Quality Management System Certification Process and Conditions

1 Purpose

NSF Health Sciences Certification, LLC's Medical Device Regulatory Certification (NSF-MDRC) program offers quality management system (QMS) regulatory certification services as an authorized/recognized Auditing Organization (AO) by the Medical Device Single Audit Program (MDSAP), as well as mock audits and second-party supplier audits. This document provides the outline of the certification process for use in MDSAP regulatory certification and mock audits, including granting, refusing, maintaining, renewing, suspending, restoring or withdrawing regulatory certification and expanding/reducing regulatory certification scope.

The independence, confidentiality and impartiality of the auditors is guaranteed by NSF-MDRC. The NSF-MDRC structural and procedural organization ensures that the criteria stated in International Organization for Standardization (ISO) 17021-1 (current version): *Conformity assessment - Requirements for bodies providing audit and certification of management systems - Part 1: Requirements* and the applicable regulatory programs are fulfilled, and that the certification organization and process are documented.

2 Scope

NSF-MDRC provides auditing and regulatory certification services related to the QMS of medical device manufacturers and service companies. A condition for regulatory certification and certificate issuance is an audit to determine compliance to the applicable ISO 13485 quality management system standard and/or regulatory scheme to which the client has applied. The audit must conclude with a positive result.

This document applies to the total regulatory certification process which includes: quotation, contract, application, Stage 1 audit, Stage 2 audit, Independent Review, certification decision, and certificate issuance as part of Initial regulatory certification, plus surveillance, recertification and suspension/withdrawal activities.

3 Normative and Informative References

4 Responsibilities

4.1 NSF-MDRC Duties and Responsibilities

4.1.1 Commitment to Impartiality

NSF Regulatory Certification, LLC's Medical Device Regulatory Certification program (NSF-MDRC) operates with integrity and is impartial in its business relationships, so as to not compromise this integrity. Impartiality is paramount to the program's performance of regulatory certification. As such, objectivity is ensured and maintained throughout its activities. NSF-MDRC personnel understand the importance of impartiality in these activities and has established policies and procedures ensuring objectivity and managing risk from conflict of interest to avoid any real or perceived lack of impartiality. Additionally, NSF-MDRC management proactively conducts risk management analyses of all auditing and certification activities to include in its management review.

4.1.2 Confidentiality

NSF-MDRC will treat all the clients' data that is made available as confidential and will use it only for the agreed purpose. Documents made available will not be provided to third parties. Exceptions to this are:

- For the submission of detailed reports to any NSF-MDRC committee in the case of complaints and/or appeals
- Access to client's file by the regulatory authority (RA) shown on the certificate(s) issued to the client
- Upon request of an RA or as required to release to RA(s) public health hazard, fraudulent activity or counterfeit products and/or certification refusal, suspension, reinstatement, restriction or withdrawal within five (5) working days
- When the client releases NSF-MDRC from its confidentiality agreement for specific reasons
- During the participation of RA(s) in audits

4.1.3 Audit Termination

NSF-MDRC reserves the right to terminate an audit in cases of:

- Obvious and demonstrated lack of interest or opposition by the senior management regarding the audit
- Members of the audit team being threatened, blackmailed, bribed, propositioned, assaulted (verbally or physically), discriminated against, or in fear of their well-being.

4.1.4 Requests for Information; Complaints and Appeals

It is the policy of NSF-MDRC to handle and resolve all complaints and appeals in a timely and effective manner. Requests for information, feedback, complaints and appeals from any party will be reviewed and, as necessary, registered and acted upon, including cases where a client exercises its option of filing a complaint with NSF-MDRC if said client is not satisfied with NSF-MDRC regulatory certification services or decisions made during the certification process. At any time, an appellant may formally present its case. NSF-MDRC process is to acknowledge receipt of the appeal or complaint, work with the client to resolve the complaint, provide the appellant or complainant with progress reports, and give a formal notice of the end of the process, including reasons for the final decision. Correspondences may be sent to MDRC@nsf.org. Please see the client contract for additional liability information, i.e., that liability of NSF-MDRC toward the client or third parties exists only insofar as is prescribed by law in the event of gross negligence.

