

1.0 Criteria for Granting Certification:

AMRPL may grant and issue the certificate to the client under the following criterion

- (a) The client has a documented Management system that is laid in accordance to its scope of certification and that it conforms to the requirements of the applicable Management System Standard as mentioned above.
- (b) The Client has completed at least one cycle of internal audit and management review of the management system established.
- (c) Both internal audit and management review have been found effective as assessed by AMRPL auditors
- (d) The client has paid all the dues including the certification fee
- (e) The client shall keep a record of all complaints and actions taken and the same shall be submitted to AMRPL auditors for verification when requested.
- (f) The client has undergone the stage-1 and stage -2 audit satisfactory and the recommendation of the audit team is favorable

2.0 Certification Process

2.1 Certification Agreement

On acceptance of the Quotation, this certification agreement is signed between AMRPL and the client for providing certification of the client's management system by AMRPL to the applicable international standard.

2.2 Stage –1 Audit & Documentation Review

AMRPL shall conduct a stage -1 audit at client site to verify the adequacy of documentation with respect to the requirements of the applicable standard and also to understand and gather further information on the client activities and processes including applicable statues, to plan for the stage -2 audit .The client shall satisfactorily resolve all the observations raised in document review along with other concerns / issues highlighted during the audit and the same confirmed to AMRPL before planning the stage -2 audit .AMRPL shall submit a formal report to the client

Note: for Multi site organizations Procedure PM 22 to be followed.

2.3 Stage -2 Audit

AMRPL's audit team shall visit the client's premises, as per an agreed plan, to verify effectiveness of the client's management system in meeting the requirements of the applicable ISO standard. AMRPL shall submit a formal report to the client.

2.4 Non-Conformity Report

If a Nonconformance is detected during audit, a Nonconformity Report shall be issued to the client. For the non-conformities raised during the audit client shall submit the correction and the corrective action plan(based on root cause) to AMRPL office within 10 working days from the last day of the audit. AMRPL shall verify the submitted correction and the corrective action and confirm the acceptance of the same to the client. Client shall take the correction and corrective action within the stipulated date and submit the documentary evidence to AMRPL to verify the effectiveness of action taken and accordingly to close the non-conformances.

In case of certification audit (fresh client) the AMRPL shall cancel the audit under the following conditions

- (a) Client does not submit Corrective Action Plan for the Non Conformity raised within 10 working days as stipulated above
- (b) In case of Major Non conformity the verification of effective of corrective action is not completed within 90 days.
- (c) In case of Minor Non conformity the verification of effective of corrective action is not completed within 30 days.

In case of certified clients AMRPL shall suspend the certificate under the following conditions

- (a) Client does not submit Corrective Action Plan for the Non Conformity raised within 10 working days as stipulated above
- (b) In case of major Non Conformity the verification of effective of corrective action is not completed within 90 days as stipulated above
- (c) In case of Minor Non conformity the verification of effective of corrective action is not completed within 30 days.

2.5 Recommendation for Certification

AMRPL shall recommend certification of the client's management system, based on the following

- (a) AMRPL has reviewed the audit reports and has accepted the recommendations of the audit team
- (b) The client has submitted the correction and corrective action for the non conformities raised within the stipulated time and AMRPL has accepted the same
- (c) In case of a major non-conformance, the effectiveness of correction and corrective action is verified by AMRPL's auditors as agreed and the non-conformity either closed or downgraded to minor.

If the client is not recommended for certification AMRPL shall accordingly inform the client

2.6 Issue of certificate

AMRPL shall issue the certificate against the applicable standard to the client only after the closure of all the non-conformances as stated in section 2.5 of this agreement.

The Certificate is the property of AMRPL, and shall be produced to AMRPL as and when requested.

Issue date: 04.07.2023	Issue No. 02	Rev. No: 01	Page 1 of 5	AMRPL-FM-060



The certification will be valid for a period of three years from the date of approval of certification, subject to the satisfactory maintenance of the Management System as confirmed through agreed surveillance audits

2.7 Surveillance Audit

Surveillance audits shall be conducted regularly at the client site at least once in a year to confirm that the Client's Management System continues to conform to the requirements of the standard to which it is certified.

The date of the first surveillance audit following initial certification shall not be more than 12 Months from the certification decision date and failure to comply with this requirement will lead to suspension and subsequently withdrawal of certification.

For the non-conformity raised during the surveillance audit the conditions stipulated in section 2.5 of this agreement shall be applicable

In the case that a surveillance audit cannot be carried out because the client's operations are affected owing to factors outside its control, e.g.: employee union strike, natural calamity, etc. the case shall be presented to AMRPL for a decision.

