.

Manual Guide

Central Administration of Drug Control

Accreditation Programs Unit

Guidance on

EDA Cosmo Lab Accreditation program of Cosmetics quality control laboratories

2022

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1. Introduction

EDA Cosmo Lab accreditation program aims to improve the quality standards of both cosmetics manufacturing factories and cosmetics quality control laboratories, continuously ensuring the safety and efficacy of the cosmetic product, coinciding with the EDA launching of the cosmetic products notification system.

2. Scope

2.1. Accreditation of all tests related to the safety and the purpose of use of different categories for all pharmaceutical forms of cosmetics, which are:

- Physical tests.
- Chemical tests.
- Microbiological tests.
- Acute toxicity tests.

2.2. Review and approval of the cosmetics certificates of analysis of EDA-accredited laboratories with their various categories as follows:

- EDA-licensed quality control laboratories in cosmetics manufacturing factories.
- EDA- licensed quality control laboratories in pharmaceutical manufacturing factories.
- EDA-licensed private laboratories.
- Service laboratories affiliated with governmental agencies.

3. Abbreviations: none

4. Definitions: none

5. Main Topic

EDA Cosmo Lab accreditation program privileges

Granting an accreditation certificate for tests related to the safety of different categories of cosmetics, valid for one year and to be renewed in accordance with the EDA regulatory rules and technical controls regarding tests for analyzing samples of cosmetics.

Pre accreditation procedures

Process	Process owner
Payment of accreditation certificate fees.	Laboratory
Fill out and send electronically the signed application form by the authorized person	Laboratory
Upload the documents specified in Annex 1 via the specified link	Laboratry
Respond to the laboratory by accepting, rejecting, or completing the requirements (3 days)	CADC
Payment for (approval of tests for a main categories of cosmetics) fees and delivery of the original copy documents of Annex 3) (3 days)	Laboratory
Inspection of the submitted testing methods and define the date for audit visit (15 days).[1]	CADC
Conduction of Assessment visit (3-5 days)	CADC
Preparation and sending audit report (5 days from the end date of visit)	CADC
Send the required CAPA plan (5 days)[2]	CADC
Study the CAPA plan and perform second audit visit if required (3 days)[3]	CADC
Preparation and submission of final audit report (15 days from the last response from the laboratory or from the end date of visit) with recommendation of acceptance or rejection	CADC
Issuance of accreditation certificate with scope schedule of accredited categories	CADC

[1]If there is a re-submission request, the laboratory sends it within two days, and the response is within two days.

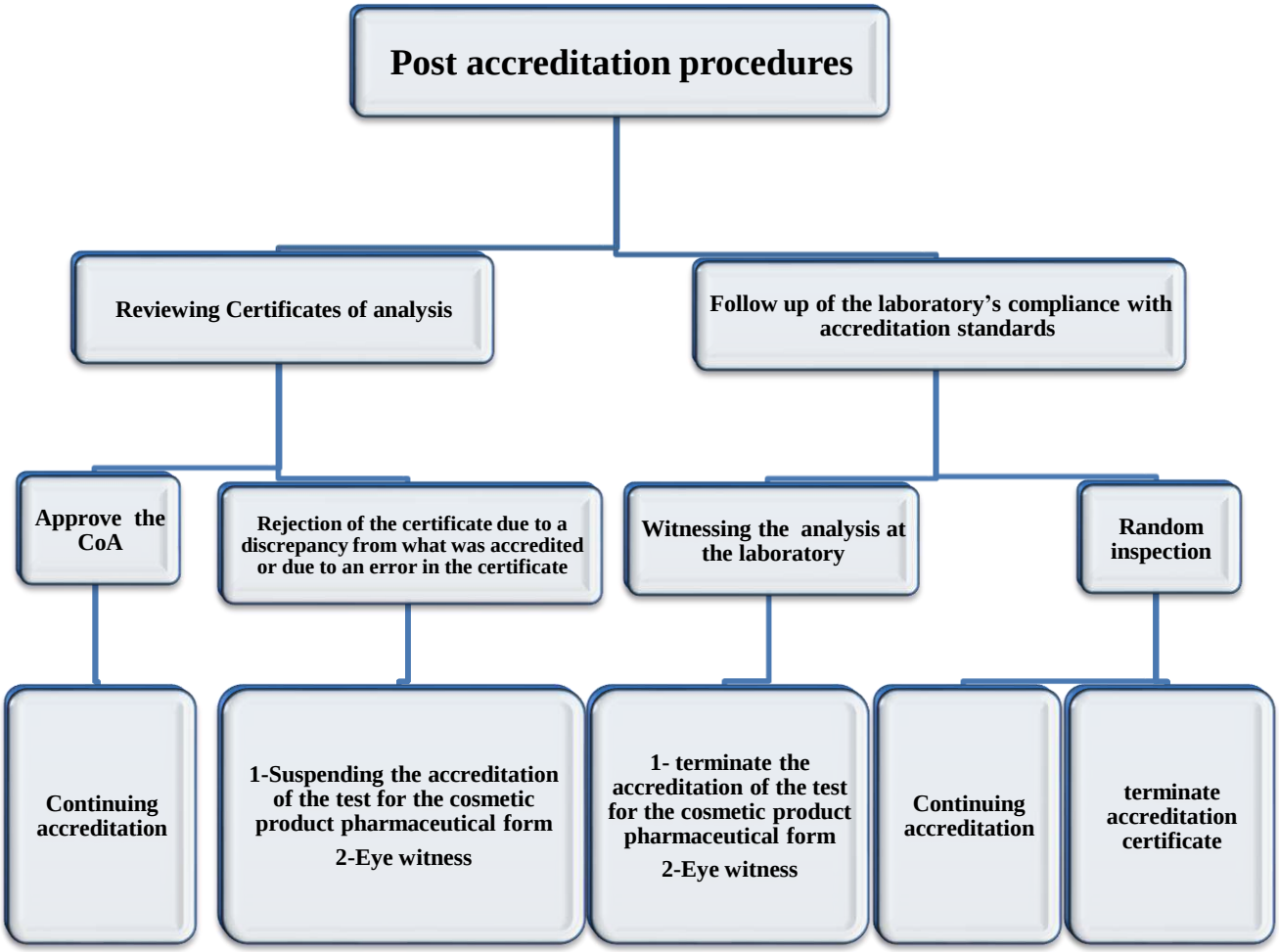
[1]The laboratory confirms the visit date on the relevant link within two days. If no confirmation is sent, this is considered implicit approval of the specified date. In the case of a re-submission request, the laboratory responds within two days, and the laboratory is responded to within two days.

