Procedure for GMP Certification: The Retail Certification Program (RCP®) and National Brand Certification Program (NBCP)

Table of Contents

1.0 Introduction 3
2.0 Purpose 3
3.0 Scope 3
4.0 Program Participation — Application for Certification 3
5.0 Pre-assessment 8
6.0 Initial Certification Assessment 8
7.0 Nonconformities (CAPA) Defined 11
8.0 The Review and Certification Decision 13
9.0 On-going Annual Audits 14
10.0 Modifications or Revisions to Certificates of Conformity 14
11.0 Special Audits 14
12.0 Recalls, Regulatory Events and Complaints 16
13.0 Withdrawing, Maintaining, Limiting, Extending & Suspending a Certification 16
14.0 Certificate Criteria Changes 17
15.0 Use of Certificates, Certification Symbols and Reference to RCP / NBCP Participation 17
16.0 UL VS Complaints and Appeals Process 17
17.0 Confidentiality 18
18.0 Accreditation 18
19.0 Certificates of Conformance 18
Appendix I: Rules for Use of Certification Symbols 20

1.0 Introduction

UL Verification Services, Inc.'s (UL VS) accredited supply chain certification services help businesses mitigate risk and protect brand value, while providing confidence to retailers, national brands and consumers. National Brands, Retailers and Vendors rely on UL's GMP certification audit reports and Certificates of Conformance. Achieving certification from UL's ANAB accredited GMP certification programs, gives a greater level of confidence in the product and gives the vendor more credibility in selling product to brands or retailers.

UL's accredited GMP certification programs are intended to meet multiple retailer / brand requirements for third party audits and corrective action resolution within the supply chain. UL's Supply Chain Audits provide essential information that enables Brand Managers, Compliance Officers, and Quality Assurance Specialists to make informed decisions directly impacting brand credibility and product marketability.

2.0 Purpose

The purpose of UL GMP certification is to assess the extent to which an organization conforms to the applicable regulations / standards / requirements regarding the products being manufactured / produced, packaged, shipped and/or stored. Such requirements are referred to as the current Good Manufacturing Practices, or cGMP.

There are two (2) GMP Certification programs covered under this Procedure for Certification:

- **Accredited Retail Certification Program (RCP):** The Retail Certification Program is focused on private label brands, and the scope limited to these types of products when performing RCP audits.

- **Accredited National Brand Certification Program (NBCP):** The National Brand Certification Program is focused on national brands, and the scope limited to these types of products when performing NBCP audits.

3.0 Scope

Certification is open to all interested organizations. All organizations that utilize UL GMP certification services are guided by this Procedure for GMP Certification and are required to comply with all the relevant provisions contained herein, including implementing appropriate changes when they are communicated by UL VS.

Stakeholders and/or their contract manufacturers / packagers / distributors (the organization) shall make all necessary arrangements for UL VS personnel to conduct assessments with respect to examining documentation, access to all areas, records, investigation of complaints, participating observers and personnel (including subcontractors) associated with the scope of the Retail Certification or National Brand Certification Audit.

4.0 Program Participation — Application for Certification

Whether a new applicant or currently certified client, organizations to undergo assessment must provide pre-audit information on the UL-provided Application, to include but not be limited to the following:

- Selection of Audit / Certification Program;
- The size and location of the facility to undergo audit,
- The number of employees at the facility (including part-time, full-time employees and contractors),
- All requested scope(s) under audit,
- A list of all finished products manufactured, packaged or stored, which may be provided for retail or wholesale trade,
- Any requested exclusions, and
- Regulatory inspection history for past 2 years, including date of last regulatory inspection and

resulting 483's, warning letters, consent decrees received.

Upon receipt of the Audit Application, UL VS determines the minimum number of days for the audit as prescribed in Accreditation documents and rules. A Contract / Proposal (Certification Agreement) will then be forwarded to the applicant. This document will be used as a contractual agreement between UL VS and the organization to carry out certification services.

A copy of the Agreement will be provided to the manufacturer for the purpose of signing. A copy will be submitted to UL VS and a copy will be retained by the organization. To the extent that there is any inconsistency between this "Procedure for Certification" document and the final contractual agreement (proposal), the terms of this procedure shall control.

Upon submission of a signed contractual agreement, the organization will be contacted by UL scheduling personnel to arrange for mutually acceptable dates during which to schedule audits. Audits will be conducted at the earliest possible date acceptable to the organization where UL auditing personnel are available.

The Agreement shall remain in effect for three years and shall automatically renew for subsequent three-year terms, until such time that UL VS informs the organization or the organization informs UL VS in writing of their intention to cease participation in the Retail or National Brand Certification Program.

Termination / Cancellation of the Agreement causes the Certificates of Conformance to be immediately withdrawn. The Certificates of Conformance are the property of UL VS and must be surrendered without delay upon request to do so. All Certification Badges provided for use by the organization shall be surrendered, and all advertising bearing the badges must be immediately removed from use and/or public domain.

Audit Scope and Standards Defined

Unless otherwise specified, the audit scope applies to one site/one supplier facility and includes the organizational structure, responsibilities, procedures, processes, and resources for implementing quality management systems in meeting specified management system objectives and regulatory requirements. Multi-site organizations are assessed based on the level of activity involved with the private label item(s). These multi-site organizations may be assessed independently based on the design of operation management.

When determining audit scope, the Audit Client will select the type of certification appropriate for their business. There are 2 types of certification within the Retail and National Brand Certification Programs. The option selected will drive the focus and breadth of auditor sampling when onsite.

- **Full scope option**: The scope of certification is intended to cover a wide range of products and processes across multiple customers. In this approach, the auditor sampling is not limited to a single customer, and the facility must provide access to records accordingly. Under the full scope option, certificates will be valid for three years + 90 days and will follow a three-year cycle (see the On-going Annual Audits section for more details).