AMRPL shall submit a formal report to the client

2.8 Re-certification Audit

The purpose of recertification audit is to confirm the continued conformity and effectiveness of the client's management system as a whole and its continued relevance and applicability for the scope of certification.

The Re-Certification audit shall include site audit and shall consider the performance of management system over the period of certification and shall also include a review of previous surveillance audit reports. The recertification audit may have a stage –1 audit in situations where there have been significant changes to the management system, the client or changes to legislation.

AMRPL shall conduct the recertification audit at least 60 days in advance to the expiration of certification so that the client has time to implement corrective actions before the expiry of the certification

For non-conformities raised during the audit, the conditions specified in section 2.5 of this agreement become applicable. AMRPL shall submit a formal report to the client.

2.9 Special Audit

AMRPL shall conduct special audits under the following conditions,

- (a) Extension to the scope of certification already granted, on the request of client. This could be clubbed with routine surveillance audit.
- (b) To investigate complaints received by AMRPL about the client.
- (c) Follow up audit in case of suspension or major non-conformity raised in any audit.
- (d) Changes to AMRPL's certification requirements.

For non-conformities raised during the audit the conditions identified in section 2.5 of this agreement shall become applicable.

AMRPL shall submit a formal report to the client.

2.10 Notice of Changes by AMRPL

AMRPL shall inform the client in advance any changes to its requirements for certification and shall subsequently verify that each client complies with this requirement. It shall necessitate a special audit in certain cases.

2.11 Notice of Changes by the client

Client shall inform AMRPL, without delay, of matters that may affect the capability of management system to continue to fulfill the requirements of the standard used for certification. These may include changes related to,

- (a) The legal, commercial, organizational status or ownership,
- (b) Organization and management (e.g. changes in key managerial, decision making or technical staff)
- (c) Contact address and sites
- (d) Scope of operation under the certified management system
- (e) Major changes to the management system and processes.

AMRPL shall review the changes and accordingly discuss with client for an early verification to ensure that the capability of the management system continues to fulfill the requirements of the applicable standard.

2.12 Maintaining Certifications

The Certification is maintained for a period of 3 years under the following conditions.

- (a) The Surveillance Audits are conducted as planned and the client has demonstrated that it continues to satisfy the requirements of the management system standard as confirmed by AMRPL.
- (b) All the non-conformance raised during previous surveillance are closed within the time frame agreed and correction and corrective actions for the non conformities raised during the current audit are identified and accepted by AMRPL as per conditions specified in section 2.5 of this agreement.
- (c) The Internal Audit and the management reviews are conducted as scheduled and there are no issues pending.
- (d) The client shall maintain suitable records of customer complaints and keep the records of investigation and remedial actions taken with respect to such complaints for verification by the AMRPL auditors.
- (e) All outstanding dues to AMRPL are paid

2.13 Suspending, Withdrawing or reducing the scope of certification

<u>(a) Suspension</u>

AMRPL shall suspend certification in cases wherein

Issue date: 04.07.2023 Issue No. 02 Rev. No: 01	Page 2 of 5 AMRPL-FM-060	0
---	--------------------------	---



- The client's certified management system has persistently or seriously failed to meet certification requirements, including requirements for the effectiveness of the management system.
- > The client does not allow surveillance and recertification audits to be conducted at the required frequencies.
- Wishful misuse of logo & reference to certification.
- > Non compliance to submission of Corrective action as stated in section 2.5 of the agreement.

The suspension shall be for a period of maximum six months and the suspended status of the client shall be publicly made available in the register of certified clients being maintained by AMRPL at its registered office. During this period the client shall discontinue the use of logo or any reference of certification in advertising matter, as directed by AMRPL, at the time of giving notice of suspension.

(b) Withdrawal

AMRPL shall withdraw the certificate under the following circumstances.

- (a) Failure of the client to resolve the issues of suspension within six months shall result in withdrawal of certification
- (b) Other reason like major legal complaint, company involved in malpractices, AMRPL loses accreditation etc.
- (c) Client voluntarily requested for a withdrawal.

Upon withdrawal of certification the client ceases to enjoy the certification status and shall accordingly return the certificate as directed by AMRPL at the time of withdrawal notice.

(c) Reduction in scope of certification

AMRPL shall decide to reduce the client's scope of certification by excluding the parts not meeting the requirements, when the client has persistently and seriously failed to meet the certification requirements for those parts of the scope of certification. Such exclusions shall be consistent with the certification standard.

Upon request from any party, AMRPL shall provide information related to the validity of a given certificate.

