CODES OF PRACTICE

1. Introduction

These Codes of Practice have been written in accordance with the requirements of the various national accreditation bodies, under whose approval AJA Europe currently operate. AJA Europe complies with all Codes of Practices applicable to the Accreditation Bodies requirements and the standards for which it offers certification.

2. Scope

AJA Europe provides independent audit and registration of management systems operated by companies against the requirements of the following relevant International Standards:

- Quality Management - ISO 9001 (QMS)
- Environmental Management – ISO 14001 (EMS)
- Information Security Management - ISO 27001 (ISMS)
- Food Safety Management - ISO 22000 (FSMS)
- Occupational Health & Safety Management Systems – OHSMS 45001
- Occupational Health and Safety - OHSAS 18001 (OHSAS)
- Medical Devices - ISO 13485 (MDMS)
- Energy Management – ISO 50001
- Business Continuity Management - ISO 22301
- Any other Certification Standards that AJA Europe may offer accredited/unaccredited certification for in the future.

3. Confidentiality

AJA Europe is responsible for ensuring that secrecy is maintained by its employees and its agents, concerning all confidential information with which they may be acquainted as a result of their contacts with the company.

Where information is required to be disclosed to a third party, either by law or in maintenance of certification (e.g. Accreditation Bodies), the client shall be informed of the information provided as permitted by the law.

4. Organisation

A copy of the AJA Europe' Organisation Chart, showing the reporting structure of the company, is available upon request.

5. General Conditions

The basic conditions for acquiring and retaining certification with AJA Europe are that the applicant company agrees to, and complies with, the following procedures and rules:

- The client shall make all necessary arrangements for the conduct of all audits including providing for examining documentation and the access to all processes and areas and records and personnel related to the declared scope of work to be certified in the Standard or Standards identified.
- AJA Europe, if not satisfied that all the requirements for certification are being met, shall inform the applicant company of those aspects in which the applicant has failed to satisfy the requirements;
- When the applicant company can show that corrective action has been taken, within a specified time limit, to meet all the requirements, AJA Europe will arrange to repeat only the necessary parts of the audit that can not be verified by submission of documentary evidence;
- If the applicant company fails to take corrective action within the specified time limit, it may be necessary for AJA Europe, at extra cost to the applicant company, to repeat the audit in full;
- Identification of conformity shall refer only to the site or sites audited and shall apply to the worded scope appearing on the certificate;
- Fees must be paid within the timescales stated on the proposal. Registration certificates will not be issued, following initial and re-audits, until fees have been paid in full. Additionally, Registration may be suspended or withdrawn if Surveillance fees are not paid in full;
- In order for the registered company to demonstrate effective management reviews and internal audits these activities shall be carried at least once per year by the registered company.
- Failure to return original registration certificates and schedules as described within these Codes of Practice shall result in legal action being taken against the company on the basis of unauthorized use of certification and accreditation marks and on the basis of inaccurate representation of certified status
- The applicant must allow AJA Europe to conduct on-going surveillance audits in line with the planned arrangements stated in the proposal;
- Certified clients must only use the Certification Marks in accordance with the AJA Europe' Use of Accreditation and Certification Marks

AJA Europe' Accredited Offices are responsible for, and will retain authority for, decisions relating to accredited certification, including the granting, maintaining, renewing, extending, reducing, suspending and withdrawing of certification

6. Application for Certification AND Possible refusal

Upon receipt of the completed questionnaire from the applicant company, a proposal outlining the Scope of Audit and costs will be submitted to the applicant company, together with an Application form. The client will be provided with the basis of the costs in terms of the man-days estimated as required for all stages of the overall 3 year period of certification. Once the application form, signed by the relevant senior management representative of the applicant company, and accompanied by the necessary fee payment and associated documentation, has been received by AJA Europe, the project will be allocated to a senior member of the audit staff. This person will be responsible for ensuring that the audit is carried out in accordance with AJA Europe' procedures.

However in certain circumstances AJA Europe may refuse to offer certification to an applicant company. These circumstances include, but are not limited to, the following instances:

* AJA do not hold the necessary accreditation in the scheme required
* The applicant company is a registered laboratory for which ISO 17025 is applicable
* The applicant company fails to provide all required and necessary information to allow AJA to accurately plan the 3-year certification programme
* The applicant company is not a legally registered entity in the country involved

7. Audit

Quality, Environmental, Information Security, Food Safety and Health and Safety, Medical Devices, Energy Management and Business Continuity Management Systems

All audits are based on sampling within a Management System and are therefore not a guarantee of 100% conformity with standard requirements.