- **Limited scope option:** The scope of the audit is limited to a specific retailer, brand or customer, implying a scope exclusion for other products or processes performed onsite. In this approach, the name of the customer will be present on the certificate, and the final audit package is expected to be used to satisfy the requirements of that customer alone. Under the limited scope option, certificates will be valid for one year + 90 days and the organization will be on a one-year cycle (see the On-going Annual Audits section for more details). The Limited Scope option will not have certification details displayed on the public certified client listing and audit clients are prohibited from

using UL Badges. Where the Audit Client is different than the auditee, the Audit Client shall receive the report and certificates.

Regardless of the type of program selected, the GMP certification audit reviews a site's Quality, Production, Equipment, Material, Packaging and Laboratory Systems against requirements and expectations.

Elements of a facility's quality system that may be within the audit scope are dependent upon the technical scope selected and agreed to with the applicant organization as follows:

- All applicable management systems (as described in the six-system approach by the FDA's Compliance Program Guidance Manual: Drug Manufacturing, Inspections Program 7356.002) will be audited during the RCP / NBCP Audit activities.
- Sufficient objective audit evidence should be available to demonstrate the operational aspects and overall effectiveness of the management system.
- The resources committed to the audit must be sufficient to meet its intended scope and depth.

It should be noted that observations found which may impact the quality or systems of the products under scope will be noted in the audit report, even if the observation discovered is directly related to items not considered under scope.

Exclusion of products or processes from the scope of the certification are only permitted where:

- the excluded products can be clearly differentiated from the products in scope, and
- those products are produced in a physically segregated area of the site, or
- the organization has specifically requested a **Limited Scope Audit.**

Products under development and/or under trial production, or both, are excluded from the scope of the audit.

The Assessment Report employed during the audit is guided by the regulatory status and key processes of the products identified under scope, as agreed to by the applicant. In cases where the organization manufactures, processes or stores two or more types of regulated/non-regulated products, governed by two or more different FDA cGMP regulations, both standards will be utilized to carry-out the audit. The following table defines the standards referenced within the audit report:

RCP / NBCP Technical Scope	Application	Standards	Assessment Tool / Report
Pharmaceuticals / OTC Drug	The Manufacturing of Drug Products including Tablets, Capsules, Softgels, Caplets, Liquids, and/or Topicals (Aerosols, Powders, Creams) The Bulk Packaging, Primary Packaging, Secondary Packaging of Drug Products (as listed above).	21CFR 210/211	Pharmaceutical Drug Risk Based Assessment Tool / Report
		FDA Guide on Aseptic Processing	Aseptic / Sterile Module
		ANSI 455-4	ANSI 455-4 GMPs Module
		Health Canada FDR Division 2, Part C	Health Canada Drug GMP Assessment Tool / Report
Dietary Supplements	The Manufacturing of Dietary Supplement Products including Powders, Tablets, Capsules, Softgels, Caplets, Gummies, Oils and/or Liquids. The Bulk Packaging, Primary Packaging, Secondary Packaging of Dietary Supplement Products (as listed above).	21 CFR Part 111, 21 CFR 121 and 117 (as applicable) + NPA GMP Standard	Dietary Supplements Risk Based Assessment Tool / Report
		ANSI 455-2	ANSI 455-2 GMPs Module
		Health Canada SOR/2003-196	Natural Health Products Tool / Report

RCP / NBCP Technical Scope	Application	Standards	Assessment Tool / Report
Dietary or Pharmaceutical Ingredient	The Manufacturing of Dietary Ingredients and/or Pharmaceutical Ingredients (active or inactive). The Bulk Packaging, Primary Packaging, Secondary Packaging of Cosmetic Products (as listed above).	ICH Q7	ICH Q7 Dietary Ingredient Assessment Tool / Report
Cosmetics	The Manufacturing of Cosmetics and Cosmetic Ingredients including Baby Products, Bath Preparations, Eye Makeup Preparations, Fragrance Preparations, Hair (non-coloring) Preparations; Hair Coloring Preparations, Makeup (other than eye); Manicuring Preparations; Oral Hygiene Products, Personal Cleanliness; Shaving Preparations; Skin Care Preparations (Creams, Lotions, Powders, Sprays), Suntan Preparations. The Bulk Packaging, Primary Packaging, Secondary Packaging of Cosmetic Products (as listed above).	ISO 22716 FDA Guide on Cosmetic GMP ANSI 455-3	Cosmetic Risk Based Assessment Tool / Report
Food	The Manufacturing of Foods (can be applied to Dietary Ingredients, if requested by applicant organizations). The Bulk Packaging, Primary Packaging, Secondary Packaging of Food Products (as listed above).	21 CFR Part 117 and 121 (as applicable)	Food Risk Based Assessment Tool / Report
Medical Device	The Manufacturing of Medical and/or Personal Care Items listed as Class I and/or Class II Medical Devices. Any factory that manufactures and / or packages Medical Device Class I Exempt products. The Bulk Packaging, Primary Packaging, Secondary Packaging of Medical Device Products (as listed above).	21 CFR Part 820 21 CFR Part 820; the requirements listed in the FDA's CDRH Classification Database for Class I GMP Exempt products and Basic Quality System GMP Requirements	Medical Device Assessment Tool / Report Medical Device Class I Exempt Assessment Tool / Report
Infant Formula	The Manufacturing of Infant Formulas The Bulk Packaging, Primary Packaging, Secondary Packaging of Infant Formula Products.	21 CFR Part 110, 106 & 107	Infant Formula Assessment Tool / Report