An appellant may appeal to the applicable RA where that body has acknowledged a process for handling appeals, including per the process for the MDSAP Regulatory Authority Council. The appellant shall have no other remedies and no right to pursue the matter in any way whether outside or within any judicial procedure including but not limited to a court or arbitration procedure. Clients herewith already irrevocably wave any rights to any judicial procedure regarding any decision by NSF-MDRC or its affiliates in a certification process.

4.1.5 Quality Records

NSF-MDRC maintains records on its activities with its clients, so that performance of these activities can be demonstrated. The records maintained include but are not limited to:

- Quotations
- Contracts
- Correspondence
- Audit documentation

These documents will be kept for at least 15 years from the expiration of the validity of the certificate.

4.1.6 Notice of Changes to the Regulatory Certification Process

NSF-MDRC will inform its clients of changes to the certification process stating at what date the modified requirements will become effective and advising clients of any action necessary on their part. If the client provides comments that the changes are not acceptable, NSF-MDRC will work with the client to determine if the client will be allowed to continue its participation in NSF-MDRC's regulatory certification program. If a resolution cannot be determined, the certification shall be terminated on the date on which the modified requirements became effective unless otherwise decided by NSF-MDRC. If the client does not comment or give confirmation within the specified period of time, NSF-MDRC takes this as an acceptance of the modification.

4.1.7 List of Certified Companies

NSF-MDRC will maintain a list of certified client organizations, stating the respective scope of application. The list will be available to the public either through our official website or will be made available upon request.

4.1.8 Openness

Openness is a principle of access to, or disclosure of, appropriate information. NSF-MDRC provides public access to, or disclosure of, appropriate and timely information about its audit process and certification process, and about the certification status (i.e. granting or maintaining of certification; expanding or reducing the scope of certification; and renewing, suspending, restoring or withdrawing of certification) of any organization, in order to gain confidence in the integrity and credibility of certification.

4.2 Client's Duties and Responsibilities

4.2.1 Regulatory Certification Audit Requirements (see also Contract)

The client will make all necessary arrangements for the conduct of the audit(s), including allowing for observers, e.g. trainee auditors; allowing auditors access to all processes and areas, records and personnel of the relevant departments for initial (including surveillance) and recertification as well as resolution of complaints; allowing representatives of the MDSAP-participating RA(s) to observe and assess NSF-MDRC's personnel during on-site audits to include access to the client's documents and records; identifying an audit representative who will act as the main point of contract for all audit-related activities; and provisioning for and making available to NSF-MDRC examination of all documents relating to the quality management system or regulatory documentation (including records). If a RA representative will be acting as an observer, NSF-MDRC will inform the client prior to the audit upon receiving such a request.

The regulatory certification audit date may be re-scheduled or canceled by the client, but will incur significant monetary charges tiered by proximity to scheduled audit date and according to the client contract terms and conditions.

The client agrees that, at the request of the RA(s), NSF-MDRC shall perform a special audit under the direction of that/those recognizing RA(s) that is/are requesting. The client understands and agrees that the RA(s) itself/themselves may perform special audits, including unannounced audits, any time it/they deem(s) necessary and within the purview of its/their jurisdiction. See Special Audits below.

The certificate holder shall keep record of complaints and remedial actions relative to the quality management system. These records shall be made available to NSF-MDRC upon request and during audits. See also Management Review and Internal Audit requirements below.

The client must have a contractual agreement with each of its critical suppliers that contains provisions for NSF-MDRC to perform unannounced audits at their premises. If a visa is required for NSF-MDRC to perform an unannounced audit at the critical suppliers' premises, the client's contractual agreement with the critical supplier must contain provisions for NSF-MDRC to obtain a visa invitation letter from the critical supplier which leaves the visit date open.

