Accredited Retail Certification Program (RCP®) *

Procedure for Certification

ANSI Accredited Program
PRODUCT CERTIFICATION

ISO/IEC 17020
INSPECTION BODY

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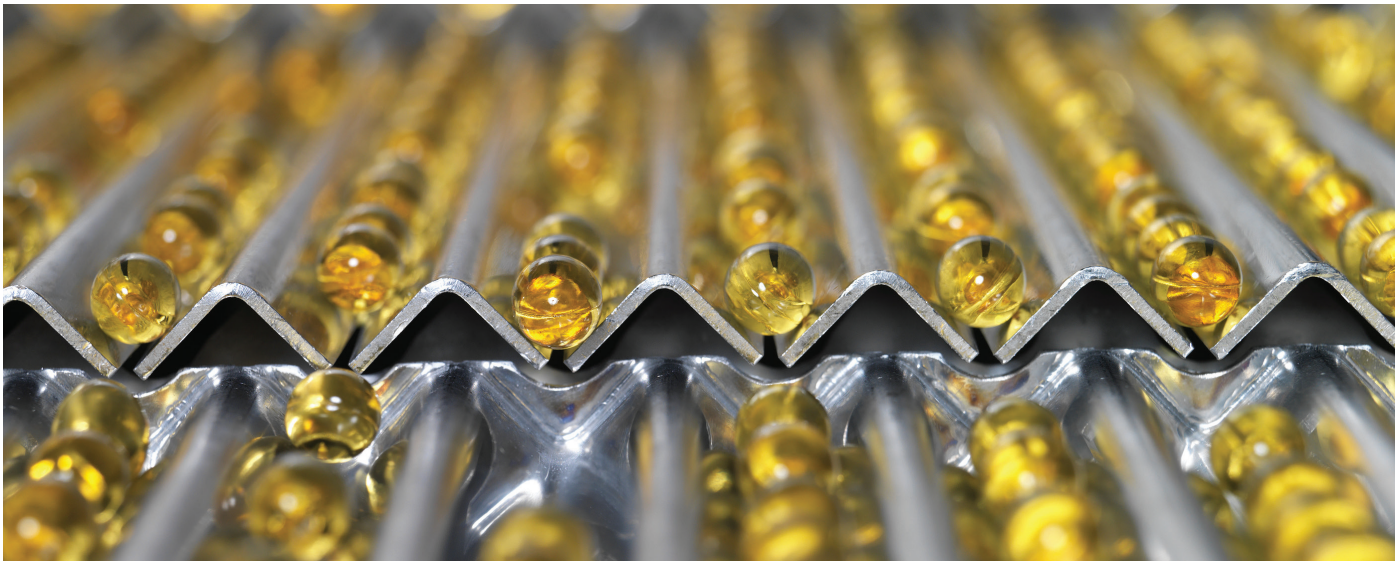


1.0 Purpose

The purpose of the UL R Retail Certification Program (RCP) is to assess the extent to which an organization conforms to the applicable regulations and/or standards regarding the products being manufactured/ produced, packaged, shipped and/or stored.

2.0 Scope

Certification is open to all interested organizations. The purpose of the Certification/Inspection process is to assess the extent of the organization's conformance with the applicable regulations and/or standards regarding the products being manufactured, as well as the requirements found within this document.

All organizations that utilize UL Registrar LLC's certification and inspection services are guided by these procedures and are required to comply with all of the relevant provisions contained herein, including implementing appropriate changes when they are communicated by UL Registrar LLC.

Stakeholders and/or their contract manufacturers/ packagers/distributors (organization) shall make all necessary arrangements for UL R personnel to conduct the RCP assessment 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 audit.

3.0 Program Participation (New Applicants/Current Clients) — Application for Certification

Organizations to undergo assessment must apply for certification by providing UL Registrar LLC pre-audit information on the Application for Certification supplied by UL R to include but not limited to the following:

- 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 audit scope(s) under audit,
- And a list of all finished products manufactured, packaged or stored, which may be provided for retail or wholesale trade.