RCP / NBCP Technical Scope	Application	Standards	Assessment Tool / Report
Non-regulated	The Manufacturing of Formulated, Electronic or otherwise Consumer Products not regulated by Food & Drug authorities. May also apply to the manufacturing of food/drug/cosmetic/medical or other consumer product labels/components/packaging. The Bulk Packaging, Primary Packaging, Secondary Packaging of Non-regulated products (as listed above).	Basic Quality System GMP requirements	UL Non-regulated Supplier Quality Assessment Tool / Report
Warehouse/ Distribution Centers	Any facility whose key processes are limited only to the warehousing/storage and distribution of finished consumer products (regulated or non-regulated) including all product types listed above	cGMPs listed within Title 21 for each product classification	UL GMP Warehouse / Distribution Assessment Tool / Report

The standard for GMP certification audits for regulated products includes the prevailing regulations as published in the Code of Federal Regulations, the Federal Register, Health Canada, USP and any other international regulations as covered in this Program document with respect to foods, formulations, pharmaceuticals, supplements, cosmetics, ingredients and medical devices. In addition, retailer, national brand or customer-specific requirements may be included where industry trends demonstrate the benefits.

The standards for non-regulated products are based on good manufacturing principles, which include but are not limited to requirements for basic written procedures for all critical activities, staff training and independence of QA/QC.

Any facility whose key processes are limited to warehousing/storage and distribution of finished products will be assessed with the requirements listed in the UL GMP Warehouse/Distribution Assessment Report. This report provides an integrated approach to FDA Standards for the holding of regulated items as it relates to those cGMPs listed within Title 21 for each product classification. This report will also apply as the basic requirements for warehouses storing non-regulated FDA products. Special care will be taken by the auditor to ensure products unaffected by temperature, humidity and/or light are not held to requirements for the control of temperature, humidity and/or light. Where products contain water, or are classified as a drug or supplement, warehouse operations should consider the standards related to control of temperature, humidity and light, in order to ensure products are not adversely affected by storage conditions or handling.

5.0 Pre-assessment

At the option of the organization, a pre-assessment audit can be conducted by UL prior to the Initial Certification audit. This pre-assessment will be charged on a per diem basis at the prevailing daily rate. The pre-assessment is a non-mandatory activity and is used to measure the applicant's readiness for a full and formal certification audit.

An Audit Summary Report will be left on-site with the organization at the conclusion of the assessment that will outline deficiencies, but a formal "audit report" will NOT be issued. The CAPA process does not apply to pre-assessment audits, and as a result, the applicant is hereby cautioned that a retailer / brand will likely not accept the results of this type of audit. The audit summary is meant to encourage the organization to take time to make necessary corrections prior to the On-site Initial Assessment Process described in the following section.

6.0 Initial Certification Assessment

The purpose of the initial certification assessment process is to determine that the organization has implemented an acceptable quality system in accordance with defined audit standards. To ensure a successful outcome to the assessment, the Organization shall:

- Have effectively implemented a quality management system that meets the cGMP requirements for the technical scope(s) applied for. The formal assessment shall take place at the auditee's location;
- Have completed one complete round of internal audits;
- Have appointed a "management or designated representative" who is responsible to oversee the safety of auditors while onsite;
- Have arranged to see that the assessment team has access to all parts of the organization's facility, subcontractor's facilities, relevant documentation, and personnel for which the scope of assessment is being sought;
- Have performed monitoring, measuring, and reviewing against key performance objectives and targets;
- Comply with applicable laws and statutes;
- Maintain operational control over processes;
- Maintain statistically valid sampling practices and procedures as required by the industry standard and/or regulatory requirements sufficient to ensure acceptance and release of final products;
- Maintain policies with proper management responsibility and approval;
- Have defined links between various parts of the management system, including: policy, performance objectives and targets, applicable legal requirements, responsibility and competence of personnel, operations, procedures, performance data, internal audit findings, and conclusions;
- Ensure that a minimum of three commercial batches for all products included in the requested scope have been produced and fully released;
- Ensure that the product(s) and/or a representative product(s) included within the requested scope of certification will be in production at the time of audit. Failure to ensure that the product(s) and/or a representative product(s) included within the requested scope of certification are in production at the time of audit will result in an aborted audit at the client's expense.

Prior to commencing any on-site certification assessment activity, the auditor will provide an audit schedule/agenda 14 calendar days prior to the audit date. This is the first stage in the on-site assessment process.

The Opening Meeting

At the commencement of the formal assessment, the audit team will meet with the organization's management to conduct an opening meeting.

The opening meeting ensures that:

- The organization's personnel have a clear understanding of the certification assessment process;
- The organization's personnel are clear on the scope of the activity for which application has been made;
- Audit exclusions are discussed, captured and documented;
- All parties involved in the process are clear with regards to the primary contact person;
- There are no points of misunderstanding with respect to any areas of a sensitive nature and confidentiality is carefully maintained regarding proprietary aspects of the organization's operations;
- Management personnel are clear and committed regarding the purpose of the assessment;
- Classification of Nonconformities (Critical, Major and Minor) is understood by the organization's management to ensure all parties are clear regarding how the audit results will be reported and recorded;
- The organization has an understanding of the UL complaints, disputes and appeals processes.

Upon completion of the opening meeting, a brief walk-through of the physical plant to orient the auditor to the facility will take place followed by an in-depth appraisal of each quality system component. This

assessment will be conducted to determine the adequacy of the organization's implementation of the specific regulatory requirement(s) pertinent to the organization's scope of certification, using audit standards that are appropriate to the products being produced.