The certified client is to provide NSF-MDRC notification via the Change Notification Form to NSF-MDRC of:

- All important and/or significant changes in its quality management system and/or scope of products, processes or operations under the certification, e.g. the legal, commercial, organizational status or ownership; contact address and sites
- Changes in the company's organizational structure and/or management personnel which have an influence on the quality management system

When requested for cause, the client will provide NSF-MDRC with the current quality documents, including but not limited to the quality manual.

4.2.2 Confidentiality

By signing the contract, the client agrees to give permission for the recognizing RA(s) to exchange information with other RA(s) that maintain confidentiality agreements.

4.2.3 Use of the Name(s), Logo, and Marks; Use of the Certificate

The client may use the NSF mark for advertising and marketing purposes during and according to the terms of certification, if allowed. The requirements for use these marks are specified in Conditions for Promoting Certification and Usage of Marks (provided as an addendum to the client contract), and include that the underlying principle is to avoid using false, misleading, or confusing claims to the public and customers, to indicate traceability back to NSF-MDRC and to have no certification ambiguity associated with the mark(s) including client's certification status or implication that the certification applies to activities and sites that are outside the scope of certification, including use implying product certification not included under NSF-MDRC services. To this end, the standard and its specific year revision is to be specified in conjunction with promotion of certification, as well as the scheme/ indicating type (medical device quality) management system certification. The "MDSAP" mark cannot be used by the certified client/certificate holder in any way, in any form of media, other than incorporated in the certificate issued by NSF-MDRC.

The certificate holder can use the NSF-MDRC certificate as evidence submitted to clients and authorities.

5 Initial Regulatory Certification Process

5.1 Quotation, Contract, and Application

i. Quotation Questionnaire: Client completes the questionnaire so that NSF-MDRC may determine the application and audit scope, including regulatory requirements and applicable standard (e.g., ISO 13485), and subsequently, the qualifications needed in assigning the audit team to provide the requested services.

ii. Quotation: Provided to the client by NSF-MDRC, detailing the services that will be provided and the associated costs, including summary of the aggregate costs over the time of certification validity.

iii. Contract and Client Purchase Order: Once the client has accepted the quotation, a contract and purchase order are required to proceed with the certification activities.

iv. Application Document Review: Acceptance or refusal with response to client.

NSF-MDRC will, if requested, hold an informational client teleconference prior to the signing of a contract. This meeting can cover, inter alia, the following points:

- The aim and benefits of certification
- The basic requirements for certification
- Performance of the certification procedure
- Standard(s) and RA requirements applied
- Verification level, scope of application
- Estimated costs
- Proposed schedules

5.2 Stage 1 Audit/Readiness for On-Site Activities Review

5.2.1 Audit Plan

The Stage 1 audit is the first stage for initial regulatory certification and is performed in the scope of an on-site visit at the client unless it is deemed to be unnecessary based on the result of an in-office review of the submitted documentation or other circumstances as determined by NSF-MDRC.

While not required, prior to an on-site Stage 1 audit, the client may receive an audit plan detailing upcoming Stage 1 audit activities. The schedule of activities may be modified with the concurrence of the lead auditor.

5.2.2 Audit Conduct

During the Stage 1 audit, the audit team evaluates the readiness of the client's QMS for a Stage 2 audit. It includes:

- Review of the client's management system documentation (the client shall submit the documents at least two weeks before the Stage 1 audit)
- Evaluation of the location and site-specific conditions
- Review of general understanding of the requirements of the standard, identification of processes, and key performance parameters
- Review of the identification of statutory and regulatory aspects
- Review of the necessary resource and time allocation for the Stage 2 audit
- Confirmation of performance of internal audits and management review

5.2.3 Audit Conclusion, Stage 1 Audit Record

A Stage 1 audit record that describes the audit results and includes any nonconformities that may have been written will be provided to the client. The audit might result in a recommendation for:

- A Stage 2 audit within three months
- A Stage 2 audit under the condition of implementation of corrective actions
- A repeat of the Stage 1 audit, complete or in-part, in which case the client will be informed that the results of Stage 1 may lead to postponement or cancellation of Stage 2

5.2.4 Management Review and Internal Audits

Prior to the performance of the initial certification audit, the client shall conduct one complete internal audit and management review cycle. All clauses of the applicable standard, any applicable regulatory requirements, are to be audited and the results presented to management for discussion during their management review.

