MTIC INTERCERT INDIA PRIVATE LIMITED

Indian Certification of Medical Devices
ICMED (Scheme)

Program Requirements

Scope

0.1 This document describes the certification process to be followed for the Indian Certification for Medical Devices (ICMED) Scheme in processing applications received from medical devices manufacturers for certification as per criteria specified under the Scheme.

0.2 Types of Certification -The following levels of certification will be available:

a) **ICMED 9000 Certification** which is as per the requirements of ISO 9001 read with the additional requirements prescribed under the Scheme in ICMED 9000.

b) **ICMED 13485** which is as per the requirements of ISO 13485 read with the additional requirements prescribed under the Scheme in ICMED 13485

0.3 The certification will be granted for each manufacturing facility/premises after due verification of compliance to the prescribed criteria.

0.4 Transfer certification - To define the process for transferring companies from their current Registrar to MTIC to obtaining ICMED registration.

NOTE: Plant, Unit, Manufacturing facility, Medical device manufacturing facility, Premises, Manufacturer are interchangeable and all these terms refer to an individual medical device manufacturing facility.

1. Application for Certification

1.1 Application Form

1.1.1 The manufacturer will apply in the application from prescribed by MTIC

1.1.2 The applicant will clearly indicate the type of certification it is applying for.

1.1.3 The applicant will provide information about each manufacturing facility to be certified.

1.1.4 The applicant will clearly indicate if any of the activities covered under the criteria for certification are being carried out at any premises other than the main premises. This is to plan and facilitate covering the applicable criteria under the same audit. For example Design or R &D or Testing or any outsourced processes

1.1.5 The applicant will specify/list all the activities to be audited and certified. It will mention whether all the activities are covered at single or multiple locations/sites. For multiple sites, overlapping activities, if any will also be mentioned.

1.1.6 Irrespective of the number of facilities of a manufacturer, to be covered under certification, each and every manufacturing facility will be audited for compliance to the Criteria as applicable.

1.1.7 The applicant will provide the list of medical devices to be covered under the scope of certification.

1.2 List of Documents

1.2.1 The applicant will submit all necessary documents (as per applied criteria) to MTIC
for document review.

1.3 Information for Applicants

1.3.1 The information describing certification processes for granting, maintaining, extending, renewing, reducing, suspending or withdrawing certification, and geographical areas in which it operates will be publicly available on MTIC website. The information will include:

a) An Application form;

b) Reference to the Certification Criteria,

c) Procedure for obtaining certification under the ICMED Scheme, a detailed description of the initial and continuing certification activity, including the application, initial evaluation, periodic surveillance, evaluations, and the process for granting, maintaining, reducing, extending, suspending, withdrawing certification and re-certification .

d) List of documents required to be submitted along with the application.

e) Information about the fees for application, initial certification and continuing certification and policy for the fee

f) Documents describing the rights and duties of applicants/ certified clients, and

g) Information on procedures for handling complaints, feedbacks and appeals.

1.4 Registration of Application

1.4.1 MTIC will respond to all enquiries received from prospective applicant organizations for certification with complete information for facilitating registration of application, within 7 working days of receipt of the query.

1.4.2 The applicant will declare (in the form of an undertaking in application) whether it has been an applicant / certified under this Scheme with or by any other certification body, and if yes then will provide the previous evaluation reports to the new certification body.MTIC may verify the information provided by contacting the earlier certification body.

1.4.4 The prospective applicant for Medical device manufacturer will along with the application declare any judicial proceedings relating to its operations, any proceedings by any Regulatory body or suspension / cancellation / withdrawal of any certification / approvals under any Regulations or otherwise. Such declaration will be a part of the undertaking mentioned in 1.4.3 above.

1.4.5 Certification is granted only against the current relevant certification criteria.MTIC will review all applications for the above and ensure the same.

1.4.6 All applications for certification will be reviewed by MTIC for adequacy and deficiencies observed, if any, will be informed to applicant within 7 working days of receipt of application. Review of applications will be done by a competent person. Records of review will be maintained.