Aborting the Audit

An audit that has already been started may be aborted when, for example:

- The safety of the auditor is in question;
- The organization refuses to cooperate during the audit process;
- The organization requests that the audit be stopped;
- The auditor immediately determines that the organization's quality systems and/or any one of the six systems noted in Section 4.0 of this procedure are significantly non-conforming with the applicable standard(s) and/or regulations.
- Failure to ensure that the product(s) and/or a representative product(s) included within the requested scope of certification are in production at the time of audit will result in an aborted audit at the client's expense.

The audit must be re-scheduled at the earliest date agreed between the parties when the organization has corrected or resolved the reason for stopping the audit.

Pre-Closing Meeting Activities

After completion of the audit and prior to the closing meeting, the auditor will meet privately with the company's designated representative and will clearly identify deficient areas or non- conformances regarding the overall quality system, which will require an organization to develop an appropriate corrective action plan (CAPA).

CAPAs will be signed by the designated company representative and copies left on site by the auditor.

The Closing Meeting

A formal closing meeting will be held on the final day of the assessment for the purpose of:

- Presenting a summary of the auditor's activities to management personnel present;
- Presenting the findings of the audit regarding matters of non-conformance (if applicable);
- Ensuring that the organization understands the classification of Nonconformities (Critical, Major and Minor) and to ensure all parties are clear regarding how the audit results will be reported and recorded;
- Listening to and acknowledging the organization's understanding of any nonconformity which may be presented (if applicable);
- Communicating that any CAPA document must be signed by the management's representative and the auditor for each nonconformity noted;
- Presenting the auditor's recommendation concerning the issuance of a Certificate;
- Answering any questions concerning the auditor's findings and recommendation to be made to the Certification Committee;
- Requesting that the organization provide any written comments or observations to UL for consideration on improving the Certification process;
- Explaining that the ultimate decision with respect to Certification lies with the Certification Committee.

An Audit Summary along with the CAPAs will be provided to the organization at the conclusion of the assessment. The Audit Summary is not a final report, but a document left behind to provide an initial snapshot of the outcome, including whether a follow-up is needed.

Generally, the following criteria indicates the need for a follow-up audit:

- Where 1 or more Majors are issued,
  and / or
- When a score falls in the medium risk/marginal compliance range.

If organization's score falls in the High Risk / Non-compliant range, this is considered an automatic failure (e.g. 'auto-fail'). The audit results will be processed and certification will be denied. The next activity, should the organization wish to proceed, would be an initial certification audit.

The UL auditor submits the audit report and supporting documents to UL for review and processing.

7.0 Nonconformities (CAPA) Defined

The following nonconformity classifications shall be used during the audit as well as being documented in the audit reports:

Critical (CAPA) Nonconformity

A critical nonconformity will or may result in a significant risk of producing the product, that when used in a finished product is harmful to the user. A critical nonconformity would preclude Certification.

Major (CAPA) Nonconformity

A major nonconformity is a systemic failure of any system, procedure or process or failure to comply with required regulations that would have significant impact on the quality, strength, identity or purity of the product or the lack of a system, process or procedure required by regulations.

A Major Nonconformity would preclude Certification until the nonconformity is corrected and verified effective upon completion of a Follow-up Audit of the facility.

Minor (CAPA) Nonconformity

Failure to adhere to an approved policy, procedure, instruction or process, or failure to comply with required regulations where:

- There is insufficient evidence to be classified as a Major;
- There is little potential for significant health risk to the consumer;
- The quality, strength, identity, purity of the product has not been compromised.

Minor CAPAs require corrective action plan and cause analysis to be accepted by UL prior to awarding of the certification. A Follow-up Audit would be required if the factory criteria falls within medium risk/marginal compliance range. Otherwise, the verification of effectiveness of Corrective Action taken will be followed up during the next annual audit activity.

Corrective Action Process

Once the audit is completed, the auditee has 30 calendar days from date of receipt to submit root cause analysis and corrective action plans for review and approval by the UL auditor. If an organization wishes to dispute a nonconformance, they should follow the disputes process as outlined in this procedure in the CAPA Disputes section.

Where CAPA Plans (including Root Cause Analysis) submitted are not approved, they will be resubmitted to the organization for revision and resubmission back to UL with a 5-calendar day response time from the date of rejection by the auditor. In no case shall the time for responding with a CAPA Plan and cause analysis

exceed 45 calendar days. If the factory does not respond or provide acceptable plans within 45 calendar days, the audit package will be submitted to certification review and certification denied or suspended.

CAPA Plans (including Root Cause Analysis) are reviewed as part of the Certification Committee review. CAPA plans may also be rejected in this step of the process, even if previously accepted by the auditor. Such CAPA plans will be resubmitted to the organization for revision and resubmission back to UL with a 5-calendar day response time from the date of rejection by the Certification Committee. Failure to respond to such CAPAs may also result in a decision to deny certification, as defined in this procedure.

Actions taken to address CAPAs are reviewed during a follow up, where applicable, and/or the next annual activity to verify action has been taken and was effective. If during the next audit activity the corrective action taken is found to be "not effective" a new CAPA shall be issued and may be elevated to a Major Nonconformity as deemed necessary by the auditor and/or the Certification Committee.

Once CAPA plans and cause analysis are approved, changes that are made by the organization to approved CAPA plans must be re-submitted to UL, ideally at the time the decision to change the approved plan is made, and at minimum prior to the next audit activity.

CAPA Disputes

Where an audited organization or audit owner seeks to reverse or reclassify a corrective action (CAPA or CAR), the nonconformance dispute form (QF 7.5.1) shall be completed and submitted to UL with required objective evidence. **Disputes shall be received within 14 calendar days of the audit or will not be considered.**

The disputant shall complete QF 7.5.1 for each finding, describing specific scientific rationale and justification of why an audit finding should be reclassified, overturned, or reversed. Objective evidence should be provided with the dispute of ALL CAPAs. The purpose of providing the objective evidence at this stage is to allow for a decision to be made on the disputed finding(s) in a timely manner so the post-audit process is not lengthened as a result of the dispute. Failure to serve notice of a dispute through formal written notification will be considered an invalid dispute.

