



## UL GMP Procedures for Certification updates:

UL is proud to announce that program enhancements have been made to the Retail Certification Program (RCP) and National Brand Certification Program (NBCP).

Some of the most noteworthy updates that have been made include:

- 3 new technical scope offerings within the RCP and NBCP programs: ANSI 455-2, ANSI 455-3 and ANSI 455-4;
- Warehouse certification clients will no longer receive a certificate per technical scope. Warehouse is now considered a scope as defined by this table. One certificate will be issued noting all the types of products stored;
- Exclusions from an auditee's scope of certification.

Below is a list of changes made in the RCP and NBCP Procedures for Certification in the form of a comparison table, with the previous requirement listed along with the "new" requirement.

Item No.	Previous Requirement	Changes to Procedures for Certification	Procedure Section	Subject Area	Requirement of Standard
1	Procedure for Certification was previously silent on exclusions.	New paragraph added describing exclusions from scope of certification and applicability of such.	3.0	RCP/NBCP Audit Scope	ISO/IEC 17065, clauses 7.2 and 7.3
2	Audit Scope + Audit Standards Defined.	Previously 2 separate sections; now combined. NEW table added describing technical scopes and applicable standard: <ul style="list-style-type: none"><li>a. NEW scopes were added to the RCP and NBCP service offerings (ANSI 455 technical scopes).</li><li>b. Warehouse certification clients will no longer receive a certificate per technical scope. Warehouse is now considered a scope as defined by this table. One certificate will be issued noting all the types of products stored.</li></ul>	3.0	RCP/NBCP Audit Scope and Audit Standards Defined	N/A
3	There was a section dedicated to Dual Regulations Under One Manufacturing Roof which defined how UL would assess facilities with two or more types of regulated/non-regulated products governed by two or more different FDA cGMP regulations.	Removed the Dual Regulations Under One Manufacturing Roof section of the Procedure. The paragraph above the new Technical Scope Table defines how dual scopes will be handled.	3.0	Dual Regulations Under One Manufacturing Roof	N/A
4	The Opening Meeting section inadvertently addressed the scope of certification, which should include exclusions from	Bullet point #3 newly added: "The opening meeting ensures that: ... Audit exclusions are discussed, captured and documented..."	5.0	The Opening Meeting	N/A



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	scope of certification, however was not explicit.				
5	An Audit Summary Report will be left on-site with the organization at the conclusion of the assessment... The final audit report will be provided to the Certification Review Committee without delay for processing...	Added information to this section to provide better clarity on the order in which the post audit process occurs. "...Once CAPAs have been approved by the auditor, or in the case where no CAPAs were issued, the Certification Committee reviews all audit records along with other appropriate documentation to render a final certification decision."	5.0	The Audit Summary Report and The Final Report	ISO/IEC 17065 clause 7.5
6	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.	Updated the timeframe for which a follow-up audit would be required: "...within a 90 to 180 calendar day window based on the last date of the Audit."	5.0	Critical (CAPA) Nonconformity	ISO/IEC 17065 clauses 7.4.7 – 7.4.9
7	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.	Updated the timeframe for which a follow-up audit would be required: "...within a 90 to 180 calendar day window based on the last date of the Audit."	5.0	Major (CAPA) Nonconformity	ISO/IEC 17065 clauses 7.4.7 – 7.4.9
8	A follow-up audit would be required if the factory criteria falls within Marginal Compliance or in the Medium to High Risk levels.	Updated the timeframe for which a follow-up audit would be required: "A Follow-up Audit would be required within 90 to 180 days of the Audit if the factory criteria falls within Marginal Compliance or in the Medium to High Risk levels."	5.0	Minor (CAPA) Nonconformity	ISO/IEC 17065 clauses 7.4.7 – 7.4.9
9	N/A – New paragraph added for clarity.	New paragraph added to provide clarity on Certification Committee's ability to reject CAPA plans, even if accepted by the auditor: "CAPA Plans (including Root Cause Analysis) are reviewed during the Certification Committee Review, as detailed in Clause 7.0 below, and may also be rejected, even if previously accepted by the auditor. Such CAPA plans will be resubmitted to the organization for follow-up and resubmission back to UL with a 5 calendar day response time..."	5.0	Additional Nonconformity Information	



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		Failure to respond to such CAPAs may also result in a decision to deny certification, as detailed in Clause 7.0 below.”			
10	2 Sections of the Procedure for Certification that outlined scoring for the 2 types of audit tools.	Removed these sections from the Procedure for Certification. Scoring is available upon request.	5.0	Risk-Based Scoring Criteria + Non-Risk-Based Scoring Criteria	N/A
11	6.0 Contract Manufacturing Section moved to a new location	Now Section 7.0	7.0	Contract Manufacturing	N/A
12	7.0 The RCP Certification Review Section moved to a new location	Now Section 6.0	6.0	The RCP/NBCP Certification Review	N/A
13	Formerly section 8.0 Surveillance Audits and Section 9.0 Recertification, defined audit window due dates.	Section 8.0 renamed to On-going Annual Audits. Audit Due Dates have been updated for all audit types (Recertification and Surveillances): “The RCP / NBCP 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, the second and third year Surveillance audits are conducted. The fourth audit activity shall be a Recertification followed by two surveillance audits. Annual Audits should occur +/- 30 days of the anniversary date of the Initial Certification Audit.”  Surveillance and Recertification are sub-sections under Section 8.0	8.0	On-going Annual Audits	N/A
14	Brief mention of special audits throughout Procedure for Certification	Section 10.0 is now dedicated to Special Audits. Procedure clearly outlines when a special audit may be required. Short-notice and Unannounced Special Audits introduced and defined.	10.0	Special Audits	ISO/IEC 17065 clause 7.10
15	The Certificate of Conformity and Certification Marks are the property of ANAB/ANSI and UL ...	ANSI fully acquired ANAB and rebranded all accreditation programs under the ANAB name. Procedure updated to reflect: “The Certificate of Conformity and Certification Marks are the property of ANAB and UL...”	14.0	14.0 Use of Certificate of Conformance, Use of Certification Symbols and Reference to	N/A



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				RCP/NBCP Participation	
16	The Certificate Holder may request a copy of the UL R Inquiries, Complaints, Disputes and Appeals process by written request to ULRegistrarQAResponse@UL.com.	UL Complaints, Disputes & Appeals Procedure is available online. Added hyperlink to procedure.  Added timeframe in which CAPA disputes must be received: "Disputes shall be received within 14 calendar days of the audit or will not be considered."	15.0	Complaints, Disputes and Appeals	N/A
17	Procedure for Certification required organizations to allow observers on-site in the scope section.	Added additional detail surrounding the requirement of organizations to allow UL or accreditation bodies to witness / observe audits and why it is required.	17.0	Accreditation	ISO/IEC 17065 clause 4.1.2.2 c 3

The updated Retail Certification Program Procedure for Certification and National Brand Procedure for Certification can be found online on our website. Please follow these hyperlinks to access:

- [RCP Procedure for Certification](#)
- [NBCP Procedure for Certification](#)

The new revisions of the RCP and NBCP Procedures for Certification will go into effect on April 1, 2022. Interested clients can make application for ANSI 455 scopes under RCP or NBCP on or after April 1, 2022.

#### **About UL Verification Services**

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