1.4.7 Only complete applications supported with all documents sought will be accepted and registered in order of receipt with a unique identification number, acknowledged and records maintained. Registration will be done within 7 days of receipt of application or information in response to the deficiencies communicated as per 1.4.6 above. In case the applicant discloses any proceedings, suspensions etc as per 1.4.3 above, the applicant will not be entertained for a period of one year from the date of conviction, suspension, withdrawal, deregistration etc.

1.4.8 If the certification of any level under the Scheme has been suspended / cancelled by any approved CB, the application from such a manufacturer will not be accepted till suspension is revoked by the concerned CB or for one year from the date cancellation of certification. This will be applicable only for the manufacturing facility whose certification has been suspended/cancelled. However, this will not be applicable to other manufacturing facilities under same legal entity.

1.4.9 The certifications (ISO 9001 and/ or ISO 13485) by CBs other than IAF MLA signatory accredited CBs will not be accepted for ICMED Scheme by MTIC

1.4.10 Where manufacturing facility is certified by Certification Bodies accredited by NABCB, audit related to scheme criteria will be carried out.

1.4.11 Where the certification (for ISO 9001 and /or ISO 13485) is carried out by IAF MLA signatory accredited CBs other than NABCB, full audit as per scheme criteria requirements will be carried out.

1.4.12 If ISO 9001 and/or ISO 13485 certification of the applicant is under suspension, application for certification will not be entertained till the suspension of ISO 9001 and/or ISO 13485 certification is revoked. In case ISO 9001 and/or ISO 13485 certification of a manufacturing facility is cancelled by any CB, the application certification Under the Scheme may be carried out considering manufacturing facility as new client.

1.4.13 The antecedents of the applicants will be checked in relation to the Scheme. Applications from manufacturers who have earlier either misused the Certification, or whose earlier certificate was cancelled because of violation of terms & conditions / misuse of certification or have been implicated / convicted by the court in relation to their manufacturing activities, will not be entertained for a period of one year of conviction / strictures by the court / cancellation of the certificate by any CB.

1.4.14 Applications from manufacturer found to be misusing the certification while their application is being processed for grant of certification, will not be processed any further, and rejected after a due notice of 15 days. Fresh applications from them will be treated as per clause 1.4.13 given above.

1.4.15 Requests for grant of certification from previous applicants as per 1.4.16 (a), (b) &(c) / expired certificates will be processed like fresh applications and the entire procedure for grant of certification will be adhered to subject to clauses 1.4.8 to 1.4.12 above.

1.4.16 An application will be rejected or closed under the following conditions;

a) if Initial Evaluation is not carried out within 3 months of registration of application

b) if the entire certification process is not completed within 6 months of registration of application.

c) If the applicant shows no progress towards completion of corrective actions within 3 months of Initial Evaluation and 6 months of Registration of application.

d) Misuse of certification under the Scheme

e) Evidence of any malpractice

f) Voluntary withdrawal of application.

1.4.17 The application fee, if charged will be non refundable.

2. Audit programme

2.1 Audit Programme

Considering the type of the certification sought, the following program will be followed:

MTIC INTERCERT INDIA PRIVATE LIMITED

Certification activity	ICMD 9001	ICMED 13485
Certification Audit – Stage 1	√	√
Certification Audit – Stage 2	√	√

Surveillance –"Once in a year", Second surveillance audit will be a unannounced audit which will be carried out within period of 9 to 12 months from previous surveillance audit."	√	√

a) For ICMED 9000 and ICMED 13485 the audit cycle will include

- Initial certification audit in two stages (Stage 1 and Stage 2) as per ISO 17021:2011 ; and
- Recertification audits (generally 3 months before the end of 3 year validity)

2.2 Sampling of manufacturing facility to be Audited

2.3 Audit Mandays

2.3.1 The mandays required to conduct an effective audit will be calculated in accordance with the following Table:

	Audit Man-days Bifurcation of Stage – I (20%) and Stage - II (80%)	
Certification activity	**ICMED 9000**	**ICMED 13485**
Certification Audit/ Surveillance/ Recertification	As per IAF MD 5 Plus 1 man day on Site	As per IAF MD 9 Plus 1 man day on Site

2.3.2 Time duration will be calculated for each manufacturing facility and each manufacturing facility will be individually audited

2.3.3 The minimum audit time for each on site audit will be at least one man-day (8 hrs. per day) .

2.3.4 Document review, audit preparate

2.3.5 ion and report preparation time will be additional and will be at least one man-day.