2.14 Certification and Use of Logo

The certificates issued by AMRPL remain the property of AMRPL and must be returned when requested. The client is authorized to use the certificate mark or its logo in advertising matter as per instruction given by AMRPL at the time of issuing the certificate.

The client, while using the its certification, shall ensure that it,

- (a) Conforms to requirements of AMRPL when making reference to its certification status in communication media such as Internet, brochures or advertising or other documents.
- (b) Does not make or permit any misleading statement regarding its certification.
- (c) Does not use or permit the use of the certification document or any part thereof in a misleading manner.
- (d) Upon suspension or withdrawal of its certification, discontinues its use of all advertising matter that contains a reference to certification, as directed by Conforms to requirements of AMRPL.
- (e) Amends all advertising matter when the scope of certification has been reduced.
- (f) The certification mark or logo shall not be used on a product or product packaging both primary packaging (which contains the product) and any outer or secondary packaging as this could be interpreted as denoting product conformity.
- (g) Shall not use the certification information or any statement in a manner to imply that the product or service is certified, This includes all product packaging, both primary packaging (which contains the product) and any outer or secondary packaging.
- (h) The logos shall also not be applied to laboratory test, calibration or inspection reports or any form of certificates issued by educational institutions as such reports/ certificates are deemed to be products in this context.
- (i) Does not imply that certification applies to activities that are outside the scope of its certification.
- (j) Shall not use the certification in such a manner that would bring conforms to requirements of AMRPL and /or the certification system into disrepute and lose public trust.
- (k) Logo shall not be applied on visiting cards. mentioned in PD-03

2.15 publicly Accessible Information

AMRPL shall make the following information publicly accessible through its web site and through documents PD-01 & PD-02.

- audit processes;
- processes for granting, refusing, maintaining, renewing, suspending, restoring or withdrawing
- certification or expanding or reducing the scope of certification;
- types of management systems and certification schemes in which it operates;
- the use of the certification body's name and certification mark or logo;
- processes for handling requests for information, complaints and appeals;
- policy on impartiality.

All other information shall be treated as confidential.

2.16 Obligations of the applicant / certified organization

The applicant / certified organization shall commit to fulfill continually the requirements of certification set by AMRPL for the scope for which certification has been granted including adapting changes in requirements for certification as and when communicated

Issue date: 04.07.2023 Issue N	. 02 Rev. No: 01	Page 3 of 5	AMRPL-FM-060
--------------------------------	------------------	-------------	--------------



- (a) When requested the applicant / certified organization shall cooperate with AMRPL in the fulfillment of the requirements for certification. This shall apply to all locations included in the certification.
- (b) In the case of where there are multiple offices of a certification body (AMRPL) or multiple sites of a client, then on that case this agreement should be considered as a legally enforceable agreement between the certification body (AMRPL) granting certification and the client that covers all the sites within the scope of the certification.
- (c) The applicant / certified organization shall provide access to information, documents and records as necessary for granting certification and maintaining certification
- (d) Certified organization shall allow the personnel from the accreditation body (e.g., UAF, NABCB) access to their sites and shall provide access to information, documents and records when requested by AMRPL
- (e) The certified client shall claim certification only with respect to the scope for which certification has been granted
- (f) The certified organization shall not use its certification in such a manner as to bring AMRPL into disrepute
- (g) The applicant / certified organization shall pay fees as determined by AMRPL
- (h) The certified client informs the AMRPL, without delay, of the occurrence of a serious incident or breach of regulation necessitating the involvement of the competent regulatory authority.
- (i) The applicant / certified organization shall inform without delay any significant changes relevant to the certification in respect of its status or its operation related
 - i) Its legal, commercial or ownership status
 - ii) The organization, top management & key personnel
 - iii) Resources and premises
 - iv) Scope of certification
 - v) Other such matters that might affect the ability of the certified organization to fulfill requirements of certification
- (j) Certified organization shall allow Regulatory Authority (RA) access to their sites and shall provide access to information, documents and records when requested by Regulatory Authority (RA).
- (k) Certified organization shall release audit report information to Regulatory Authority (RA) that recognize ISO 13485 when requested.

2.17 Obligations of AMRPL

- (a) AMRPL shall make publicly available information about the status of certification that it has granted the certified organization. The information shall be updated regularly. The information shall include the following
- geographical areas in which it operates;
- the status of a given certification;
- the name, related normative document, scope and geographical location (city and country) for a Specific certified client.