- The audit of the applicant company's management system shall be carried out in two stages: Stage 1 (on-site, where applicable) – this is an audit to determine the state of readiness of the applicant's management system against the criteria of the nominated International Standard and includes a review of the document management system;
- Stage 2 (on-site) audit of the applicant company's management system to ensure the practical system in operation complies with the documented system and with all elements of the nominated standard(s). If AJA is not able to verify the implementation of corrections and corrective actions of any major nonconformity within 6 months after the last day of stage 2, AJA will conduct another stage 2 prior to recommending certification.

All records produced for the implementation and operation of the appropriate management system shall be readily available for inspection by the auditor(s).

The applicant company shall ensure that AJA Europe are advised of the name of the Management Representative who has authority and responsibility for maintaining the QMS, EMS, ISMS, FSMS, OHSAS or MDMS (as appropriate). This individual shall be required to maintain contact with AJA Europe. Any change to this designated person must be confirmed to AJA Europe in writing.

8. Certification and Surveillance

When the responsible manager of AJA Europe is confident that the company meets all the requirements for certification, following a thorough

review of the audit reports, the applicant shall be informed and a Registration Certificate and Schedule issued. The Registration Certificate and Schedule shall remain the property AJA Europe and shall not be copied or reproduced in colour, without the prior approval of a manager of AJA Europe. Permission is granted to produce mono/greyscale photocopies for the purpose of providing clients with evidence of registration.

Regardless of the frequency of the Surveillance routine, certification cycles are for a three-year period and a full re-audit will be required prior to the expiry date of the Registration Certificate and Schedule, in accordance with Accreditation Body requirements. Failure to submit for audit prior to the expiry date will result in a period during which the company's registration will deem to have expired.

Normally the man-day allocations for a three-year re-audit will be slightly less than for the original registration audit.

Periodic surveillance visits shall be carried out following notification of the intended visit and will cover aspects of the relevant management system at the discretion of the nominated auditor. The certificate holder shall allow AJA Europe the right of access for surveillance purposes whenever deemed necessary and AJA Europe shall reserve the right to make unannounced visits as required. The certificate holder will be informed of the results of all surveillances.

Surveillance visits must be conducted no later than 12 months after the previous audit. Any deviation to this must be requested, in writing to the Compliance & System Certification Manager.

The certificate holder shall maintain a register recording all customer complaints relating to the activities covered by the worded scope of operations on the certificate and make this available to AJA Europe upon request.

9. Renewal of Registration

AJA Europe client companies will be subject to re-audit at the end of every three-year cycle. Three-months prior to the re-audit date a new proposal of costs will be raised covering the new three-year cycle. If you do not complete the recertification audit or AJA Europe is unable to verify the implementation of corrections and corrective actions for any major nonconformity prior to the expiry date of the certification, then recertification shall not be recommended, and the validity of the certification shall not be extended in other word you will have no valid certificate for that specific time. However, AJA Europe can restore certification within 6 months provided that the outstanding recertification activities are completed, otherwise consider to be a new client. The recertification date on the certificate shall be on or after the recertification decision and the expiry date shall be based on prior certification cycle.

10. Extension/Reduction of Certificate Scope

If you require an extension to the Scope of Registration, to cover new products/processes/locations, you are required to complete and return a new questionnaire. This will allow AJA Europe to determine whether additional audit time is required to cover the changes required. The application procedure outlined in clause 6 of these Codes of Practice will be followed and an audit will be carried out on the areas not previously covered. The costs of extending the scope of the certificate will be based on the nature and programming of the audit required.

If you require a reduction of your Scope of Registration, it is mandatory that AJA Europe is advised immediately of changes in organisation or products i.e. closure of sites or removal of product previously supplied under original scope on certificate. Upon review and acceptance of the information, AJA Europe will notify if an additional audit, and also a change the worded scope, is required. The cost of this reduction in scope of the certificate will be based on the nature and programming of the audit if required or administration costs for a new certificate.

In both cases an amended certificate detailing those aspects of the company activities covered by the extension, will be issued following a successful audit (where applicable). The original certificate issued to the company will be returned to AJA Europe.

11. Notification of Change in Company Activities and/or Scopes of Certification

The company shall inform AJA Europe in writing and without delay of any intended changes relating to the following:

- the legal, commercial, organisational status or ownership
- organisation and management
- contact address and sites
- scope of operations under the certified management system (increases or reductions)
- major changes to the management system and processes
- occurrence of a serious OHS incident or breach of regulation necessitating the involvement of the competent regulatory authority

AJA Europe will determine whether the notified changes require any additional audit activity. Failure to notify AJA Europe may result in certificate suspension. Also the company shall amend all advertising matter when the scope of certification has been reduced.