3.1.1 Preliminary information to be provided to MTIC

MTIC will inform client regarding documentation to be provided by manufacturing facility for "Document review" in compliance to scheme criteria requirements as applicable

3.1.2 Before starting the application review, the applicant will provide MTIC with the documentation in compliance to ICMED 9000 and ICMED 13485 requirements, as applicable.

3.1.3 Apart from information regarding the equipment and facilities of manufacturing facility particularly sterilization process, the applicant will provide information regarding the plan and frequency of controls carried out on incoming material, production facilities and testing equipment in order to allow auditors to have a preliminary overview of the manufacturing facility.

3.1.4 The documentation to be provided will include the following:

a) Quality Manual – Addressing all the requirements as per criteria document

b) Procedures – (Procedures related to process and general area of operation such as purchase, H.R. etc)

c) Quality Plan – Addressing controls applied & verification frequency of inspection of Incoming material, Process controls and and final Product(s) etc.

d) Standard operation procedures/ Work instructions

e) Form and Formats.

3.2 Audit Team

3.2.1 MTIC will appoint an Audit Team having the necessary competences ~~and skills~~ required to conduct the audit.

Audit Type	Audit Team composition
Certification Audit	Auditor + Technical Expert (if Auditor is not qualified for medical device

	sector)
Surveillance	same as above

3.3 Audit Plan

3.3.1 MTIC will ensure that the Audit is conducted during working days in which all manufacturing and support processes are functional.

3.3.2 No audit will be planned in case the manufacturing facility is non-operational

3.3.3 The Auditors, if more than one, may conduct part of the audit in parallel being focused on specific processes/ areas.

3.3.4 All the activities as included in the scope of certification of manufacturing facility such as design, manufacture, construction, marketing, installation, servicing or supply of the medical device etc will be audited irrespective of location.

3.3.5 The audit of the controlling/ head office will be planned in case it is catering to multiple manufacturing facilities to verify all the functions of its activities.

4. Certification Audit

4.1 Stage 1 Audit

4.1.1 The stage 1 audit is performed to:

a) Audit the client's management system documentation;

b) Evaluate the client's location and specific conditions and to undertake discussions with the client's personnel to determine the preparedness for the stage 2 audit;

c) Review the client's status and understanding regarding requirements of the standard, in particular with respect to the identification of key performance or significant aspects, processes, objectives and operation of the management system including scheme requirements;

d) Collect necessary information regarding the scope of the management system, processes and location(s) of the client, and related statutory and regulatory aspects and compliance

(e.g. quality, environmental, legal aspects of the client's operation, associated risks, etc.);

e) Review the allocation of resources for stage 2 audit and agree with the client on the details of the stage 2 audit;

f) Provide a focus for planning the stage 2 audit by gaining a sufficient understanding of the client's management system and site operations in the context of possible significant aspects;

g) Evaluate if the internal audits and management review are being planned and performed, and that the level of implementation of the management system substantiates that the client is ready for the stage 2 audit.

h) Auditors will identify personal protective equipment which may be reasonably required during while auditing processes in stage – 2 audit and report in stage – 1 audit and ensure availability of the required personnel protective equipment during Stage – 2 audit.

4.1.2 The Stage – I audit will be carried out by a competent audit team on site to judge the adequacy of the system to meet requirements of applicable ICMED 9000 and ICMED 13485 criteria. It will result in a formal report

4.1.3 The stage 1 audit will be carried out at the client's premises in order to achieve the objectives

4.2 Stage 2 Audit

4.2.1 The Objectives of stage 2 audit will be to verify compliance to the applicable certification criteria, regulatory requirements, verification of documents and records, and interviews with personnel involved in various relevant activities. The stage 2 audit will be conducted on site.

4.2.2 .Competence of people at manufacturing facility will be audited to verify the effective knowledge QA/ QC and of internal procedures, applicable standards related to medical device being produced. The competency of the personnel will be as per applicable regulation. The requirement is as follows.