UL R will utilize a site audit duration matrix or other time matrix to determine the minimum number of days for the audit as prescribed in ANAB/ANSI Accreditation documents and rules.

Upon receipt of the Audit Request Profile Sheet, a Contract/Proposal

(Agreement) will be forwarded to the applicant. This document will be used as a contractual agreement between UL Registrar LLC and the organization to carry out certification services.

Two copies of the Agreement will be provided to the manufacturer for the purpose of signing. One copy will be submitted to UL Registrar LLC and one 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.

The Agreement shall remain in effect for three years and shall automatically renew for subsequent three year terms until such time that UL Registrar LLC informs the organization or the organization informs UL Registrar LLC in writing of their intention to cease participation in the Retail Certification Program upon thirty calendar (30) days prior written notice to the other party.

Cancellation of the Agreement causes the Certificate of Conformance/ Inspection to be immediately withdrawn. The Certificate of Conformance/Inspection is the property of UL Registrar LLC and must be surrendered without delay upon request to do so. All Certification Badges provided for use by the organization shall be surrendered as well and all advertising bearing the badges removed immediately from use and/or public domain.

Upon submission of a signed contractual agreement (proposal), the organization will be contacted by UL Registrar LLC 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 Registrar LLC auditing personnel are available.

Audit Scope

Unless otherwise specified, the audit scope applies to one site/one supplier factory 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.

Elements of a factory'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 Audit activities contingent upon the systems relationship to the retailer specific product(s) (where applicable) and per the applicant organization's agreement.
- 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.

The Assessment Tool/Report utilized by UL R is guided by the regulatory status of the products manufactured at the factory and included in scope of assessment as agreed to by the applicant:

- Any factory that chooses to be audited to ISO 22716 will be assessed with the requirements listed in the ISO 22716 Cosmetic Assessment Tool/Narrative Checklist Report.
- Any FDA-regulated facility that chooses to be audited to Over-the-Counter Drugs, Finished Pharmaceuticals, and Ophthalmic will be assessed with the requirements listed in 21 CFR Parts 210 and 211 using the UL Registrar LLC Part 210/211 Pharmaceutical Drug Risk Based Assessment Tool.
- Any FDA regulated facility that chooses to be audited to Dietary Supplement or Vitamin will be assessed with the requirements listed in 21 CFR Part 111 using the UL Registrar Dietary Supplement Risk Based Assessment Tool.
- Any FDA regulated Dietary Ingredient and Pharmaceutical Ingredient will be assessed with the requirements listed in the ICH Q7 Dietary Ingredient Assessment Tool/Narrative Checklist Report.
- Any FDA regulated Food process will be assessed with the requirements listed in the Part 110 and/or Part 117 Food & Food Manufacture Best Practices Assessment Tool/ Narrative Checklist Report.
- Any FDA regulated Infant Formula process will be assessed with the requirements listed in the Part 110, 106 & 107 Infant Formula Assessment Tool/Narrative Checklist Report.
- Any FDA regulated Medical Device will be assessed with the requirements listed in the FDA's CDRH Classification Database for Class I GMP Exempt products, Class I GMP Non-exempt products, Class II products, or Class III products. These requirements will be listed in the Part 820 Medical Device Assessment Tool/ Narrative Checklist Report.
- Any product that meets the labeling requirements for Cosmetics as listed in the FDA's Title 21, Part 700 of the Code of Federal Regulations, will be assessed on the requirements listed in the Cosmetic Assessment Tool/Narrative checklist report.

Any products' label claim that is not consistent with the requirements listed above, will be determined

to be Non-regulated and audited against the requirements listed in the Non-regulated Supplier Quality Assessment Tool/Narrative Checklist report. The Assessment Tool/Narrative Checklist Report includes basic and generic Quality System and GMP requirements as developed by UL R's technical team.

Audit Standards Defined

The standards for the RCP audits for regulated products shall be 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 RCP Program document with respect to food, pharmaceuticals, supplements, cosmetics, and medical devices.

In addition, any retailer or manufacturer (contracting work to the facility) specific requirements may be included by specific reference, i.e., annual product reviews for cosmetic products, HACCP programs for dietary supplements, etc.