[2]The time period for correcting any item in the corrective action plan does not exceed one month.

[3] The central administration of drug control studies the submitted corrective actions within a period not exceeding ten days.

[4]The laboratory is granted an additional period to complete the corrective actions in accordance with the time periods stated previously, and in case the requirements are not fulfilled, the application is considered cancelled.

Post accreditation procedures



- **The applicant company delivers cosmetic product certificate of analysis to the reception unit at the General Administration of approval and evaluation where the Department approves it from the Accreditation Programs Unit and issues the final report.**

Minimum Requirements of applying for the program

- **It is necessary to have a list of the following instruments according to the required tests for each category:**

  Balance – Oven – water bath with shaker – stirrer – pH meter – hotplate – Atomic absorption spectrophotomer (AAS)/ Inductively Coupled Plasma spectrophotometer (ICP) – SPF analyzer – Gas Chromatography (GC) – UV spectrophotometer.

- **If the laboratory desires to accredit a test that requires the provision of an additional instrument, the laboratory is committed to provide the instrument before applying for accreditation, provided that the results of these tests are approved in accordance with EU Cosmetic Regulation (EC) No. 1223/2009.**

- **In case of applying for microbiological tests accreditation, a microbiological laboratory shall be available and includes as a minimum the following instruments :**

- Autoclave
- Two Laminar air flow units in controlled room (with air locked double doors)
- Fridge
- Three incubators
- Microscope
- Baths and ovens
- Balance

- **In case of applying for accreditation of acute toxicity tests, the laboratory shall send evidence of the availability of all instruments and capabilities necessary to perform the test.**

Controls for updates

If the laboratory desires to update the methods of analysis after granting the accreditation or amend any of the documents submitted, the Central Administration of Drug Control must be notified first to conduct studying and re-evaluation, if necessary.

The accreditation programs unit responds to the laboratory within a period not exceeding ten days.

Accreditation Renewal

The same accreditation procedures are followed and the laboratory's performance is evaluated to renew accreditation according to the following score system:

Performance indicator	Score
The laboratory's commitment to the published time periods to implement the steps of granting accreditation	10
Laboratory representatives cooperation with the accreditation team during assessment visits and eye witness visits to the laboratory	10
The assessment points acquired by the laboratory during all assessment visits at the stage of granting accreditation and throughout the validity period of accreditation certificate, in accordance to the required standards.	40
No temporary suspension of accreditation of one or more tests of the cosmetic product pharmaceutical form during the accreditation period	20
No suspension of accreditation of one ormore tests of the cosmetic product pharmaceutical form during the accreditation period	20
Total	**100**

***The quality control laboratory is awarded additional 5 points in case of being accredited in accordance to ISO/IEC 17025:2017 or an equivalent standard.**

***The renewal of accreditation will not be approved if the laboratory obtains a score less than 75%.**

Service fees

SN	Service provided	Service fees
1	Application to obtain/ renew the accreditation certificate.	5000 LE
2	An application for approving / renewing of test accreditation for a main category of cosmetic group	20000 LE
3	An application to approve an additional test product for an approved category during the certificate validity period	5000 LE

4	Approving of analysis results for single batch of a local cosmetic product	2000 LE
5	Approving of analysis results for single batch of a imported cosmetic product	4000 LE

General terms and conditions

1- The laboratory adheres to the regulatory rules and technical controls issued by the Authority regarding cosmetics sample analysis tests.