"The manufacture & Quality Assurance will be conducted under the active direction and personal supervision of competent technical staff consisting of at least one person each for manufacturing & Quality Assurance who is a whole time employee and who is

i) a Graduate in Engineering or Pharmacy from a University recognized by the Central Government for such purposes and has had at least eighteen month practical experience in

the manufacturing or Quality Assurance of devices after his graduation; or

ii) a Graduate in Science, from a University recognized by the Central Government for such purposes and has had at least three years practical experience in the manufacturing or Quality Assurance of devices after his graduation; or

iii) a Diploma in Engineering or Pharmacy from a Board or Institute recognized by the Central Government or the State Government, as the case may be, for such purposes and has had at least four years practical experience in the manufacturing or Quality Assurance of devices after his diploma; or

iv) having a foreign qualification, the quality and content of training of which are comparable with those specified in clause(i), clause (ii) and clause (iii) above and is permitted to work as competent technical staff. “ -

4.2.3 Safety during audits

4.2.3.1 The Audit at medical device manufacturing facility involves risks linked to work

environment. The responsibility for risk analysis and the identification of the most suitable means of protection ~~is~~ will be that of the manufacturer.~~.~~

4.2.3.2 Auditors must have personal protective equipment which may be reasonably required to while auditing different manufacturing processes of manufacturing facility particularly sterilization.

4.3 Non conformities

4.3.1 Any non conformities observed during audit, with respect to the certification criteria will be informed in writing to the applicant for taking necessary action. The non conformities will be classified as Major or Minor depending on their severity.

a) **Major Non conformity** – A non conformity that affects the capability of the management system to achieve the intended results. A number of minor NCs on the same aspect will be clubbed together and raised as single major NC.

b) **Minor Non conformity** – All other gaps and non conformities will be classified as Minor. These will generally be related to other implementation issues which do not directly affect the capability of the management system to achieve the intended results.

4.3.2 In case of major and minor NCs the organization will carry out root cause analysis and inform the same along with correction and corrective actions, within a period of one month or 3 months respectively. All non-conformities are required to be closed before initial certification through verification of adequacy of the correction and corrective actions. All Major non-conformities, will invariably require a follow-up audit.

4.4 Audit Report

4.4.1 MTIC will send the Audit Report within 7 working days from the date of the completion of the audit to the client.

4.4.2 The audit reports for stage 1 and stage 2 will clearly provide evidence and conclusions about the fulfilment of the audit objectives as described above and will contain sufficient detailed information regarding conformity with all the relevant certification requirements, including the Certification Criteria. The Audit report will have the following as minimum:

a) Scope of the Certification,

b) Name and address of manufacturing facility (ies) audited

c) Name(s) of auditor/members of the team

d) Date & time of audit

e) Audit Criteria

f) Structure of the audited manufacturing facility

g) Report on auditing including that for all “Additional Requirements” with evidence of compliance

h) Nonconformities, if any

i) Processes excluded by the Scope of the certification, if any,

NOTE: ISO 17022 may be referred to for further guidance on Audit reporting

5. Certification Decisions

5.1 Certification decision will be the sole responsibility of MTIC and the decision will be taken by its internal person(s) competent for the job provided they have not been involved in the process of audit of the organization. Impartiality and absence of conflict of interest will be ensured before entrusting the task of certification decision making

5.2 Conditions for granting a certificate:

5.2.1 MTIC will grant the certification when all the following conditions are met with:

a) The audit report with suitable recommendation is available

b) All NCs raised have been closed.

c) There are no other issues impacting grant of certification

There will be no conditional grant of certification.

6. Certificate

6.1 The manufacturer may achieve one of the following certificates**:**

Certificate	Object	Extension	Certificate Number
Single Manufacturing facility	All the processes carried out	Single manufacturing facility	One certificate number

Multi-Site	Group of manufacturing facilities sharing common facilities or processes	Group of manufacturing facilities	One number (the certificate will have an annexure with the list of certified Manufacturing facilities)

Company	Entire company	All manufacturing facilities	One number per company (the certificate will have an annexure with the list of certified manufacturing facilities)

6.2 **Certification Documentation** - The certificate will include the following information:

a) Certificate number

b) Certification scheme name

c) Reference to certification criteria

d) Manufacturer's name (that of the legal entity) with all locations in the schedule

e) Certified Manufacturing facility address

f) Scope of certification

g) Scheme logo

h) logo of MTIC

i) Accreditation number with logo

j) Date of certification

k) Expiry date

l) Signature of the authorized representative

In case of company certification, Annex to the certificate the list of the certified manufacturing facilities.