If it is determined during the certification audit that this requirement has not been fulfilled, additional auditing activities will be required prior to issuing the certification.

5.3 Stage 2 Audit/On-Site Certification Audit

5.3.1 Audit Team Selection

The second stage of initial certification is the Stage 2 audit. NSF-MDRC will ensure that the auditors were not involved in QMS consulting activities for the client in the three years preceding the planned audit. At a time prior to the audit, the client will be informed about the audit team members. All NSF-MDRC auditors have signed a nondisclosure agreement regarding information obtained during the audit process and related activities, except where prohibited by law. The client may also refer to nondisclosure language in the contract.

Under the MDSAP, the client is not allowed to object to the composition of the audit team (as described in ISO 17021-1:2015, clause 9.2.3.5), but may use the formal complaint process to notify NSF-MDRC of its concerns of said composition.

The certification audit will generally be carried out by at least two auditors (lead auditor, auditor). If specific technical issues must be addressed in order to assess the quality management system or regulatory requirements, an appropriate technical expert will be included on the audit team. This technical expert may act as the second auditor or be an additional member of the audit team, depending on client needs and competency requirements.

5.3.2 Audit Plan

Prior to the certification audit, the client receives an audit plan detailing the activities that will occur during the audit, including that all sites covered by the certificate must be audited for initial certification. The schedule of activities may be modified with the concurrence of the lead auditor, but are ultimately at the discretion of NSF-MDRC.

5.3.3 Audit Conduct

The audit team will conduct an opening meeting to discuss how the audit will be conducted, to outline any requirements and to provide additional information to the client.

During the audit, the audit team evaluates the quality management system's compliance with the implemented standard(s) and applicable regulatory requirements.

The audit team may use a question list as a guide in conducting the audit. The use of the question list does not preclude the audit team from going beyond the stated questions in order to better understand the client's procedures and practices or to investigate potential or suspected problems with implementation.

The client organization's role during the audit is to demonstrate the practical application of the documented procedures and regulatory requirements.

The auditor's role is to check on the practical application of the documented procedures and to assess the compliance with the requirements of the standard(s) and applicable regulatory requirements.

5.3.4 Audit Conclusion

Upon completion of the audit, the client will be notified of the outcome of the audit in a closing meeting.

Any nonconformities will be documented and explained by means of the Nonconformity Report. They are submitted to the client and countersigned by the client's audit representative to confirm their receipt.

A client with a certification audit ending in no nonconformities will receive a recommendation for certification by the audit team. It is important to note that a recommendation from the audit team does not guarantee certification, as that decision is made by the certification department.

A client with a certification audit ending with only minor nonconformities will receive a recommendation for certification by the audit team upon acceptable review of proposed corrections and corrective actions, except were the specific standard requires closure of any or all nonconformities before a recommendation can be granted.

5.3.5 Nonconformity Report

If nonconformities are found, the client must propose and implement corrections and corrective actions, where necessary, and submit the completed nonconformity reports with the supporting documents (if requested) prior to the recommendation for certification. It must be noted that the project will not proceed to the certification step until all outstanding issues have been completed and reviewed with a positive result by the audit team.

The client must provide a remediation plan (including for each nonconformity: the outcome of the investigation of the nonconformity and its cause(s); the planned correction; and the planned corrective action) within 15 calendar days from the Stage 2 audit closing meeting date. Otherwise, NSF-MDRC reserves the right to require additional on-site audit time prior to issuing the certification.