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.

In a facility that manufactures products that are both regulated and non-regulated, the requirements specified in the paragraph entitled Dual Regulations under One Manufacturing Roof shall apply.

Dual Regulations under One Manufacturing Roof

In cases where the organization manufactures 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 unless the certificate holder or audit client has specifically requested on their Application for Certification that UL R carry out the audit to the "lower Standard."

If this is the case, the audit will be specifically governed and carried out using the lower Standard i.e., OTC Drugs vs. Supplements and/or Medical Devices, whichever is lower. In this case, the assessment will be to the lower Standard as requested by the organization. UL R's audit activities, Certificate of Conformity and RCP Audit Report will only cover and be specific to the lower Standard and corresponding products unless the audit is conducted covering all Standards.

4.0 RCP Pre-Certification On Site Assessment (Preassessments may NOT be used to satisfy retailer audit requirements)

At the option of the organization, a pre-assessment audit can be conducted by UL Registrar LLC 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 audit.

An Audit Summary Report will be left on-site with the organization at the conclusion of the assessment, but a formal "pre-assessment report" will NOT be issued to the organization.

NOTE: Many retailers may not accept an Audit Summary Report. A Pre-assessment is for the applicant's information regarding their readiness for full certification.

NOTE: CAPAs will not be issued during Pre-assessments.

IMPORTANT: The applicant is hereby cautioned that a retailer will likely not accept the results of this type of audit.

Regardless of whether the pre-assessment reveals significant omissions or deviations, UL R will notify the Organization, in order to allow them time to make necessary corrections and implement those changes prior to the Final On-site Initial Assessment Process described in the following section.

5.0 Initial Certification Assessment Process

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, as defined herein. In order 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 client'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 and provide access to all documentation needed to seek an acceptable level of compliance and conformance to retailer specific requirements;
- 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 advanced audit schedule/agenda 14 calendar days prior to the audit date. Prior to commencing the formal assessment, the audit team will meet with the organization's management to conduct an opening meeting. This is the first stage in the on-site assessment process.

The 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;
- 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 R Disputes and Appeals Process.

Upon completion of the opening meeting, a brief walk-through of the physical plant in order 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 by the auditor in order to determine the adequacy of the organization's implementation of the specific regulatory requirement(s) pertinent to the organization's scope of certification.

As product standards specify cGMP conformance in regulated industries, UL Registrar LLC will verify that manufacturers are in conformance with the applicable manufacturing regulations. The audit will be conducted based on the 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 3.0, in the paragraph entitled Audit Scope 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 non-conformance(s) 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 of Conformance/Inspection;
- Answering any questions concerning the auditor's findings and recommendation to be made to the Certification/Review Committee;
- Requesting that the organization provide any written comments or observations to UL Registrar LLC for consideration on improving the Certification process;
- Explaining that the ultimate decision with respect to Certification lies with the Certification/Review Committee.

The RCP Audit Summary Report and The RCP Final Report

An Audit Summary Report will be left on-site with the organization at the conclusion of the assessment. The Audit Summary Report shall not be sent to the organization's retailer(s).

The final audit report will be provided to the Certification Review Committee without delay for processing.

Reports shall be released by UL Registrar LLC to the organization and any retailers as specified by the audit client and/or auditee or as otherwise agreed to in advance between the audit client and UL.

The Certification Review Committee will review all audit records along with other appropriate documentation and issue a final audit report, Certificate of Conformance/Inspection and ANAB/ANSI Accreditation Marks, the UL R Certification Marks and the applicable UL Certification Badge to the organization within a reasonable period of time after receipt of payment. The organization shall not use any audit records or any part thereof in a misleading manner.

Assessment Results

All audit types will be assessed utilizing the methodology of the six system approach. The six systems evaluated will be the Quality System as a whole, plus the interaction with the Facilities and Equipment System, Production System, Material/Vendor System, Packaging System, and the Laboratory or Inspection System. Within each Assessment Tool/Narrative Checklist Report, each system contains the list of requirements intended to demonstrate effective control of the system and also, in cases deemed necessary to ensure consistency, guidance for the auditor on inspectional techniques and sampling to be used.