AMRPL shall give due notice of any changes to its requirements for certification. It shall take into account the views expressed by interested parties before deciding on the precise form and the effective date of the changes. Following a decision on, and publication of, the changed requirements it shall verify that each certified client carries out necessary adjustments

3.0. GENERAL TERMS AND CONDITION

(a) Termination- The client and AMRPL shall have the right to terminate this agreement at any time giving 30 days of written notice of such termination. The client shall, in case of termination, reimburse to AMRPL all the dues up to date of termination. AMRPL, if it so wishes, shall also charge a termination fee to be negotiated at the time of termination and this is in addition to the dues that are payable to AMRPL. In no case such termination fee shall not exceed 15% of the value of the agreement. All reimbursable are payable at the end of said 30 days period.

(b) Confidentiality- AMRPL shall not disclose any information about the client or individual to a third party without the written consent of the client or the individual concerned. If AMRPL is required by law to release confidential information to a third party, the client or the individual concerned shall, unless regulated by law, be notified in advance of the information provided.

(c) Conflict of Interest AMRPL shall have top management commitment to impartiality in management system certification activities. AMRPL shall have a policy that it understands the importance of impartiality in carrying out its management system certification activities, manages conflict of interest and ensures the objectivity of its management system certification activities.

(d). Force majeure-Delay in or failure of performance of either party hereto shall not constitute a default hereunder or give rise to any claim for damage if and to the extent such delay or failure is caused by an act of war, natural disaster, fire, explosion, labor dispute or any other event beyond the control of the party affected and which, by the exercise of reasonable diligence, said party is unable to prevent. The party affected shall notify the other party in writing of the causes and expected duration immediately after the occurrence of any such event.

(e) Law & disputes- The agreement for certification between LMS and client shall be governed by prevailing law in India. Any dispute arising in connection with the agreement, which cannot be settled by private negotiations between the parties, shall be referred to arbitration as per the Indian Arbitration Act, subject to Bhopal jurisdiction. The decision of the arbitration shall be binding for the both parties

(f) Appeals: Client shall appeal to AMRPL in respect of the following,

- I. Non acceptance of client's application for certification
- II. Granting, suspending, withdrawing or denying of certification

Issue date: 04.07.2023 Issue No. 02	Rev. No: 01	Page 4 of 5	AMRPL-FM-060
-------------------------------------	-------------	-------------	--------------



AMRPL shall deal with the appeals according to its procedure and shall be responsible for all decisions at all levels of the appeal handling process. AMRPL shall acknowledge the receipt of the appeal and shall provide the client with progress reports and the outcome.

(g) Complaints: AMRPL shall investigate the complaint received about the client to decide what action need to be taken and the same shall be communicated to the client at an appropriate time. The identity of the complainant shall not be disclosed.

(h) <u>Fees</u> The fees shall be detailed in the quotation submitted by AMRPL. Fees are charged on the basis of applicable rates at the time of submission of the quotation. AMRPL may revise the fee submitted in the quotation during the Certification period. Clients shall be notified of any change in the fee.

If any special audit is performed on the client as detailed in section 2.10 of this agreement, AMRPL shall charge an extra fee for such audits to cover the audit charges and other administrative costs and this shall be payable within 7 days from the date of invoice.

Cancellation of Audit shall involve re-imbursement of expenses incurred by AMRPL, if any.

(i) Access to the client site: The client, at the request of AMRPL, shall permit access to their sites and records for AMRPL's auditors and authorized personnel on behalf of the accreditation body to which AMRPL is accredited. The same shall be communicated to the client in advance.

(j) <u>Agreement Period</u>: This agreement comes to force on and remains in the force until the expiry of the certificate, unless withdrawn for justified reasons or withdrawn by either party upon due notice given to the other party.

(k) Liability: AMRPL's liability shall be limited to providing certification of the client's management system and shall not in any way be responsible for the liabilities arising out of the client's products or services.

The A Mark Ratings Private Limited, certification body, having its registered offices at 301, Sagar Complex Kolar Road Banjari Aashirwad Colony Bhopal - 462042 (M.P.), INDIA hereinafter referred to as AMRPL, hereby agrees to

M/S	having its
registered offices at (Address):	Hereinafter referred to as the client, to
certify the client's management system at	No. of Sites against the international standard
on the conditions of the above (P1-P	4) certification agreement.

For Multiple Sites (as per IAF MD 1:2018) please give details

Signed by Authorized Representatives of AMRPL and the Client Organization

For A Mark Ratings Private Limited	For the client;	
Date:	Date:	
Name: Signature:	Name: Signature:	
Designation:	Designation:	
Company Seal:	Company Seal:	

Issue date: 04.07.2023	Issue No. 02	Rev. No: 01	Page 5 of 5	AMRPL-FM-060
------------------------	--------------	-------------	-------------	--------------