Disputes that will NOT be considered are as follows:

- CAPA disputes not received within two weeks (14 calendar days) from the last day of the audit.
- CAPA findings being disputed due to the firm being unable to produce SOPs, records, and/or other audit evidence requested during the audit.
- Disputes submitted after the audit report is issued.
- Disputes submitted for the same nonconformance that was disputed before by the disputant and a decision had already been rendered that the nonconformance would stand as written.
- Disputes for every finding issued by the auditor within an audit. UL will consider any firm that disputes every CAPA as frivolous and such disputes will NOT be considered as valid and the CAPA will stand as written by the auditor for all CAPAs.[1]

Upon receipt of completed QF 7.5.1 Nonconformance Dispute Form and supporting objective evidence, Client Services initiates the Disputes Workflow for processing by UL's Technical Services team.

The dispute will be assigned to an independent party for investigation, to personnel not involved in the certification activities related to the dispute. To ensure that there is no conflict of interest, personnel who have provided consultancy for a client, or been employed by a client, will not be used to review or approve the resolution of a dispute for that client for a minimum of two years following the end of the consultancy /

[1] At the sole discretion of the impartial department manager, limited CAPAs issued during the audit and then disputed will be considered (i.e. one or two CAPAs were issued and one or two CAPAs are being disputed). Notwithstanding the bullets above which will apply as a condition of bullet #5.

employment.

Once the dispute investigation is complete, the outcome will be documented on QF 7.5.1 and Client Services will notify the disputant of the outcome. The results of disputes are final.

8.0 The Review and Certification Decision

The purpose of the Certification Committee is to review the auditor's records which include the checklist / report, notes, audit schedule, CAPAs and recommendation for certification concerning the issuance of the UL Certificates of Conformance and render a certification decision. It is the responsibility of the Certification Committee to grant, issue, suspend, withdraw or withhold issuance of the certificate.

If the Certification is granted, UL will:

- Notify the organization that Certification has been granted provided continued conformity with these procedures for certification;
- Provide the organization with Certificates of Conformance;
- Authorize the organization to reference UL and use the UL Certification Badges in its advertising subject to the provisions stated for their use in paragraph 14.0.

If the Certification Committee denies the granting of a certificate, the organization shall be notified in writing the reasons for not awarding certification. All outstanding fees shall be paid at that time.

The Certification Committee makes the final decision regarding when a Follow-up Audit is required to be conducted prior to awarding or continuing certification. Follow-up Audits should be conducted within a 90 to 180 calendar day window based on the last date of the Audit. The purpose of the follow-up audit is to assure conformance to the requirements and for verification of effective action.

Follow-up Audits shall bear additional costs to the certified organization or applicant in addition to the costs related to annual audit.

Once the CAPA is closed and deemed effective, the certification (Certificates and UL Certification Badges) will be issued.

Clients that underwent their Initial Certification assessment and failed to demonstrate effective Corrective Action for Major Nonconformance shall be denied certification and the next audit activity will be an Initial Certification assessment.

Clients who have an existing certification and fail to demonstrate effective corrective action for a Major Nonconformance may result in suspension for the existing certificate until such time that effective corrective action has been demonstrated or otherwise may lead to Certificate Withdrawal.

Auto-fail results in a denial of certification and a need for re-audit.

9.0 On-going Annual Audits

As RCP and NBCP are ongoing programs, annual audits are required to be scheduled within a set window. Annual audits shall take place +/- 30 days of the anniversary date of the Initial Certification Audit. Where audits are not performed within required audit windows, the organization risks suspension or possibly withdrawal (see clause 13.0).

Audit Cycles are defined as follows:

- For organizations enrolled in the Full Scope RCP or NBCP option, they will remain on a three-year cycle with the first year being the Initial Certification audit, and the second and third year,

Surveillance audits. The fourth audit activity shall be a Recertification followed by two surveillance audits.

- For organizations enrolled in the Limited Scope RCP or NBCP option, they will remain on a one-year cycle with the first year being the Initial Certification audit, and every year after being a Recertification audit.

Regardless of the option selected, the audit cycle will continue until the organization chooses to end their participation in the program or certification is denied.

Audit duration for on-going annual audits is generally the same duration as the initial Certification audit unless there has been a significant change in the number of employees, number of sites, size of the location or number of items provided to the retail or wholesale trade.

A certified organization may request an extension of time for a surveillance audit once in every three year cycle, but it may only be granted for rare cases (i.e. death in the family, medical emergency, etc.). Such requests must be documented on the Application for Extension of Time form. The length of extension allowed will be determined by UL management, but in no case will it exceed 6 months. There is a fee associated with this type of request.

10.0 Modifications or Revisions to Certificates of Conformity

Certificates of Conformity are only valid at the location(s) that appear on the certificate. If an organization changes locations, the organization may be subject to a special audit in order to maintain the validity of the certificate. After all audit fees have been paid, a revised Certificate of Conformity will be issued to the organization.

Changes in ownership, physical location, key personnel, and/or changes in facilities must be provided in writing to UL who will determine whether the changes impact the existing Certification. When there is a change in geographical location, or addition of a technical scope or product family, request must be submitted to UL in written format. UL will determine if a special audit is required.

11.0 Special Audits

In addition to the aforementioned reasons for a special audit (e.g. changes in location, ownership, physical location, key personnel), special audits may also be required at short notice or unannounced for the purpose of investigating complaints, in response to changes, or as follow-up on suspended clients. Such audits shall bear additional costs to the certified organization or applicant in addition to the costs related to annual audit.