6.3 Validity

6.3.1 The certificate will be valid for 3 years from the date of issue.

7. Surveillance audits

7.1 Surveillance audits, announced and unannounced will be carried out on site at a frequency mentioned in clause 2.1, by a competent audit as as per clause 3.2 above. The audit mandays for surveillance audits will be as defined in clause 2.3

7.2 Non conformities observed during surveillance audit will be categorized as major and minor as defined in clause 3.4.

8. Suspension

8.1 MTIC will issue instructions to the certified organization for suspension of certification when

a) the major NCs issued are not closed in timelines prescribed

b) repeated major NCs are raised in consecutive surveillance assessments

c) there is failure to organize a surveillance audit within the specified time period

d) there is non payment of outstanding dues

e) any major changes have taken place in the legal status, ownership, name etc without prior information to MTIC

f) any wilful misuse of the logo of the Scheme is detected

g) any wilful false declaration in the application form or otherwise is detected

h) excessive or serious complaints against the certified organization management system are received and are found to be valid

i) the certified oranization voluntarily requests a suspension. Such request must be submitted in writing to MTIC along with the reasons. MTIC may decide to accept the request but may not allow the client to revoke suspension on its own.

8.2 MTIC will issue due notice of at least one week for suspension of certification to the certified organization.

8.3 When certification is suspended, M T I C will require that, during the period of suspension, the certified organization makes no misleading claims.

8.4 MTIC will revoke suspension only when Corrective actions have been taken and verified by MTIC

9. Renewal of certification

9.1 The certification will be renewed at the expiry of 3 years validity period. However the renewal process and the renewal of certification decision will be taken on or before the certificate expiration date. In order to achieve the same MTIC will send the Renewal notice to the certified units at least four months prior to expiry of certificate validity period.

9.2 The certified organization will apply for renewal in the prescribed format along with fee, if any prescribed by MTIC at least 3 months before expiry of the certification.

9.3 The onsite surveillance audit conducted towards the end of third year and before the expiration of the certificate will be considered as the recertification audit (refer clause 2.3). The objectives of this audit will be a combination of stage 2 and surveillance audits, unless there has been any changes in product and process requirements, which would then also require assessment of the organization's revised processes, controls and systems.

9.4 MTIC will review the performance of the certified unit who has sought renewal of the Certificate, with respect to compliance to certification criteria during the entire certification cycle, prior to a decision on the renewal of the certificate. The review will essentially be based on the following:

a) Surveillance and recertification audit reports for the audits carried out during the certification cycle. The NCs raised and the satisfactory resolution of the issues raised and their effectiveness.

b) Any suspension of certificate during the previous validity period;

c) corrective actions taken

d) complaints if any received,

e) Adverse information from stakeholders and regulators, if any.

9.5 The review will be conducted by competent person (s) designated for the job.

9.6 The decision for renewal of certificate will be taken by the competent personnel authorised for the same, based on the satisfactory performance of the certified organization.

9.7 MTIC will not renew certification with conditions for compliance to be verified subsequently. There will be no conditional renewal of certification.

9.8 When performance of the certified unit is not satisfactory, MTIC withhold the renewal of the certificate clearly stating the reasons and give time for effecting corrective actions. The verification and decision on renewal should be taken within 3 months of the certification expiry date.

9.9 The corrective actions will be verified generally on site unless MTIC can verify the same off site prior to considering for renewal of certificate. The justification for offsite review will be recorded.

9.10 In case the manufacturing unit does not complete satisfactorily actions within three months, the certificate will stand expired from the date of expiry of previous validity.

9.11 When a certificate is not renewed, it will expire at the end of validity period.

10. Withdrawal

10.1 Certification body will withdraw the certificate when

a) Certified organization contravenes the terms and conditions of certification and provisions of the ICMED scheme

b) The certified organization is not conforming to the requirements of the Certification Criteria and the corrective actions taken are not ensuring compliance,

c) the proposed plan for corrective actions will take a considerable time beyond 6 months for implementation;

10.2 MTIC will withdraw the certificate at the request of the certified plant, if the operation(s) in the certified organization can no longer be carried due to reasons of natural calamities such as flood, fire, earthquake etc, lock out declared by the management, or closure of business operations etc.