2- The laboratory is committed to analyzing the submitted cosmetic samples in accordance to the guidance of the Central Administration for Drug Control.

3- The laboratory is committed to keeping samples for each batch that has been analyzed until the certificate of analysis is approved by the Central Administration for Drug Control.

4- The laboratory is obligated to keep an exact copy of the analysis file for each batch of each product for a period of not less than five years.

5- The laboratory is committed to providing all the necessary instruments to conduct the tests required to fulfill the scope of accreditation.

6- If the laboratory does not adhere to the time frames specified for completing any procedure, the application will be considered as if it did not exist, and the laboratory has the right to submit a petition to the head of the Central Administration of Drug Control to grant an additional period, and in the event of refusal, the laboratory will submit a new application if it desires to obtain accreditation.

7- The laboratory is obligated to notify the Central Administration of Drug Control as soon as any amendments occur in the submitted documents, and the accreditation committee will respond within a t not exceeding ten days by accepting or suspending the accreditation certificate until the amendments are completed.

8- If the accreditation application is rejected, the laboratory has the right to submit a new application after a period of not less than three months has passed from the date of rejection, along with paying the prescribed fees.

9- The laboratory may conduct some microbiological tests and acute toxicity tests for government agencies or other accredited laboratories after obtaining the approval of the Central Administration for Drug Control.

10- The laboratory may apply to accredit a new category or one or more additional tests during the validity period of the certificate, noting that all tests will be renewed annually on the date scheduled to renew the certificate.

11- If the laboratory wishes to renew the accreditation certificate, the application must be submitted within a period of time of not less than three months before the renewal date.

12- The laboratory's performance is evaluated annually according to the announced scoring system to decide whether or not to renew the accreditation.

6-References

1. **EU Cosmetic Regulation (EC) No1223/2009**
2. **SCCS – Cosmetic 2018-10th REVISION**
3. **WHO good practices for pharmaceutical quality control laboratories, Annex 1, WHO TRS 957, 2010**
4. **WHO good practices for pharmaceutical microbiology laboratories, Annex 2, WHO TRS 961, 2011**
5. **WHO guidelines on quality risk management Annex 2, WHO TRS 981, 2013**
6. **Guidance on good data and record management practices, Annex 5, WHO TRS 996, 2016.**
7. **WHO guidelines for preparing laboratory information file, Annex 13, WHO Technical Report Series 961, 2011.**

8. EudraLex The Rules Governing Medicinal Products in the European Union Volume 4 EU Guidelines to Good Manufacturing Practice Medicinal Products for Human and Veterinary Use Annex 19 Reference and Retention Samples

9. General European OMCL Network (GEON) Quality Management system documents

10. ICH quality guidelines.

11. Latest editions of pharmacopeias USP and BP, FDA guidance.

12. ISO/IEC 17025 (2017) General requirements for the competence of testing and calibration laboratories

13. ISO 22716 /2007 (Cosmetics — Good Manufacturing Practices (GMP(

14. ISO 21149 Cosmetics – Microbiology – Enumeration and detection of aerobic mesophilic bacteria

15. ISO 18415 Cosmetics – Microbiology – Detection of specified and non-specified micro-organisms.

16. ISO- methods for the detection of specific microorganisms: E. coli (ISO 21150), Pseudomonas aeruginosa (ISO 22717), Staphylococcus aureus (ISO22718) and Candida albicans (ISO 18416).

17. ISO/FDIS 16212 Cosmetics – Microbiology – Enumeration of yeast and mould.

18.ISO 17516:2014.

The official mail for accreditation program
dc.cosmolabaccredit@edaegypt.gov.eg
The accreditation program communication links

Link of Appointment Form

https://form.jotform.com/212603597453054

EDA Accreditation, Annex 1:

https://forms.office.com/r/ehiNFCWqR2

EDA Accreditation, Resubmission of Annex 1:

https://forms.office.com/r/Gp1MuwbNeF

EDA Accreditation, Visit Confirmation Letter:

https://forms.office.com/r/vHBs4sW1n8

EDA Accreditation, CAPA Plan:

https://forms.office.com/r/xU4gduBqKn

EDA Accreditation, CAPA Plan Implementation 1:

https://forms.office.com/r/6L67hz3RgN

EDA Accreditation, CAPA Plan Implementation 2:

https://forms.office.com/r/Xa1A5kwR6B

EDA Accreditation, Attachments of Accredited Product - Results of Analysis:

https://forms.office.com/r/vyaN4AQdGu

EDA Accreditation, Annex of Updates :

https://forms.office.com/r/41L4AViWSM

7.1-Attachments

Attachment 1: Microbiological analysis results data requirement

Attachment 1

Microbiological analysis results data requirement

Microbial count test

1- The sample size, sampling date, and the sampler name.