When a special audit is required, UL will notify the certified clients of the conditions under which special audits are to be conducted. In both short notice and unannounced cases, UL will exercise additional care in the assignment of the audit team because of the lack of opportunity for the organization to object to audit team members.

A short notice or unannounced special audit may be required when:

a) external factors apply, such as:
   i. available post-market surveillance data known to UL on products included in the scope of the audit indicate a possible significant deficiency in the quality management system
   ii. significant safety related information becomes known to UL
b) significant changes occur which have been submitted as required by the regulations and this procedure, or become known by UL, and which could affect the decision on the client's state of compliance with regulatory requirements.

The following are examples of such changes which could be significant and relevant to UL when considering

that a special audit or short notice audit is required, although none of these changes is an automatic trigger of special / short notice audit:

a) QMS – impact and changes;
b) New ownership;
c) New facility, site change:
   i. Modification of the site operation involved in the manufacturing activity (e.g. relocation of the manufacturing operation to a new site or centralizing the design and/or development functions for several manufacturing sites);
d) New processes, process changes;
   i. Significant modifications to special processes (e.g. change in production from sterilization through a supplier to an on-site facility or a change in the method of sterilization);
e) QMS management, personnel:
   i. Modifications to the defined authority of the management representative that impact:
      - quality management system effectiveness or regulatory compliance;
      - the capability and authority to assure that only safe and effective medical devices are released;
f) Product related changes:
   ii. New products, categories;
   iii. QMS & Product related changes:
      - Changes in standards, regulations
      - Post market surveillance, vigilance

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

12.0 Recalls, Regulatory Events and Complaints

Regardless of the regulatory status of the products being produced, each organization must maintain records of all product complaints received from purchasers or other interested parties, including corrective measures taken to preclude those problems from recurring in the future. These records should be maintained in a separate file in order to be reviewed and evaluated as part of the effectiveness of the organization's quality system.

Where a facility becomes aware of a regulatory event pertaining to their firm, UL shall be notified via email to ULWarningsRecalls@ul.com. The following events are considered 'regulatory events' requiring notification:

- FDA issued form 483
- FDA issued warning letter
- Product recall or market withdrawal
- Import Alert
- Field Alert Report
- Injunction

Whether or not the regulatory event pertains to product under scope, UL shall be notified in order to investigate the potential impact to product under scope. Such notification shall be submitted to UL without undue delay.

Upon receipt of such notice, UL performs a review of the situation, including additional information from the firm, if necessary. A decision will be rendered regarding whether or not a special audit will be required and if a new certificate needs to be issued based on the regulatory event. Special audits may be done on short notice after information becomes known that may have impact on the certification. Where the integrity of audit results are under investigation, UL may agree to execute these audits at our own cost, and clients must agree to the short notice window requested.

In any event, all regulatory activities will be reviewed as part of the next audit. If analysis of a regulatory event indicates that the certified organization no longer conforms with these Procedures for Certification, UL's Certification Committee reserves the right to suspend or withdraw Certification.

13.0 Withdrawing, Maintaining, Limiting, Extending & Suspending a Certification

An organization may at any time terminate its participation in the Retail Certification Program or National Brand Certification Program with UL. If an organization wishes to terminate its involvement with the RCP or NBCP, the organization shall cease to make reference to involvement with the UL Retail Certification Program or National Brand Certification Program. It is the understanding of the organization that if they cease the RCP or NBCP, they will likely be subjected to multiple audits for any or all of the participating retailers or brands.

UL VS may, at its discretion, withdraw or suspend the Certification of an organization for cause, such as:

- non-payment,
- violating the terms of Certification listed in this document, including failure to notify UL VS of significant changes that may affect the quality and safety of the products supplied to their customers,
- Evidence of flagrant nonconformance against the cGMP requirements,
- Inability to implement corrective action within required timelines
- Failure to complete the next audit activity within required timeframes
- Auditor intimidation or threats - UL VS will not condone or tolerate violence, including threats, verbal abuse, intimidation or harmful acts against any UL employee or auditor.
- Evidence of falsification of records; or
- Evidence of Certificate or Certification Symbol misuse.

Upon suspension, withdrawal, or termination of certification, UL removes the certified organization from the public directory where applicable and the client must discontinue its use of all advertising matter that contains any reference thereto, returns the certificate, and takes any other required measure as requested by UL VS.

UL VS maintains an impartial and nondiscriminatory complaints and appeals program to evaluate the consideration of complaints and appeals against any and all decisions. (See Section 16.0)

UL VS may terminate its Certification program at any time provided that all qualified companies are notified at least six (6) months in advance.

14.0 Certificate Criteria Changes

As retailer and national brand requirements change, UL VS may revise this document and any checklists accordingly at any time. When substantive changes are made to the Certification process, UL will notify those organizations of the change(s) and if necessary, of the effective date, allowing the organization time to implement the change(s).

Proposed changes may be provided for review to all certified organizations. UL VS may allow for a 30 calendar day review and comment period. Comments and/or feedback received within the 30 calendar days will either be communicated or handled directly with the petitioner or organization prior to implementation of such changes.

15.0 Use of Certificates, Certification Symbols and Reference to RCP / NBCP Participation

The Certificate of Conformity and Certification Marks are the property of ANAB and UL and are on loan to

the certified organization for its use in accordance with this document.

The organization may refer to involvement with the UL Retail Certification Program or UL National Brand Certification Program and publish their Certification status and use the UL Certificate in any professional, technical, trade or other business publication. Claims regarding certification must be consistent with the scope of certification. Such references must not imply product endorsement. The client shall not use its certification in such a manner as to bring UL into disrepute and shall not make any statements regarding its certification that UL VS may consider misleading or unauthorized. The rules for Use of Certification Symbols, which outlines correct use of the certificate, marks and badges, can be found at the end of this document.