The audit team will provide a quantitative output to the audit based on those requirements that can be verified as implemented and effective by the organization. Where conformance can be demonstrated and verified by the auditor, the Assessment Tool/Narrative Checklist Report will be scored with a "yes" and the organization will receive full credit for the value of the requirement listed. Where conformance to the requirement cannot be demonstrated, the Assessment Tool/Narrative Checklist Report must be scored with a "no" and the organization will lose full credit for the stated requirement.

Nonconformities (CAPA) Defined

The following nonconformance 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 Pharmaceutical or Dietary Supplement RCP Certification until the nonconformity is corrected and verified effective upon completion of a follow-up audit of the facility.

RCP Certification will be withheld or not granted until a written CAPA plan and root cause analysis is submitted and is accepted by UL Registrar LLC within 30 calendar days of issuance of the CAPA.

A follow-up should be conducted to assure conformance to the requirements and for verification of effective action within 90 calendar days of the date the auditor accepted the CA Plan.

Once the CAPA is closed and deemed effective, the certification (certificates, UL R and ANSI/ANAB Accreditation Marks, and UL Certification Badges) will be issued.

Failure to demonstrate effective corrective action for a Critical Nonconformance shall result in suspension for the existing certificate until such time that effective corrective action has been demonstrated.

For clients that underwent their Initial Certification/Recertification assessment and failed to demonstrate effective Corrective Action for a Critical Nonconformance shall be denied certification and the next audit activity will be an Initial Certification assessment.

Major (CAPA) Nonconformity

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 RCP Certification until the nonconformity is corrected and verified effective upon completion of a follow-up audit of the facility. RCP Certification will be withheld or not granted until a written CAPA plan and root cause analysis is submitted and is accepted by UL Registrar LLC within 30 calendar days of issuance of the CAPA.

A follow-up should be conducted within 90 calendar days of the date the auditor accepted the CAPA plan to assure conformance to the requirements and for verification of effective action. Once the CAPA is closed and deemed effective, the certification (certificates and UL R and ANAB/ANSI Marks, and UL Certification Badges) will be issued.

Failure to demonstrate effective corrective action for a Major Nonconformance shall result in suspension for the existing certificate until such time that effective corrective action has been demonstrated.

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

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.

A Minor Nonconformity requires a written Corrective Action plan and a cause analysis with a response to be submitted within 30 calendar days or as agreed to between the auditor and the auditee.

The Minor Nonconformity, corrective action plan and cause analysis must be accepted by UL Registrar LLC prior to awarding of the certification. A follow-up audit would be required if the factory criteria falls within Marginal Compliance or in the Medium to High Risk levels. The verification of effectiveness of Corrective Action taken will be followed up during the next annual audit activity.

If the Corrective Action is verified as ineffective at the next annual audit activity, the nonconformance shall be documented as a new CAPA, and considered for elevation to a Major Nonconformance.

Additonal Nonconformity Information

CAPA Plans submitted and not approved will be resubmitted to the organization for follow-up and resubmission back to UL R 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 CA Plan and a cause analysis exceed 45 calendar days. If factory does not respond or provide acceptable plans within 45 calendar days, certification will not be granted for that audit activity and/or existing certificates will be suspended.

The verification of effectiveness of CA taken will normally be followed up during the next surveillance or recertification audit activity. If during the next annual 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 Review Committee.

Once CAPA plans and cause analysis are approved, changes that are made by the organization to approved CA plans must be re-submitted to UL Registrar LLC.

Risk Based Criteria

Pharmaceutical and Dietary Supplement

Based on the enhanced Pharmaceutical Audit Tool, Dietary Supplement Audit Tool and the resulting PEAR, the scoring criteria has changed from three colors: Green/Compliant (100-80), Yellow/ Marginal (79-60) and Red/ Noncompliant (59-0) to a new risk model. The new approach now has five risk ranges.