2- All equipment used in the test procedure i.e. incubators, autoclave, pH meter, balance, LAF and any other equipment used with their code numbers.

3- The batch numbers of media and any diluent or neutralizer used in the test, their preparation date, and sterilization cycle number.

4- The number of the SOP used to carry out the test.

5- The analyst and supervisor signature.

Attachment 2: Categories to be accredited

Attachment 2

Categories to be accredited**:**

No	Category	Required tests
1-	**Skin Care products (hand, face, body)**	• **Heavy metals by AAS/ICP** • **Physical tests** • **Microbiological tests**
Additional tests for sub-categories		
a-	**Sunbathing products**	**SPF**
2-	**Hair care products**	• **Heavy Metals by AAS/ICP** • **Physical tests** • **Microbiological tests**
Additional tests for sub-categories		
a-	**Products for waving, straightening and fixing**	**Limit for formaldehyde by GC/UV**
b-	**Cleansing products (lotions, powders, shampoos)**	**1,4 Dioxane by GC**
c-	**Anti-dandruff shampoos**	**1,4 Dioxane by GC**
3	**Shaving products (creams, foams, lotions, etc.)**	• **Heavy Metals by AAS/ICP** • **Physical tests**

		• **Microbiological tests**
4	**Products for making up and removing makeup from the face and the eyes**	• **Heavy Metals by AAS/ICP** • **Physical tests** • **Microbiological tests**
5	**Products intended for application to the lips**	• **Heavy Metals by AAS/ICP** • **Physical tests** • **Microbiological tests**
6	**Products for care of the teeth and the mouth**	• **Heavy Metals by AAS/ICP** • **Hydrogen peroxide by titration** • **Physical tests** • **Microbiological tests**
7	**Products for nail care and nail lacquer**	• **Heavy Metals by AAS/ICP** • **Hydrogen peroxide by titration** • **Physical tests** • **Microbiological tests**

8	**Products for external intimate hygiene**	• **Heavy Metal by AAS/ICP** • **1,4 Dioxane by GC** • **Physical tests** • **Microbiological tests**
9	**Kids fingers paints, and kids face painting** **1**	• **Heavy metals by AAS/ICP** • **Limit for formaldehyde by GC/UV** • **Physical tests** • **Microbiological tests**
10	**Any cosmetic products containing high percent of ethanol or isopropanol** **2**	• **Methanol by GC**

Attachment 3: List of Physical, Chemical & Microbial tests and their limits for quality control of cosmetic products

Attachment 3

List of Physical, Chemical & Microbial tests and their limits for quality control of cosmetic products:

A- Physical test; the pH range:

the pH of cosmetic product should be in the range (4-8) excluding hair colorant and excluding the product with PH mentioned in Annex 3 according to their composition ingredients as shown in the table*. Certain product which formulated with PH value outside this range are acceptable if they had evidence to demonstrate that the PH is necessary to achieve the required cosmetic effect and have a demonstrable safety report.

A	**Category**	**pH range**

1	**Skin care products** (a) Cleanser (b) Toner (c) Sunscreen (d) Moisturizers (e) Serum (f) AHA and BHA exfoliators. (g) Vitamin C products (h) Retinol products	(a) 4.5-7 (b) 5-7 (c) 5-7.5 (d) 5-7 (e) 4-6 (f) 3.7-5 (g) 3-4 (h) 3.7-5
2	**Hair care products** (a) Shampoos for adults (b) Shampoo for babies (c) Hair dyes: i. Black & brown shades ii. Other shades (d) Developer	(a) 5-8 (b) 5-7 (c)i. 9-11 ii.6-11 (d) 1.8-4

	(e) *straightening products containing metal hydroxides (f) Some hair treatments products containing keratin & protein	(e) up to 12.7 (f) <4
3	**For products contain Thioglycolic acid and its salts as** (a) *Hair products: for general or professional use (b) *Depilatories (c) Hair rinse-off products For products contain Thioglycolic acid esters (d) Hair waving or straightening products	 (a) 7- 9.5 (b) 7 - 12.7 (c) up o 9.5 (d) 6 - 9.5
4	**Soap (1% aqueous solution)**	8-11