16.0 UL VS Complaints and Appeals Process

UL VS maintains a Complaints and Appeals process which is publicly available online. QSLP 7.7 Complaints & Appeals describes the process intended to be used to assist in and resolve complaints and appeals between parties with an interest in the UL VS audit, certification, and/or decision-making process.

17.0 Confidentiality

UL VS maintains a high level of confidentiality at all levels of its organization concerning information obtained in the course of its business. No information will be disclosed to any third party unless in response to legal process or the organization has requested such disclosure in writing, in which case UL VS will notify the organization prior to disclosing the information.

Reports may be released by UL Verification Services Inc. (UL) to the organization and any retailers / brands as specified by the audit client and/or auditee or as otherwise agreed to in advance between the audit client and UL. This is typically agreed to via an agreement which UL VS maintains on file.

18.0 Accreditation

The inspection (ISO 17020:2012) / certification (ISO 17065:2012) services offered in this Procedure will be conducted in conformance with the ISO/IEC 17020 and 17065 Standards as UL VS is dually accredited by ANSI National Accreditation Board (ANAB). UL VS is required by accreditation bodies to share information for the purpose of demonstrating conformance to the standards for which UL VS is accredited.

Such records may include audit results and UL's certification / audit processes and procedures. If the certification client does not wish to allow their records to be shown to the accreditation body, notification must be provided to UL VS in writing. UL VS holds confidentiality agreements with all accreditation bodies.

UL VS is required by accreditation standards to coordinate witness and observation programs in which an Accreditation Body assessor must accompany UL's auditor to fulfill accreditation assessments. UL VS is also required by accreditation standards to maintain robust auditor witnessing and observation programs in which a Competent Evaluator is assigned to accompany UL's auditor to promote calibration among auditors. Applicant and certified organizations must agree to make arrangements as necessary to support such witness or observation programs. Organizations which refuse such support may be subject to Certificate suspension or withdrawal.

19.0 Certificates of Conformance

Upon completion of an acceptable audit and after thorough review by the UL VS Certification Committee, an accredited Certificate of Conformance is awarded to the UL VS client.

Use of Certificates of Conformance, Use of Certification Marks and Reference to RCP or NBCP Participation shall be in accordance with the rules noted in Appendix I of this document.

Full scope Retail Certification or National Brand Certification Program participants receive the benefit of having their certifications listed on the UL VS website for public display (found here). The minimum amount of information displayed is as follows: Certified Facility Name, City / State, Identification of the Product, the Standard to which Conformity has been certified, and the status of the certificate (i.e. Current, Withdrawn, Suspended).

Organizations who participate in the Limited Scope options within the RCP and NBCP programs will not have certification details displayed on the public certified client listing. When requested, UL VS will provide information around the validity of any certification under the program.

About UL Solutions

UL Solutions is a premier global independent safety science company that has championed progress for 120 years. It's more than 10,000 professionals are guided by the UL Solutions' mission to promote safe working and living environments for all people. UL Solutions uses research and standards to continually advance and meet ever-evolving safety needs. We partner with businesses, manufacturers, trade associations and international regulatory authorities to bring solutions to a more complex global supply chain. For more information about our certification, testing, inspection, advisory and education services, visit ul.com.

About UL Verification Services Inc. (UL VS)

UL Verification Services Inc. – Supplier Quality Audits & Certification (SQAC) is a division of UL Solutions. SQAC's mission is to be the global leader in advancing sustainable audit and certification services within supply chains, worldwide. UL SQAC provides independent, third-party manufacturing/process assessments against a defined standard that aims to minimize supply chain risk, help protect brand value, and promote consumer and product safety. For more information on UL's services, please email UL VS.

About ANAB

ANSI National Accreditation Board, a not-for-profit organization who is the voice of the U.S. standards and conformity assessment system. The organization empowers its members and constituents to voluntarily strengthen the U.S. marketplace position in the global economy while helping to assure the safety and health of consumers, protect the environment, and safeguard the integrity of U.S. businesses. The institute oversees the creation and use of thousands of American National Standards that directly impact businesses in nearly every sector. ANAB is also actively engaged in accreditation that provides assurance that standards, goods, and services meet essential requirements throughout the global supply chain. Visit ANAB at ANSI National Accreditation Board | ANAB for more information.

*This procedure for certification includes the requirements for inspection under ISO 17020:2012. Furthermore, this document contains the rules and procedures for Process Certification under ISO 17065:2012. Unless otherwise noted within this document, the word "certification" has the same meaning as does the term "inspection." The term "audit and/or assessment" within this document is synonymous with the term "inspection."

Appendix I: Rules for Use of Certification Symbols

1.0 GENERAL REQUIREMENTS

The UL Enhanced Certification Marks and UL Certification Badges are certification marks owned by UL LLC. Permission to use the UL Certification Badges and Certificates of Conformance, which includes the UL Enhanced Certification Marks, is granted or withdrawn at the sole discretion of UL Verification Services, Inc., UL LLC, UL AG or UL SarL. Subject to the terms and conditions of the certification agreement, UL allows an organization whose management system or process has been certified by UL the limited non-exclusive, non-transferable right to use the applicable UL Certification Badges in any professional, technical, trade, website or other business publications in order to advertise their accomplishments of UL certifications. Any such reference shall not imply any product conformity, certification or endorsement based on the UL certification / audit process, nor shall the UL Enhanced Certification Marks or UL Certification Badges be placed or used on any products themselves or in advertising or marketing materials for any products.