The UL Registrar LLC GMP Risk Rating Model

FINAL RISK PRIORITY NUMBER	RISK LEVEL
100 to 96	Reasonable Risk
95.99 to 89.99	Limited Risk
89.98 to 80.99	Average Risk
80.98 to 71.99	Medium Risk
71.98 and below	High Risk

Each audited facility will fall into one of the above risk levels and will receive an overall Risk Priority Number.

The risk levels can be defined as:

- Reasonable Risk: With all audit activities, there is assumed risk, but no current threats identified.
- Limited Risk: A minor departure from GMP/GCP Requirements.
- Average Risk: A minor departure from GMP/GCP/SOP Requirements, and objective evidence gathered during the audit that may conclude limited/ no health risk to the consumer.
- Medium Risk: A Deviation from GMP/GCP (i.e. departure from Regulations and Requirements) or for which a 483 may be issued by FDA and would conclude some health risk to the consumer.
- High Risk: Potential risk of harm/ death to the user/warning letter may be issued by the FDA.

Additionally, the Final Risk Priority Number (FRPN) correlates to the level of risk deemed at the audited organization. Though this FRPN will look like a numerical score, it will

simply express the level of risk based on a mathematical calculation associated with the level of risk noted on the PEAR. The audit tool and final report will not contain an overall numerical score like previous reports. This enhanced tool is strictly risk-based, so the outcome of the audit is also strictly risk-based.

Requirements will be weighted based on the risk severity and probability of occurrence. Corrective Actions will be defined as Critical, Major and Minor. Any Critical or Major CAPAs will require a follow-up assessment, as will falling within the Medium and High Risk Levels.

Non Risk Based Scoring Criteria

Food, Medical Devices, Cosmetics, Ingredients, Non-regulated

When nonconformities/deficiencies are identified during the course of the assessment, additional deductions from the score shall be applied to render a final score. Nonconformities will be identified as either Major or Minor, depending on the type of production and severity of the deficiency noted. When the vendor receives one or more Major Nonconformities, additional points will be deducted from the scoring criteria noted above.

For each Major Nonconformity identified during the audit, an additional five percentage points will be deducted from the Assessment Tool/Narrative Checklist Report score. For example, at the conclusion of the audit, the factory is awarded a checklist score of 90% with one major nonconformity being issued. The 90% score would thereby be reduced by 5% for a new score of 85%. The score is reduced automatically once the auditor has placed the total number of Major and/or Minors in the "Score Matrix" section of the completed Assessment Tool/Narrative Checklist Report.

When the vendor receives one or more Minor Nonconformities, additional points will be deducted from the scoring criteria noted above. For each Minor Nonconformity received during the audit, an additional two percentage points will be deducted from the Assessment Tool/Narrative Checklist Report score.

For example, at the conclusion of the audit, the factory is awarded a checklist score of 90% with one minor nonconformity being issued. The 90% score would thereby be reduced by 2% for a new score of 88%. The score is reduced automatically once the auditor has placed the total number of Major and/ or Minors in the "Score Matrix" section of the completed Assessment Tool/Narrative Checklist Report.

The total value will be calculated for each system and then overall for a final score. The final score will be categorized according to the breakdown below:

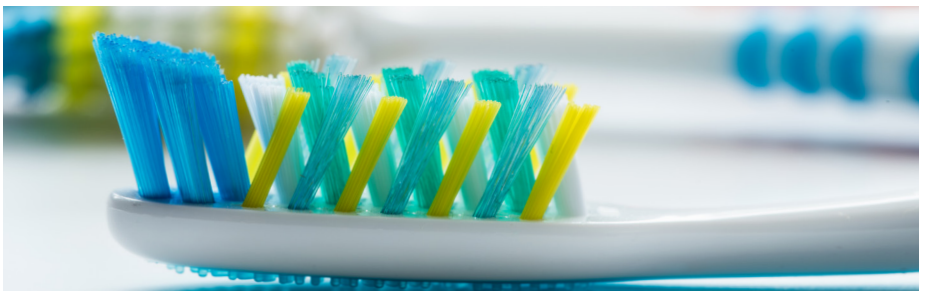
GRADE	SCORE
Green	80 to 100
Yellow	60 to 79
Red	0 to 59

A Major Nonconformity will preclude certification and will require a follow-up audit. Furthermore, a score that is within the yellow or red will require a follow-up audit.