B	**Chemical tests**	**Limit of Safety**
1	**Determination of 1,4 Dioxane** (a) Shampoo, shower gel, cleansing product (b) Any products contain SLS, SLES, PEG	 (a), (b) NMT 10 ppm
3	**Determination of Methanol** Products contain ethanol or isopropanol (e.g., body mist)	-NMT 5% as % of Ethanol or Isopropanol
5	**Determination of Formaldehyde** (a) Nail hardener (b) Oral product (toothpaste, mouth wash)	 (a) NMT 5% (b) NMT 0.1%

	(c) other products	(c) NMT 0.2%
10	**Determination of Hydrogen peroxide** (a) Hair products (b) Skin products (c) Nail hardening products (d) Oral products, including mouth rinse, tooth paste and tooth whitening or bleaching products (e) Tooth whitening or bleaching products (professional use) (f) Products intended for eyelashes	 (a) NMT 12 % (b) NMT 4 % (c) NMT 2 % (d) ≤ 0.1 (e) > 0.1 % ≤ 6 % (f) NMT 2 % All % calculated as H_2O_2 present or released
17	**Determination of heavy metals** (a) pb (b) As (c) Cd (d) Hg	 (a) NMT 10 ppm (10 µg/g) (b) NMT 3 ppm (c) NMT 3 ppm (d) NMT 3 ppm

C	**Microbiological tests for cosmetic products**		
	Category of products	**Type of test**	**Specification**
1	**All cosmetic products except the products used around the eyes, products used for infants under three years, and products used**	Total microbial count (T.M.C.)	N.M.T 10^3 CFU/ml or gm
		Specified micro-	

	on mucous membranes	organisms: a) Staphylococcus aureus b) Pseudomonas aeruginosa c) Candida albicans d) Escherichia coli	Absent in 1ml or 1gm
2	**Products used around the eyes, products for infants under three years, and products used on mucous membra**nes	Total microbial count (T.M.C.)	N.M.T 10^2 CFU/ml or gm
		Specified micro-organisms: a) Staphylococcus aureus b) Pseudomonas aeruginosa c) Candida albicans d) Escherichia coli	Absent in 1ml or 1gm

7.2-Annexes

Annex1: المستندات المطلوب تقديمها

Annex1

Documents required to be submitted:

1) A valid factory license (if the laboratory is located inside the factory)/private laboratory license.
2) An updated quality manual or equivalent document containing the latest version of the organizational structure of the institution to which the laboratory belongs (if the laboratory is inside the factory), showing the location of the laboratory in this structure, as well as the organizational chart of the laboratory (Lab Organogram).
3) Procedures, instructions and policies.
4) An updated list of instruments and reference materials.
5) A commitment from the laboratory to provide all instruments , chemicals and reference materials.
necessary to perform all tests required for approval.
6) The analysis methods used and their verification methods.
7) A copy of the contract in the event of conducting tests in another laboratory, and a stamped approved approval from the responsible in the contracted laboratory to conduct assessment visits regarding the submitted tests for accreditation.
8) In the event that some tests are analyzed in a laboratory at a government agency, a stamped and signed pledge must be submitted from the laboratory submitting the request.
9) A copy of the payment receipt for service fees of application to obtain the accreditation certificate.
10) Delegation letters.
11) A copy of the application form signed by the commissioner.

Annex2: Assessment check list

2Annex

Assessment check list

1. Organization and Management	
Clause	**Requirement**
1.1	The laboratory, or the organization of which it is part, should be an entity that is legally authorized to function and can be held legally responsible.
1.2	The laboratory should be organized and operated so as to meet the requirements laid down in these guidelines.
1.3	The laboratory should have managerial and technical personnel with the authorities and resources needed to carry out their duties, to identify the occurrence of departures from the quality management system or from the procedures of performing tests and/or calibrations, validation and verification and to initiate actions to prevent or minimize such departures.
1.4	The lab should have arrangements to ensure that its management and personnel not subject to commercial pressures or conflicts of interest that may adversely affect the quality of their work.
1.5	The lab should have a policy and procedure in place to ensure confidentiality of information contained in marketing authorizations,

transfer of results or reports, and to protect data in archives (paper and electronic).

1.6 The lab should define, with the aid of organizational charts, the organization and management structure of the laboratory, its place in any parent organization and the relationships between management, technical operations, support services and the quality management system.

1.7 The lab should specify the responsibility, authority and interrelationships of all personnel who manage the performance or verify the work which affects the quality of the tests and/or calibrations, validations and verifications.

1.8 The lab should nominate trained substitutes/deputies for key management and specialized scientific personnel.

1.9 The lab should provide adequate supervision of staff, including trainees, by persons familiar with the test and/or calibration, validation and verification methods and procedures, as well as their purpose and the assessment of the results.

1.10 The lab should have management which has overall responsibility for the technical operations and the provision of resources needed to ensure the required quality of laboratory operations

1.11 The lab should designate a member of staff that will ensure compliance

with the quality management system and should have direct access to the highest level of management at which decisions are taken on laboratory policies or resources.