The client must provide evidence of implementation of the remediation actions addressing any grade 4 or 5 nonconformity within 30 calendar days from the Stage 2 closing meeting date. Requests for other documentation related to nonconformities is at the discretion of NSF-MDRC. Otherwise, NSF-MDRC reserves the right to require additional on-site audit time prior to issuing the certification or reserves the right to suspend the certification.

5.3.6 Audit Report

A detailed audit report that describes the audit results and includes any nonconformities that may have been written will be provided to the client.

5.3.7 Additional Off-Site Audit Time

Additional audit time may be required, post-audit, to handle the review and closure of nonconformities. This additional audit time may be spent on-site or off-site at the auditor's discretion. The auditor may also elect to add additional time during the next audit in order to verify the effectiveness of the client's corrective actions.

5.3.8 Failed Initial Regulatory Certification Audits and Subsequent Actions

If the certification audit resulted in nonconformities of grade 4 or 5, the client must propose and implement corrections and corrective actions per Nonconformity Report above.

If NSF-MDRC is not able to verify implementation of corrections and corrective actions of nonconformities of grade 4 or 5 within six months after the last day of the Stage 2, then NSF-MDRC will conduct another Stage 2 prior to recommending certification.

If the certification audit resulted in one or more grade 5 nonconformities, or more than two grade 4 nonconformities, or a public health threat, or any fraudulent activity or counterfeit product, the audit team will not recommend the client for certification.

5.4 Independent Review and Final (Certification) Review

The audit team reviews the Stage 1 and 2 audit information and agrees on the audit conclusions, including a recommendation whether to grant certification, along with any conditions. The audit information, including nonconformities and any associated plans, corrections, and/or corrective actions, is passed to personnel different from and independent of the audit team for review and prior to a final certification decision. Personnel do not review and approve their own work.

5.5 Certification Decision and Granting (or Refusal) Certificate

NSF-MDRC final reviewer(s) conduct the final step in the certification process, using the highest degree of professional integrity and requisite technical competence. After the recommendation of the audit team, the final reviewer decides on whether the certification will be granted and the certificate issued or whether other additional actions are required. Certification begins with the certification decision date, including that for recertification. This also includes decision(s) for refusing certification, and during the certification period the

suspending, restoring, withdrawing, or renewing certification, and/or expanding or reducing the certification scope.

Once issued, the certificate is valid for three years. The certification's continued validity is dependent on the surveillance audits having a positive outcome.

6 Surveillance and Maintenance of Regulatory Certification

6.1 Process

The certification requires periodic surveillance audits to determine whether the implemented quality management system remains in compliance with the standard(s) and applicable regulatory requirements identified under the certification scope. Surveillance audits are conducted on-site and are conducted at least on an annual (calendar year) basis, but may be conducted more frequently at the discretion of NSF-MDRC.

The first surveillance audit after an initial certification audit must be conducted within 12 months from the last day of the certification audit. For scheduling purposes with the client, a flexibility of three months earlier is permissible. The second surveillance audit will occur in the second year following initial certification (24 months).

Additional annual surveillance audits should be scheduled based on the anniversary of the original certification/recertification audit. For scheduling purposes with the client, a flexibility of three months earlier or later is permissible, but it must be understood that this flexibility is at the discretion of NSF-MDRC and the client must be aware that it may affect the audit program such that the time frame between surveillance audits can be less than one year. This is particularly important when noting the timing of the recertification audit.

Surveillance audits are on-site, but are not necessarily full system audits. During the surveillance audits, an evaluation is made that includes:

- Management responsibility and quality management system review
- A review of actions taken on nonconformities identified during the previous audit
- Complaints handling
- Effectiveness of the management system with regard to achieving the certified client's objectives and the intended results of the respective management system(s)
- Progress of planned activities aimed at continual improvement
- Continuing operational control
- Review of any changes
- Internal audit conduct and results
- Corrective and preventive actions
- Applicable regulatory requirements
- Use of marks and/or any other reference to certification

The basic process of conducting the surveillance audit is similar to the Stage 2 audit including audit team selection, audit plan, opening and closing meeting, nonconformity reports (if needed), and a written report with the audit results.