12. Publicity by Certificate Holders

A certificate holder has the right to publicise the fact that the management system which it utilises has been certified, and can apply the relevant marks to stationery and promotional material relating to the scope of certification as detailed on the certificate. The company may not apply the marks to their products or packaging. The regulations shown on the AJA Europe' Use of Accreditation and Certification Marks must be adhered to

In every case the company shall ensure that no confusion arises between certified and non-certified products/processes and activities in its publications and advertising. The company shall not make any claim that could mislead purchasers to believe that a product/process or activity is covered by certification when, in fact, it is not.

In addition, the certificate issued does not imply that the governing board or relevant government ministers of the country of accreditation has approved the related product, processes or services. The company shall ensure that this is not implied in any advertising.
A certified client shall not use its certification in such a manner that brings AJA Europe (as the Certification Body) and/or the certification scheme into disrepute and cause loss of public trust.

13. Misuse of Certificates

AJA Europe will take all reasonable precautions to control the use of the certificates issued. Incorrect references to the scope of certificates or incorrect use of the certificate marks found in advertising, catalogues etc shall be dealt with by suitable actions, which could include suspension or withdrawal of certificates, legal action and/or publication of the transgression.

14. Suspension of Certificate

A certificate may be suspended for a limited time in cases where:

- Evidence of widespread failure to implement the Management System requirements for a period of time not less than 3 months
- Failure to permit re-certification or surveillance audits to be conducted at the required frequencies
- Falsification and/or fabrication of records of implementation
- Failure to respond to Corrective Action Requests
- Non-payment of certification fees owed to AJA Europe
- Complaints having not been addressed in an appropriate manner
- Expiry of a certificate after the 3 year registration period has elapsed
- Request from the client for voluntary suspension
- Any special visit due to the any serious incident and the involvement of the competent authorities. Based the result this may impact on certification. i.e. suspension or withdrawn

The company shall immediately cease to identify the coverage of any certificate under suspension. AJA Europe shall notify in writing an official suspension of certificate to the company, this

notification will indicate the conditions that will allow removal of the suspension. At the end of the suspension period an investigation will be undertaken to determine whether the required conditions for removal of suspension have been followed. If the conditions have been satisfied the certificate will be re-instated, if the conditions have not been satisfied the certificate shall be withdrawn.

All costs associated with suspension and subsequent re-instatement of the certificate will be charged to the certificate holding company.

15. Withdrawal of Certificate

A certificate may be withdrawn in cases such as:

- if the company does not meet required conditions raised on suspension of certificate

The withdrawal of a certificate will be notified to the company in writing and the company does have the right of appeal against this decision. AJA Europe will not be liable for reimbursement of any audit fees paid and AJA Europe will publish the withdrawal of the certificate.

Reinstatement of 'withdrawn' certificates may require a full re-audit to be conducted and where appropriate, fees to be paid in advance.

Withdrawal of the certificate will require that all promotional materials endorsed with the AJA Europe certification logos must be withdrawn from use immediately and any use of accreditation marks on company publicity and stationery material will be in error and in contravention of the intellectual property rights of the owners of the marks.

16. Cancellation of Certificate

A certificate may be cancelled in cases such as:

- if the company does not wish to renew the certificate
- if the company goes out of business

AJA Europe will not be liable to reimbursement of any audit fees paid and AJA Europe will publish notification of the cancellation of the certificate. Cancellation of the certificate will require that all promotional materials endorsed with the AJA Europe certification logos must be withdrawn from use immediately and any use of accreditation marks on company publicity and stationary material will be in error and in contravention of the intellectual property rights of the owners of the marks.

17. Fees

Fees will be detailed in the proposal submitted to the applicant company. All costs are based on the charge rate applicable at the time of proposal and AJA Europe reserve the right to increase charges during the certification period. Such increases will be notified to the client company in writing.

Once application is made, the company is liable for the first year fees, regardless of whether the company progresses to registration, as costs will already have been incurred.

For subsequent three-year registration cycles a new proposal of cost shall be prepared three months prior to the three-year re-audit due date with an accompanying invoice and application.

Once application is made, the company is then committed to payment of the first year fees of the subsequent three-year cycle.

Additional fees will be charged for additional work not included in the scope of the original proposal and for any extra, unscheduled visit, surveillance visits required due to non-compliances being identified in the continuing adequacy and/or implementation of the relevant management system

All fees quoted shall exclude travel and accommodation expenses associated with the audit/surveillance activities (unless otherwise specified in the proposal of cost) and this will be charged extra, at cost.

All fees are subject to local taxes in the country concerned at the appropriate rates.

18. Appeals and Disputes

In the event of certificate withdrawal or the failure to recommend and approve a client company for registration, the company has the right of appeal on this decision. if the company indicates their lack of acceptance of the audit team findings, then they should refer to the "Appeals and Complaint Information section", provided within the AJA Europe report, which details procedure for submitting a formal appeal. This also details your right to dispute the appeal committee member appointments.