1.12 The lab should ensure adequate information flow and guarantee communication and coordination between the staff at all levels.

1.13 The lab should ensure the traceability of the sample from receipt, throughout the stages of testing, to the completion of the analytical test report and maintain a registry with keeping records on all incoming samples and accompanying documents.

1.14 The lab should maintain an up-to-date collection of all specifications and related documents (paper or electronic) used in the laboratory.

1.15 The lab should have appropriate safety procedures.

1.16 The laboratory should maintain a registry with receiving, distributing and supervising the consignment of the samples to the specific units.

2. Quality Management System

Clause	Requirement
2.1	The lab should document the elements of its quality management system in quality manual or equivalent documents, for the organization as a whole and/or for a laboratory within the organization.

2.2 The Quality Manual or equivalent documents should provide (as a minimum) the following policies:

(a) a quality policy statement, including at least the following:

(i) A statement of the laboratory management's intentions with respect to the standard of service it will provide;

(ii) A commitment to establishing, implementing and maintaining an effective QMS.

(iii) The laboratory management's commitment to good professional practice and quality of testing, calibration, validation and verification;

(iv) A requirement that all personnel concerned with testing and calibration activities within the laboratory familiarize themselves with the documentation concerning quality;

(b) The structure of the laboratory (organizational chart);

(c) The operational and functional activities pertaining to quality, so that the extent and the limits of the responsibilities are clearly defined;

(d) outline of the structure of documentation used in the laboratory quality management system;

(e) The general internal quality management procedures;

(f) References to specific procedures for each test;

(g) Information on the appropriate qualifications, experience and competencies that personnel are required to possess;

(h) Information on initial and on-job training of staff;

(i) A policy for internal and external audit;

(j) A policy for implementing and verifying corrective and preventive actions;

(k) A policy for dealing with complaints;

(l) A policy for performing management reviews of the quality management system;

(m) A policy for selecting, establishing and approving analytical procedures.

(n) A policy for handling of OOS results;

(o) A policy for the employment of appropriate reference substances and reference materials;

(p) A policy to select service providers and suppliers.

2. Standard Operating Procedures	
Clause	**Requirement**
2.3	The laboratory should establish, implement and maintain authorized written SOPs including, but not limited to, administrative and technical

operations e.g.

(a) personnel matters, including qualifications, training, clothing and hygiene;

(b) change control;

(c) internal audit;

(d) dealing with complaints;

(e) implementation and evaluation of corrective and preventive actions;

(f) the purchase and receipt of materials and services;

(g) the procurement, preparation and control of reference substances;

(h) the internal labeling, quarantine and storage of materials;

(i) the qualification of equipment;

(j) the calibration of equipment;

(k) preventive maintenance and verification of instruments and equipment;

(l) sampling, if performed by the laboratory, and visual inspection;

(m) the testing of samples with descriptions of the methods and equipment used;

(n) the evaluation and investigation of atypical and OOS results;

(o) validation of analytical procedures;

(p) cleaning of laboratory facilities, including bench tops, equipment, work stations, clean rooms (aseptic suites) and glassware;

(q) monitoring of environmental conditions, e.g. temperature and

humidity;

(r) monitoring storage conditions;

(s) disposal of reagents and solvent samples;

(t) Safety measures.

2.4 The activities of the laboratory should be systematically and periodically audited.

The audits should be carried out by trained and qualified personnel, who are independent of the activity to be audited.

Such audits should be recorded, together with details of any corrective and preventive action taken.

2.5 Management review of quality issues should be regularly undertaken (at least annually), including

(a) Reports on audits or inspections and any follow-up required to correct any deficiencies.

(b) the outcome of investigations carried out as a result of :

-complaints received;

- doubtful (atypical) or aberrant results reported in collaborative trials and/or in inter-laboratory comparison reports;

- Corrective actions applied and preventive actions introduced as a

result of these investigations.

3. Documentation Control	
Clause	**Requirement**
3.1	The laboratory should establish and maintain procedures to control and review all documents. A master list identifying the current version status and distribution of documents should be established and readily available.
3.2	The procedures should ensure that: (a)Each document, whether a technical or a quality document, has a unique identifier, version number and date of implementation; (b)Appropriate, authorized SOPs are available at the relevant locations, e.g. near instruments; (c)Documents are kept up to date and reviewed as required; (d)Any invalid document is removed and replaced with the authorized, revised document with immediate effect; (e)A revised history page includes references to the previous document; (f)Obsolete documents are retained in the archives to ensure traceability of the evolution of the procedures; any copies are destroyed;

(g)All relevant staff are trained for the new and revised SOPs; and quality documentation.

3.3 The presence of change control system that ensures that:

(a) During the review and revision procedure, documents are prepared by the original initiator, or a person who performs the same function. Documents are reviewed, approved and authorized at the same management level as the original document.