6.0 Contract Manufacturing

The initial certificate shall specify the scope that was fully audited at the facility. Where contract manufacturing is performed, the certificate scope may be revised to include production of products from contractors upon satisfactory completion of a UL R facility audit for applicable contract manufacturers.

Contract manufacturers will need to be audited annually to maintain the certificate of conformance. Contract manufacturer certificates will only be valid for 1 year.



7.0 The RCP Certification Review

The purpose of the UL Registrar LLC Certification Review is to review the auditor's audit summary report, notes, any required checklist/audit report, audit schedule, CAPA's and recommendation for certification concerning the issuance of the UL Registrar LLC Certificate of Conformance. It is the responsibility of the Certification Review Committee to grant, issue, suspend, withdraw or withhold issuance of the certificate.

If the Certification is granted and all fees have been paid, UL Registrar LLC will:

- Notify the organization that Certification has been granted for a period of three years (or for Contract Manufacturers, 1 year), provided continued conformity with these procedures for certification;
- Provide the organization with a Certificate of Conformance;
- Authorize the organization to reference UL Registrar LLC and use the UL Certification Badges in its advertising subject to the provisions stated for their use in paragraph 14.0.

If the Certification Review 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.

8.0 Surveillance Audits

Surveillance audits are conducted annually to assure continued conformance with respect to the appropriate standard(s) and applicable regulations; the year after an RCP Certification/recertification audit, UL Registrar LLC will conduct a surveillance audit on or before the initial audit anniversary date.

Surveillance audits shall be conducted only after the organization has been notified in writing by UL Registrar LLC of the pending audit.

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 Registrar LLC management, but in no case will exceed 6 months. There is a fee associated with this type of request.

9.0 Recertification Audits

The RCP Program is an ongoing program with three year cycles (except for Contract Manufacturers, which will be a 1 year audit cycle). The first year is the Initial Certification audit and in the second and third year surveillance audits are conducted. The fourth audit activity shall be a Recertification followed by two surveillance audits.

For contract manufacturers, annual recertification audits will be conducted in lieu of surveillance audits.

90 days prior to the expiration date of the certificate, a recertification audit should be conducted. The recertification audit will be 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 trade. The surveillance audit cycle will resume in the year after the recertification audit.

The three year cycle (or one year for Contract Manufacturers) of certification/recertification followed by two annual surveillance audits (one year recertification audits for Contract Manufacturers) will continue until the organization chooses to end their participation in the program.

10.0 Modifications or Revisions to the Certificate of Conformity

The Certificate of Conformity is only valid at the location(s) that appear(s) on the certificate. If an organization changes locations, the organization may be subject to a surveillance or 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 Registrar LLC 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, the Scope Extension form will be completed and returned to UL Registrar LLC. UL Registrar LLC will determine if a special audit is required.

11.0 Complaints & Recalls

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.

In the event of a warning letter, recall or market withdrawal of product that is covered and described on the certificate's scope of certification, UL Registrar LLC shall be notified via email to ULWarningsRecalls@ul.com without undue delay. Upon receipt of such notice, UL Registrar LLC performs a review of the recall or warning letter, 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 recalled product or market withdrawal.

In any event, all recalls/withdrawals will be reviewed as part of the next audit. If analysis of a complaint or significant recall or if any other information indicates that the certified organization no longer conforms with these Procedures for Certification, UL Registrar LLC's Certification/Review Committee reserves the right to suspend or withdraw Certification.

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

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

UL Registrar LLC 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 or failure to notify UL Registrar LLC of any significant changes that may affect the quality of the products supplied to the participating retailers.