During the surveillance audit, any nonconformities/nonconformity reports from the last audit that have not been previously verified for the effectiveness of their corrective action and closed

will be reviewed for implementation. See below on Special Audits for particular requirements for grade 4 or 5 nonconformities or other serious issues found at audit.

6.2 Nonconformity Report (see Initial Regulatory Certification)

6.3 Special Audits

Special audits include audits for the expansion of scope, short-notice audits, and unannounced audits. Special audits may be conducted by RA request. Special audits for expansion of scope may be conducted in conjunction with surveillance.

Short-notice or unannounced audits may be necessary to investigate complaints, in response to notification of changes, or as follow-up on suspended clients, in which case NSF-MDRC will exercise additional care in the assignment of the audit team because the client cannot object.

An unannounced audit will be carried out if any of the following conditions occur:

- Request from RAs, noting that RAs themselves may perform special audits, including unannounced audits, as deemed necessary, per their jurisdictional purview, and to include assessment of NSF-MDRC
- There are serious doubts about the effectiveness of the quality management system, particularly if it is determined that defective/nonconforming products were put into circulation
- There is evidence of fraudulent activity and/or that counterfeit items were manufactured
- There is the existence of serious and/or frequent nonconformities (e.g. more than two grade 4 and/or one or more grade 5 nonconformities cited during the previous audit)
- There is information that indicates a threat to public health and/or safety

At any time, NSF-MDRC has the right to conduct unannounced audits at the manufacturers' premises as well as at the premises of the manufacturers' critical subcontractors/suppliers. The timing of the unannounced audit(s) is unpredictable and in addition to normally scheduled audits. Unannounced audits are typically conducted by at least two auditors over not less than one day, and are conducted with focus on the nonconformity, the correction, and the (systemic) corrective action both for the QMS and any devices within or outside client control that were produced under the nonconformity. It is the obligation of the holder of the certificate to ensure, through contractual agreements (e.g. visas), that an audit at the critical subcontractor's/supplier's premises can be conducted. Costs for unannounced audits, including any and all expenses, will be charged to client.

NSF-MDRC has the right to contract with an organization that provides security and protection of its staff during unannounced audits. The costs associated with this contract, as well as any and all expenses of that contracted organization, will be charged to the client.

Clients that reside in areas that require a visa for entrance are required to provide NSF-MDRC with an open-dated invitation letter to be used at the discretion of NSF-MDRC for the purposes of performing a special/unannounced audit. The format for such a letter is provided as an attachment to the contract.

For unannounced audits in the cases of release of nonconforming products and/or serious/frequent nonconformities, NSF-MDRC allows approximately six to nine months for

client implementation of its corrective action plan, unless the client provides evidence that the plan will be completed earlier.

7 Recertification and Renewal of Regulatory Certification

Before the expiration of the certificate in the third year of certification, a recertification audit of the company's quality management system is performed to extend the certification validity for another three years.

During a recertification audit, all clauses of the quality management system as well as any applicable regulatory requirements are audited. Due to the fact the company has been certified, the recertification audit may require less time on-site than the initial certification audit.

The audit process is as described above. NSF-MDRC makes renewal decisions based on the results of the recertification audit, plus system performance over the period of certification, as well as complaints from users.

8 Expansion and Reduction of Scope

NSF-MDRC reviews applications for scope expansion and determines audit activities necessary to decide whether the extension may be granted.

NSF-MDRC reserves the right to reduce the scope of certification in any of these circumstances:

- Upon request from the client
- As the result of an audit outcome
- As a result of other activities

When the client has persistently or seriously failed to meet regulatory certification requirements for parts of its scope, the scope shall be reduced to exclude those parts not meeting requirements.