(b) Staffs acknowledged, by a signature, that they are aware of applicable changes and their date of implementation.

4. Records

Clause	Requirement

4.1 The laboratory should establish and maintain procedures for the collection of technical and scientific records

4.2 Records should include all original observations, including calculations and derived data, calibration, validation and verification records and final results of tests.

4.3 Quality and technical/scientific records (including analytical test reports, certificates of analysis and analytical worksheets) should be legible, readily retrievable, stored and retained within a suitable

environment.

4.4 Quality Management records should include reports of both internal, external audits, management reviews, complaints and their investigations and records for the implementation and evaluation of CAPA corrective and preventive actions.

5. Data Processing Equipment and Data governance	
Clause	**Requirement**
5.1	When computers are used in the collection, processing, recording, reporting, storage or retrieval of test and/or calibration data, the laboratory should ensure that: (a) Computer software developed by the user should be documented in sufficient detail and appropriately validated or verified as being suitable for use; (b) Procedures are established and implemented for protecting the integrity of data. Such procedures should include measures to ensure: - The integrity and confidentiality of data entry or collection and the storage, transmission and processing of data; -The protection of data from unauthorized access and an audit trail of any amendments should be maintained, especially for the electronic

data;

(c) computers and automated equipment are maintained so as to function properly and are provided with the environmental and operating conditions necessary to ensure the integrity of test and calibration data;

(d) Procedures are established and implemented for making, documenting and controlling changes to information stored in computerized systems;

(e) Electronic data should be backed up at appropriate regular intervals according to a documented procedure;

(f) Backed-up data should be suitably archived and stored to be retrievable and to prevent data loss.

6. Personnel

Clause	Requirement
6.1	The laboratory should have appropriate managerial and technical personnel and be suitably qualified and experienced. The laboratory should have sufficient staff to perform its delegated functions and be suitably educated, skilled and trained.
6.2	The technical management should ensure the competence of all personnel who are responsible for:

- operating specific equipment, instruments or other devices;

- performing tests and/or calibrations, validations or verifications;

- performing specific tasks should be appropriately qualified in terms of their education, training and experience, as required;

The technical management also has the duty of the evaluation of results as well as signing analytical test reports and certificates of analysis.

6.3 Staff undergoing training should be appropriately supervised and should be assessed on completion of the training including contract staff.

6.4 The laboratory should maintain current job descriptions for all personnel involved in tests and/or calibrations, validations and verifications.

The laboratory should also maintain records of all technical personnel, describing their qualifications, training and experience.

7. Premises

Clause	Requirement
7.1	The laboratory facilities should be of a suitable size and construction and to be designed to suit the functions and operations to be conducted in them.

7.2 The laboratory facilities should have adequate safety equipment located appropriately and measures should be in place to ensure appropriate cleaning.

The laboratory should be equipped with adequate instruments and equipment, including work benches, work stations and monitored fume hoods.

7.3 The environmental conditions (lighting, energy sources, temperature, humidity and air pressure) should be appropriate, controlled and suitably monitored.

7.4 Archives should be provided to permit the secure storage and the retrieval of all documents and to which accesses should be restricted.

7.5 Procedures should be in place for the safe removal of types of waste including toxic waste reagents, samples and solvents.

7.6 The lab should have appropriate storage facilities.

7.7 There must be segregation of storage for samples, retained samples, reagents, laboratory accessories, reference substances and reference materials.

The environment of storage areas should be controlled and monitored and with controlled access.

7.8 There should be appropriate safety procedures for the receipt and

storage of toxic or flammable reagents.

Segregation of the storage of flammable substances, fuming and concentrated acids and bases, volatile amines and other reagents.

7.9 Gases also should be stored in a dedicated store.

8. Equipment, instruments and other devices

Clause	Requirement
8.1	All equipment should be adapted, located, calibrated, qualified, verified and maintained as required.
8.2	The laboratory should have the required test equipment, instruments and other devices for the correct performance of the tests and/or calibrations, validations and verifications. When laboratory uses equipment outside its permanent control, it shall ensure that documented requirements for this equipment are met.
8.3	All instrumentation, and other devices, must comply with the relevant standards, specifications, and qualification and requirements.

9. Contracts

Clause	Requirement
9.1	The laboratory shall have written procedures for the selection of

suppliers of materials, and the provision of services, including maintenance and calibration.

9.2 The laboratory shall have documentary evidence for the evaluation of suppliers of critical consumables and services.

The lab shall maintain an updated list of approved suppliers.

9.3 When the laboratory subcontract tests to a third party, the customer's awareness is must.

9.4 The laboratory shall maintain a registry of all subcontractors that it deals with and a record of the laboratory assessment of the competence of sub-contractors.

9.5 The laboratory take responsibility for all results reported, including those provided by the subcontracting laboratories.