UL Registrar LLC also has the right to suspend or withdraw Certification and remove the organization's name from the certified companies list for failure to complete the next activity by the applicable anniversary date of the audit cycle. Upon suspension, withdrawal, or termination of certification, the client discontinues its use of all advertising matter that contains any reference thereto, returns the certificate, and takes any other required measure as requested by UL Registrar LLC.

UL Registrar LLC maintains an impartial and nondiscriminatory inquiries, complaints, disputes and appeals program to evaluate the consideration of inquiries, complaints, disputes and appeals against any and all decisions. (See Section 15.0)

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

13.0 Certificate Criteria Changes

As retailer requirements change, UL Registrar LLC may revise this document and any checklists accordingly at any time. When substantive changes are made to the Certification process, UL Registrar LLC 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 R may allow for a 30 calendar day review and comment period. Comments and/or feedback received within the 30 calendar days will either be comunicated or handled directly with the petitioner or organization prior to implementation of such changes.

14.0 Use of Certificate of Conformance, Use of Certification Symbols and Reference to RCP Participation

The Certificate of Conformity and Certification Marks are the property of ANAB/ANSI and UL Registrar LLC 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 Registrar LLC Retail 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 Registrar into disrepute and shall not make any statements regarding its certification that UL Registrar may consider misleading or unauthorized. Prior approval is required by completing and signing the UL Registrar LLC Agreement for Use of Certification Symbols, which outlines correct use of the certificate, marks and badges.

15.0 Inquiries, Complaints, Disputes, and Appeals

The Inquiries, Complaints, Disputes, and Appeals Committee will review all inquiries, complaints, disputes and appeals from an applicant, certified organization or individual. The audit report/CAPA, written testimony and any additional documents provided by the applicant will be reviewed prior to any decision being rendered.

The Certificate Holder may request a copy of the UL R Inquiries, Complaints, Disputes and Appeals process by written request to ULRegistrarQAReportRelease@UL.com.

16.0 Confidentiality

UL Registrar LLC 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 Registrar LLC will notify the organization prior to disclosing the information. Upon request, UL Registrar LLC will send duplicate copies of a confidentiality agreement to the organization. One signed copy of the agreement should be signed and returned prior to the audit. [1]

1 Reports may be released by UL Registrar LLC to the organization and any retailers as specified by the audit client and/or auditee or as otherwise agreed to in advance between the audit client and UL R.

17.0 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. UL R is accredited by the American National Standards Institute (ANSI) and ANSI-ASQ National Accreditation Board (ANAB). UL R is required by accreditation bodies to share information for the purpose of demonstrating conformance to the standards for which UL R is accredited. Such records may include audit results and UL Registrar's certification/ inspection 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 R in writing. UL R holds confidentiality agreements with all accreditation bodies.

18.0 Certificates of Conformance/Inspection

Upon completion of an acceptable audit/inspection and after thorough review by the UL R certification committee, an ANSI and ANAB accredited Certificate of Conformance is awarded to the UL R client.
An additional UL Certificate of Conformance is issued with the scope Management System Certification.
Use of Accredited Certificates of Conformance, Accredited Inspection Certificates, the UL Management System Certification, Use of Certification Marks and Reference to RCP Participation shall be in accordance with section 14 of this document.

For more information, please contact ULRInfo@ul.com.

UL REGISTRAR ISSUES THIS

CERTIFICATE OF CONFORMANCE

To:

Company
Address
Address

Facility:

Company
Address
Address

FOLLOWING ASSESSMENT OF ITS GOOD MANUFACTURING PRACTICE & QUALITY SYSTEM AND FINDING IT IN CONFORMANCE WITH:

Standard

UL R Scheme: Retail Certification Program
Procedure for Certification, QSLP 2.1-1
(Rev. Date) RCP®

FOR THE FOLLOWING SCOPE OF CERTIFICATION:

Scope Under Audit

Certificate Number: axx-xxxxxx-x
Issue Number: 1
Certificate Issue Date: 00/00/0000
Expiration Date: 00/00/0000

Authorized by:

Authorized Signature

UL Registrar LLC
4 Fork Street, 1st Floor
Mount Pocono, Pennsylvania 18344
United States of America
800-903-5660