11. Change of location/Ownership/Name

11.1 The certified organization will inform MTIC of any change in the location of the manufacturing unit.

11.2 On receipt of such information, MTIC will issue instructions to the certified organization for suspension of certification with immediate effect.

11.3 The manufacturing unit will be subject to an onsite audit at the new site like an Initial audit of an applicant.

11.4 If the audit is satisfactory, MTIC will transfer the Certificate to the new location.

11.5 MTIC will endorse the change of premises on the Certificate.

11.6 In the event of change of Ownership, the organization will provide necessary documentary evidence. The new management of the organization will submit its acceptance to the agreement with MTIC, and payment of fees. The same process will be followed as and when an existing applicant undergoes a change in management. Such changes will not call for a visit to the production site.

11.7 In case of change of Name, the manufacturer will inform the change in the name to MTIC supported with documentary evidence, and if satisfied MTIC will endorse the Certificate in the new name.

12. Complaints and appeals

12.1 MTIC will have a documented procedure for handling of complaints and appeals.

12.2 The procedure for complaint handling will include complaints from all stake holders, especially its certified organization as well as customers of its certified organizations.The procedure for receipt and handling of complaints will be made available to public on the website and will also be easily accessible on the website.

12.3 Upon receipt of a complaint or appeal, MTIC will confirm whether the complaint or appeal relates to certification activities for which it is responsible and, if so, will address it. MTIC will acknowledge receipt of a formal complaint or appeal.

12.4 MTIC will be responsible for gathering and verifying all necessary information (as far as possible) to progress the complaint or appeal to a decision.

12.5 The procedure will include the process steps for receiving and recording, evaluating and establishing validity of the same, investigating and make decisions on complaints and appeals. The process step will also include the activities of root cause analysis, correction and corrective actions.

12.6 If the complaint relates to a certified organization, then the examination and evaluation of the complaints will take in to consideration the effectiveness and implementation of the certified organizations system.

12.7 The complaint handling process will document the actions to be taken by MTIC as well as the certified organization,. Some of these actions/conditions will also be included in MTIC s legally enforceable contract with the certified organization.

12.8 MTIC will record and track complaints and appeals, as well as actions undertaken to resolve them.

12.9 The decision resolving the complaint or appeal will be made by, or reviewed and approved by, person(s) not involved in the certification activities related to the complaint or appeal. To ensure that there is no conflict of interest, personnel (including those acting in a managerial capacity) who have provided consultancy for a certified organization, or been employed by the certified organization, will not be used by the certification body to review or approve the resolution of a complaint or appeal for that certified organization within two years following the end of the consultancy or employment.

12.10 Whenever possible, MTIC will give formal notice of the outcome and the end of the complaint process to the complainant.

12.11 In respect of appeals ensure that the individual(s)/committee entrusted with handling of appeal and its resolution decision will be independent of the persons involved in certification related recommendations and decision and their position hall be such that it will not be possible to influence their decisions with respect to the subject of the appeal.

12.12 The procedure will also have provision for giving a written statement to the appellant, of the appeal findings including the reasons for the decisions reached and also communicating to the appellant about the provision for giving an opportunity to formally present his case.

12.13 Based on the presentation made, the individual or a committee appointed for hearing the

case will take a final decision on the appeal and a formal notice of the outcome and the end of the appeal process will be given to the appellant.

12.14 MTIC will give formal notice of the outcome and the end of the appeal process to the appellant.

12.15 MTIC will take any subsequent action needed to resolve the complaint or appeal.

13. Fee

13.1 A fee to be charged to the organization for various activities of the certification scheme, without any discrimination between manufacturing facilities, geographical location, size of the manufacturing facility.

13.2 The fee structure will be publicly accessible and also be provided on request. The fee structure will provide break up of costs.

13.3 MTIC will notify and obtain consent to its fee structure from the organizations prior to grant of certification. As and when the fee undergoes a change, the same will be communicated to all including applicants and the manufacturing facility certified under this scheme of certification for their acceptance.

