are required, then the client should request this in writing from **ATC INTL**.
- h) In case of certification withdrawal or cancellation, the original certificate(s) must be returned to ATC INTL. From the cancellation date, websites should not display the logo, and stationery should not be issued displaying the logo to avoid misleading clients and potential clients regarding the registration status. In cases of scope reduction or increase, the certificate(s) should be returned to ATC INTL for re-issue.
- i) At all times certificate(s) remain the property to **ATC International LTD** and can be recalled upon request.
- j) The certification marks shall not be used on laboratory test reports, calibration certificates and inspection reports.

## 24. Privacy Notice

We take the privacy and the protection of personal information seriously. Our Privacy Notice sets our details about we gather, use and share personal information and about individual privacy rights. How we use personal information depends upon the context in which it is made available to us.

## 25 Arbitration and Disputes

Any dispute, controversy, proceedings or claim between the parties relating to this Agreement shall be settled amicably. If no agreement is reached, the matter will then be referred to an arbitrator nominated by both parties.

## 26 Applicable Law and Jurisdiction

This Agreement and any dispute, controversy, proceedings or claim between the parties relating to this Agreement shall be governed by, and construed in accordance with, the laws of England and Wales.

For more information about how to use of logo and certificate, refer to the how to use of logo and certificate Instruction , "Work Instruction 06"