9 Refusal, Suspension, Withdrawal, and Restoration of Regulatory Certification

9.1 Refusal

Refusal is the decision to not grant initial regulatory certification, following independent review. The personnel who are responsible for certification decisions, including refusals, are not outsourced, understand the standard and regulatory certification requirements, and are different from those personnel who carried out the audit(s). NSF-MDRC is responsible for, retains authority for, and will provide information and update clients on refusal decisions.

9.2 Suspension

If the certification is placed on suspension, the client's certification is temporarily invalid and the client cannot actively promote the certification, in any form of media, until such time as the certification is reinstated. NSF-MDRC is also obligated to make the suspension public.

NSF-MDRC has the right to place a certificate on suspension due to any of, but not limited to, the following:

- Nonconformities graded as 4 or 5 that are not closed with the stated time period
- Improper use or misrepresentation of the certificate or certification
- The identification of one or more nonconformities graded as 4 or 5 during a surveillance audit
- Failure to meet financial obligations to NSF-MDRC

- Conditions where public safety and/or health is at risk
- Not allowing the audit to be performed
- Not allowing the AO or RA(s) access to the premises
- Any other reasons which result specifically from these conditions or are agreed formally between NSF-MDRC and the client

The suspension will last until the next regularly scheduled audit, but at a maximum of six months. Failure to resolve the issues that led to the suspension will result in the certification being withdrawn or in a reduction in the scope of the certification.

9.3 Withdrawal

If the certification is withdrawn, the client immediately loses the right to use any marks and the ability to advertise or promote the certification. See also Conditions for Promoting Certification and Usage of Marks, which is provided as an addendum to the client contract.

NSF-MDRC has the right to withdraw a certificate for any of the following:

- The certificate or certification is improperly used.
- One or more nonconformities graded as 4 or 5 are identified during a surveillance audit.
- There are any other reasons which result specifically from these conditions or are agreed formally between NSF-MDRC and the client
- The certificate holder ceases to supply a product, process or service for an extended period of time (determined by NSF-MDRC).
- The system rules are changed and the client will not or cannot ensure conformance to the new requirements.
- The client fails to meet the financial obligations of NSF-MDRC.
- The client requests the cancellation of certification.
- The client does not inform NSF-MDRC of a change of location.
- The client does not have the periodic audits carried out according to this document or the client holds up or restricts the proper performance of the periodic audits.
- If permanent unannounced access to the premises of the manufacturer or its contracted critical suppliers is no longer assured.

9.4 Restoration

Restoration is the decision to initiate certification again following suspension and restore the suspended certification if the issue that resulted in the suspension has been resolved, or the decision to initiate certification following expiration of certification within six months, provided that any outstanding recertification activities are completed. The NSF-MDRC personnel who are responsible for restoration decisions understand the standard and regulatory certification requirements and conduct an effective review prior to the decision. NSF-MDRC is responsible for, retains authority for, and will provide information and update clients on restoration decisions.

10 Voluntary Withdrawal and Revocation of Recognition

In the event that the AO's recognition is revoked, NSF-MDRC will make every effort to rectify the reasons leading to revocation. If this is not performed within a time frame agreed upon by the RA, then NSF-MDRC will transition all certified companies to another AO that offers the same services and holds the same recognition.

If NSF-MDRC chooses to voluntarily terminate its recognition, it will do so by means of a written notification sent to the RA within 30 days. It is the responsibility of NSF-MDRC to provide any remedies to any certified companies affected by this withdrawal, appropriate to the nature of the problem that is acceptable to the RA and in accordance with program requirements. These remedies could include the notification of the withdrawal to the certified companies and any plans to transition the certified companies to another AO that offers the same services and holds the same recognition to minimize any impact felt by any certified company. Additionally, NSF-MDRC will cease to use any advertising materials containing reference to the recognition and will return any recognition documents to the respective regulatory authority. All unpaid fees will be paid upon the withdrawal.

11 Termination of Contract

See your certification contract terms & conditions for specific information on termination of the contract by either party, including prior written notice.