The Certificates are the property of UL VS. The Certificate(s) may be photocopied, scanned, or duplicated provided that the print and UL Enhanced Certification Mark is legible and the certificate is reproduced in its entirety in a secured or unalterable format (i.e. ".jpg"). UL maintains the right to require the organization to cease using the UL Enhanced Certification Marks, UL Certification Badges, or Certificates at any time as outlined in the current Procedures for GMP Certification. The UL Marks must be applied in a proper and lasting manner. If you have questions regarding how to use the UL Enhanced Certification Marks and UL Certification Badges, please contact UL VS.

Auditees that participate in the Limited Scope Certification option are prohibited from using the Badges or certificates. Certificates are permitted to be used by the paying client only. The same rules surrounding use apply in this scenario.

Failure to strictly abide by the rules of the Procedure for GMP Certification, including the requirements of this section, may result in the suspension or withdrawal and discontinuance of further use of the Certificates and the UL Certification Badges.

2.0 CERTIFICATES OF CONFORMANCE

Each organization will receive two (2) Certificates upon successfully achieving certification or re-certification.

- ANAB Accredited Process Certification Certificate of Conformance: This Certificate of Conformance includes the Certified Process UL Mark, the ANAB Mark and the IAF-MLA Mark. The ANAB and IAF-MLA Marks signify the certification of your organization's processes **only within the scope of your certification.** The below marks are **only allowed to be used on the UL Certificate of Conformance**:

UL Enhanced Certification Mark | ANAB Accreditation Mark | IAF-MLA Mark

- ANAB Accredited Management System Inspection Certificate: The ANAB accredited UL VS Certificate includes the ANAB Mark and ILAC Mark. The ANAB Accreditation Mark and the ILAC Mark signify UL VS' technical competence as an inspection body and are only allowed on the UL Certificate. This certificate includes a Management System Mark which signifies the certification of your organization's Management System **only within the scope** (i.e., product and/or product type and/or referenced cGMP CFR and/or product group, etc.) of your Certification. **The below marks are only allowed to be used on the UL Management System Inspection Certificate**:

UL Enhanced Certification Mark | ANAB Accreditation Mark | ILAC Mark

3.0 REQUIREMENTS FOR USE OF CERTIFCATION MARKS

The UL Enhanced Certification Marks and Accreditation Marks, (e.g. ANAB Marks, IAF-MLA Mark and ILAC Mark) can only be used as described below and herein:

- These Marks may be used **ONLY** on Certificates issued to your organization by UL.
- **The UL Enhanced Certification Marks and Accreditation Marks shall not be used on any product.**
- The UL Enhanced Certification Marks and Accreditation Marks shall not be used in advertising or promotional materials.

Note: The Certificates may be reproduced as permitted above, but the UL Enhanced Certification Marks and Accreditation Marks alone shall not be reproduced in any manner, hard copy or electronically.

Failure to strictly abide by the rules in this section and in the UL VS Procedures for Certification may result in the suspension or withdrawal and discontinuance of further use of UL VS Certificates and the UL Certification Badges.

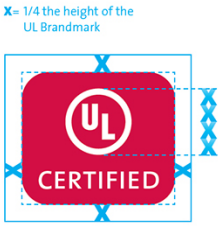
4.0 REQUIREMENTS FOR USE OF UL CERTIFICATION BADGES

Once you have received the Certificates bearing the UL Enhanced Certification Marks, UL Certification Badges are available for your creation/use in advertising or other printed or electronic media. The **UL Certification Badges are designed to promote and advertise your UL Certifications**, providing an attractive way to share this information with the marketplace. UL Certification Badges may appear on a range of materials, from brochures, web content, marketing collaterals, etc. Below is an example UL Enhanced Certification badge:

UL Enhanced
Management System Badge

UL Enhanced
Process Certification Badge

The UL Certification Badges shall be used solely in accordance with the guidelines in this agreement. See below for the clear space and minimum requirements of the UL Certification Badges.



Note:
To maintain visual integrity, applications using alternative reproduction techniques, such as silk screening, may require presenting the logomark at a larger size than is indicated here.

There are 2 variations of the UL Certification Badge

Attribute UL Badge

1.) The variation used by a UL Management System Certification Client is the Attribute Badge.
Attribute 1 – "Management System" or "Process"
Attribute 2 – Applicable Standard/CFR of your Certification

2.) The variation used by a UL Process Certification Client is the Attribute Badge.
Attribute 1 – "Process"
Attribute 2 – Applicable Scheme of Certification

- When applying the UL Certification Badges to various applications, such as promotional items, point-of-sale pieces, etc., adhering to the guidelines laid out in this procedure is a must. Clear space and proportion of the UL Certification Badges are imperative and required.
- UL Certification Badges cannot appear larger than the organization's name on any promotional materials.

- UL Certification Badges may not be used on business cards, company stationary, or company vehicles.
- Text on UL Certification Badges must accurately reflect the scope / scheme of UL Certification.
- The UL Certification Badges shall be used only in association with a UL Certified Management System and or/ Certified Process. If a Management System and/or Certified Process is no longer certified by UL, the UL Certification Badges must be removed or promotional materials destroyed.
- If an organization uses or plans to use the UL Certification Badges in advertising or promotion, UL has the right to review the materials prior to publication.
- UL shall have the right, on demand, to acquire any or all advertising and promotional material using the UL Certification Badges from the organization.

If non-scoped products that are NOT specified or included on the UL VS Certificates are included on a website or other advertising media where the UL Certification Badges are being displayed, a footnote/statement must acknowledge which product and/or product type and/or referenced CFR and/or product group, etc. is not within the scope of certification. See below for correct footnote/statements of clear acknowledgement of standards/products:

Correct Statement
Management System Certified by UL with regard to (standard/CFR)
Management System, with regard to (standard/CFR), is Certified by UL.
Process Certified by UL with regard to (scheme)