AJA Europe must receive notification of the intent to appeal within seven days of the company's receipt of the withdrawal notice from AJA Europe, or the failure to recommend for registration. The company must submit a formal, documented, substantiation for the appeal, together with any supportive documentation/ information, to AJA Europe within fourteen days of the receipt of the withdrawal notice or the failure to recommend for registration.

All client company appeals will be initially reviewed by the local office Compliance & System Certification Manager and the AJA Europe audit staff responsible for the recommendation to withdraw the certificate or decision not to recommend for registration - who must provide evidence to support their recommendation. Should the local office Compliance & System Certification Manager reject the appeal then it will be forwarded to the Group Compliance & System Certification Manager who, if they concur, must then forward it to the AJA Europe CEO for appraisal. Should the CEO concur with the Compliance & System Certification Manager's findings then the appeals committee, drawn from the independent members of the governing council shall consider the appeal.

The appealing company will be advised of the names of the governing council appeals committee that will review their appeal and the company has the right to dispute the members of the appeals committee by formal notification of their dispute. This dispute will be reviewed by the chairman of the council or, if the chairman is a member of the appeals committee, by the vice-chairman. The result of the governing council appeals committee review will be notified to the company.

The decision of the governing council appeals committee is final and shall be binding on both parties. Once the decision on the appeal has been made no counter claim by either party can be made to amend or change the decision.

In instances where the client company's appeal has been successful, and the certificate is re-issued (in the case of withdrawal) or the recommendation for registration goes forward, no claim can be made against AJA Europe for reimbursement of costs or any other losses incurred as a result of the initial withdrawal or failure to recommend.

Submission, investigation and decision on appeals shall not result in any discriminatory actions against the appellant

19. Complaints

Registered companies are required to keep a record of all complaints from clients, users of their products or the general public, including subsequent remedial actions to their management system. AJA Europe will review these records during surveillance visits.

Should a client company have any reason to complain regarding the conduct of AJA Europe employees, then the complaint should be made in writing to the AJA Europe local office. Complaints may also be directed to the AJA Europe group Compliance & System Certification Manager; the address can be obtained from local office staff.

Complainants will receive an acknowledgment of receipt immediately and the complaint will be investigated and decided upon within a maximum of 30 days from initial receipt.

Should AJA Europe receive a complaint, indicating that a certified client no longer complies with AJA Europe requirements, then it may be necessary to either initiate withdrawal of certification, or conduct either a full re audit of the client, or an unscheduled short notice audit related to the apparent cause of complaint at extra cost to the client.
All certified clients shall make available, when requested, records of all complaints and corrective actions taken, in accordance with the management system standards or other normative documents.

20. Directory of Certified Companies

A directory of all companies certified by AJA Europe is maintained within each of the Accredited Offices. This is published and made available upon request to both certified and non-certified companies and members of the public.

21. **QA Register**

All AJA Europe certified companies, under UKAS accreditation, will on confirmation of registration, be sent an application form for entry into the QA Register maintained in the UK by the Stationery Office (TSO) and published on a dedicated internet website. Should a registered company wish to be entered they should complete the application and return it to AJA Europe' UK office for processing and forwarding to TSO.

22. **Accreditation Body Visits**

In accordance with ISO/IEC 170021-1, AJA Europe clients shall, where the accreditation body so nominates a need to, accept the presence of officers of the Accreditation Body attending an audit to be conducted by AJA Europe, in order to allow those officers the ability to review the activities and conduct of AJA Europe personnel. Attendance by accreditation officers shall in no way affect the certification decision making process of the AJA Europe Lead Auditor. This requirement to allow access is to be applied to all new and existing clients.

23. **Liability**

AJA auditors carry out an inspection for conformity against an international standard, which in respect of the time allocated can only be considered as a snap shot of the activities of the auditee and not an exhaustive evaluation. At no point does AJA hold itself up, purport or profess to be a regulatory authority or expert consultants within the areas audited and can only operate within the general working knowledge of the field involved as defined by the scope of activity. AJA holds itself removed from any responsibility or liability to the auditee for any implications or actions resulting from legislative/regulatory non-compliance on behalf of the auditee including any actions taken subsequent to the audit resulting in legal or financial failures of the auditee.

AJA Europe reserve the right to amend these Codes of Practice at any time. Only companies who have entered into certification agreements with AJA Europe will be updated of these changes

24. Release of information (ISO 13485 Registrations)

Where requested by interested parties and regulators who take into consideration ISO 13485 accredited certification for the purpose of their recognitions, ISO 13485 Medical Device Reports will be made available, if so requested. You will be advised in advance of this action.