14. Transfer Certification –

Responsibilities –
Lead Auditors - Ensure all audit documentation is provided for review.
Reviewers - Conducted reviews on all audits.
Reviewers - Conduct certification decision reviews.

Process

14.1 The objective of a quality system transfer assessment is to determine whether MTIC can accept the work of the previous registrar in order to issue a MTIC certificate in place of the previous registrar's certificate.

14.1.1 The intent is for MTIC to continue the existing audit and certification cycle began by the previous registrar.

14.1.2 MTIC must be assured that the work of the previous registrar has been in accordance with all accreditation requirements for the desired program and MTIC's own requirements, in addition to ensuring that the subject QMS conforms with the requirements of the assessment standards and other criteria.

14.1.3 Stage 1 Audits do not apply to transfer assessments. However normal Stage 1 rules will apply for any scope expansions, recertification audits or changes to registration status conducted after the initial transfer.

14.2 A desktop transfer assessment.

14.2.1 The desk review will include a review of all assessment reports since the registration assessment or the last triennial reassessment (if one has been performed since the registration audit), evidence of customer corrective action completion from the most recent assessment, and a copy of the current certificate.

14.2.2 For the desktop approach to be valid the following must be confirmed.

14.2.2.1 A continuous assessment or reassessment visit has been performed within the last year (based on the clients current audit frequency).

14.2.2.2 Minimum clauses have been audited at every surveillance audit and that a reasonable risk based process approach to auditing the subject QMS has been conducted.

14.2.2.3 Evidence is provided that any major non-conformances issued over the cycle have been resolved. If any major non-conformances were issued on the last assessment, evidence must be provided of an on-site special assessment or MTIC must conduct an on-site conversion assessment.

14.2.2.4 Evidence must be provided that the prior registrar closed any minor non-conformances from their last assessment. If the prior registrar did not close the non-conformances, then the corrective action taken for each is to be provided to MTIC for review. Before a transfer can be approved, acceptable responses must be provided to show closure.

14.2.2.5 There are no unresolved significant customer complaint trends.

14.2.3 It is important to be cognitive that MTIC is assessing the subject QMS and not the performance of the previous registrar.

14.2.3.1 If over the certification cycle any clauses or sub-clauses, in the opinion of the assessor, do not appear to have been adequately addressed by the previous registrar and which therefore may indicate ongoing certification risk, the assessor may take into consideration other management system performance information.

14.2.3.2 Such indicators may include, but not be limited to, management review output, internal audit output, CAPA effectiveness and adverse customer complaint trends.

14.3 If it is not possible to ascertain that the subject QMS is operating effectively in the desktop

assessment, an onsite assessment will be required.

14.3.1 The onsite assessment will include all elements of a regular surveillance audit (based on the point in the certification cycle the transfer is occurring) and additional processes where there is insufficient evidence of assessment / conformance from previous audit reports.

14.4 Desktop and onsite transfer assessments are to be conducted by a Lead Assessor qualified in

the applicable programs. The audit team will meet the qualifications for a Registration assessment.

2.0 CERTIFICATES AND CONTINUOUS SURVEILLANCE

2.1 Upon concurrence of the reviewer, MTIC will issue certificates in the requested

2.1.1 The certificates will contain the following elements:

2.1.1.1 The scope of registration of the MTIC certificate(s) will be exactly the same as the scope of the previous registrar's certificates, unless that scope statement violates existing MTIC requirements and approval from the reviewer is obtained

2.1.1.2 The registered entity name, address, trade-names and all site/offsite locations will match the previous registrar's certificate unless that violates existing MTIC requirements and approval from the Reviewer is obtained

2.1.1.3 Unless time equivalent to a triennial audit and a full clause audit is successfully conducted, the expiry date of the MTIC certificate will match the expiry date of previous registrar's certificate.

2.2 MTIC will continue the existing audit cycle of the previous registrar.

2.2.1 A desktop evaluation of transfer may not count towards any reduction of further continuous surveillances in the audit cycle or reduction of time for further surveillance.

2.2.2 MTIC will ensure that audits are scheduled and conducted within the waitlist period per MTIC program rules (dependent on annual surveillance).