ISO/IEC 17065
Product Certification Body
CERT. #AI-1184

The UL Logo, Enhanced Certification Mark, ANSI Accreditation Mark, and IAF Mark indicate satisfactory assessment against the applicable Code of Federal Regulations in accordance with the UL Registrar LLC RCP© Procedure for Certification, the UL LLC Agreement for Use of Certification Symbols, and the scope of assessment. This certificate remains the property of UL Registrar LLC, to whom it must be returned upon request. Revision 9/12/2016
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SAMPLE

UL REGISTRAR ISSUES THIS

CERTIFICATE OF INSPECTION

To:

Company
Address
Address

Facility:

Company
Address
Address

FOLLOWING INSPECTION OF ITS GOOD MANUFACTURING PRACTICE & QUALITY SYSTEM AND FINDING IT IN CONFORMANCE WITH:

Standard

FOR THE FOLLOWING SCOPE OF INSPECTION:

Scope Under Audit

Certificate Number: ixx-xxxxxx-x
Issue Number: 1
Certificate Issue Date: 00/00/0000
Expiration Date: 00/00/0000

Authorized by:

Authorized Signature

UL Registrar LLC
4 Fork Street, 1st Floor
Mount Pocono, Pennsylvania 18344
United States of America
800-903-5660

ANAB ACCREDITED ISO/IEC 17020 INSPECTION BODY CERT. #AI-1614

ilac-MRA

The UL Logo, ANAB Accreditation Mark, and ILAC Mark indicate satisfactory assessment against the applicable Code of Federal Regulations in accordance with the UL Registrar LLC RCP© Procedure for Certification, the UL LLC Agreement for Use of Certification Symbols, and the scope of assessment. This certificate remains the property of UL Registrar LLC, to whom it must be returned upon request. Revision 9/12/2016

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UL REGISTRAR ISSUES THIS

CERTIFICATE OF CONFORMANCE

To:

Company
Address
Address

Facility:

Company
Address
Address

FOLLOWING ASSESSMENT OF ITS GOOD MANUFACTURING PRACTICE & QUALITY SYSTEM AND FINDING IT IN CONFORMANCE WITH:

Standard

FOR THE FOLLOWING SCOPE OF CERTIFICATION:

Scope Under Audit

SAMPLE

Certificate Number: mxx-xxxxxx-x
Issue Number: 1
Certificate Issue Date: 00/00/0000
Expiration Date: 00/00/0000

Authorized by:

Authorized Signature

UL Registrar LLC
4 Fork Street, 1st Floor
Mount Pocono, Pennsylvania 18344
United States of America
800-903-5660

The UL Logo and Enhanced Certification Mark indicate satisfactory assessment against the applicable Code of Federal Regulations in accordance with the UL Registrar LLC RCP© Procedure for Certification, the UL LLC Agreement for Use of Certification Symbols, and the scope of assessment. This certificate remains the property of UL Registrar LLC, to whom it must be returned upon request. Revision 9/12/2016

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About UL

UL is a premier global independent safety science company that has championed progress for 120 years. Its more than 10,000 professionals are guided by the UL mission to promote safe working and living environments for all people. UL 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 Registrar LLC

UL Registrar LLC is a division of UL LLC. UL Registrar's mission is to be the global leader in advancing sustainable audit and certification services within supply chains, worldwide. UL Registrar 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 Registrar's services, please email ULRInfo@ul.com.

*This procedure for certification also 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."

QSLP 2.1-1 RCP Procedure for Certification. Rev. 2/16/2017

About ANAB

ANAB (formerly ACLASS) is a brand of ANSI-ASQ National Accreditation Board, a non-profit, non-governmental organization that provides accreditation services to public- and private-sector organizations under the ANAB, and FQS brands. The ANSI-ASQ National Accreditation Board is in partnership with the American National Standards Institute and the American Society for Quality.

About ANSI

American National Standards Institute (ANSI), 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. ANSI is also actively engaged in accreditation that provides assurance that standards, goods, and services meet essential requirements throughout the global supply chain. Visit ANSI at www.ansi.org for more information.