10. Reagents	
Clause	**Requirement**
10.1	The laboratory shall ensure that all reagents and chemicals used in testing are of an appropriate quality and purchased from reputable, approved suppliers.
10.2	In the preparation of reagent solutions in the laboratory:

(a) responsibility for this task should be clearly specified in the job description of the person assigned to carry it out;

(b) Prescribed procedures should be used which are in accordance with published Pharmacopoeial or other standards where available;

(c) Records should be kept of the preparation and standardization of volumetric solutions.

10.3 All reagents, reagent solutions and volumetric solutions should clearly and with appropriate label.

10.4 In the transportation and subdivision of reagents:

(a) Whenever possible they should be transported in the original containers;

(b) When subdivision is necessary, clean containers should be used and appropriately labeled.

10.5 - All reagent containers should be visually inspected to ensure that the seals are intact and that the reagents are not tampered, both when they are delivered to the store and when they are distributed to the units.

10.6 - Water used as a reagent should be of the appropriate grade for a specific test should be used as described in the pharmacopoeias or in an approved test when available.

- Precautions should be taken to avoid contamination during its supply, storage and distribution.

- The quality of the water should be verified regularly to ensure that the various grades of water meet the appropriate specifications.

10.7 Stocks of reagents should be maintained in a store under the appropriate storage conditions.

10.8 The person in charge of the store is responsible for looking after the storage facilities and their inventory and for noting the expiry date of chemicals and reagents.

Training may be needed in handling chemicals safely and with the necessary care.

11. Reference Substances and Reference Materials

Clause	Requirement
11.1	The laboratory should use appropriate reference substances (RS) and reference materials (RM) whenever possible.
11.2	There should be an appropriate procedure to register and identify RSs.
11.3	All RSs should be identified on receipt which is quoted in the analytical report and work-sheet.

RS register should be maintained with the following information available:

(a) The identification number of the RS;

(b) A precise description of the RS;

(c) The source of the RS;

(d) The date of receipt;

(e) The batch designation or other identification code;

(f) The intended use of the RS;

(g) The location of the RS, and any special storage conditions;

(h) Any further necessary information;

(i) Expiry date or retest date;

(j) The certificate of analysis.

11.8 A person should be nominated to be responsible for reference substances and reference materials.

11.10 In addition a file should be kept in which all information on the properties of each reference substance is entered including the safety data sheets.

11.11 For reference substances prepared in the laboratory, the file should include the results of all tests and verifications used to establish the reference substances and expiry date or retest date; these should be signed by the responsible analyst.

In case of presence Pharmacopoeial reference substances, they should be regularly checked for validity (current status) from the issuing pharmacopoeia

by various means, e.g. web sites or catalogues.

11.12 All reference substances prepared in the laboratory or supplied externally should be checked at regular intervals to ensure that deterioration has not occurred.

11.14 In the case that the result of retesting of a reference substance is noncompliant, a retrospective check of tests performed using this reference substance since its previous examination should be carried out where consideration of possible corrective actions, risk analysis should be applied.

12. Calibration, verification of performance and qualification of equipment, instruments and other devices

Clause	Requirement
12.1	Each item of equipment should be uniquely identified.
12.2	Each item of equipment should be labeled to indicate the status of qualification and the date when re-qualification is next required.
12.3	When installed, the equipment should be subjected to supplier IQ/OQ.
12.4	There must be a detailed plan for the qualification of all equipment and instrumentation.
12.5	Specific procedures should be established for each type of measuring

equipment, taking into account the type of equipment, the extent of use and supplier's recommendations .e.g. pH and balances.

12.6 Equipment should be operated only by authorized personnel and instrument manuals and SOPs on the use, maintenance, verification, calibration, qualification should be available.

12.7 Maintenance and qualification and intermediate checks records should be available for each of the instruments.

12.8 Each instrument shall have a usage/maintenance logbook.

12.9 Instrument maintenance procedures should be established.

12.10 "out of service" equipment should be appropriately marked.

12.11 Following service, qualification or maintenance, instrumentation should be appropriately authorized and signed back into use.

13. Traceability

Clause	Requirement
13.1	The results of all analyses should be traceable, where appropriate, ultimately to a primary reference substance.
13.2	The calibration or qualification of instrument procedures should be traceable to a certified reference material and to SI units (metrological traceability).

14. Incoming samples

Clause	Requirement.
14.1	The laboratory shall collaborate with the sample provider to ensure that it obtains sufficient information about samples and objectives of testing and that the required analysis is performed and reported.
14.2	The laboratory should have a sampling plan and an internal procedure for sampling available to all analysts and technicians working in the laboratory. There should be an SOP for sampling and staff members who perform sampling should be appropriately trained and provided with appropriate equipment.
14.3	A standard test request form should be filled out and should accompany each sample submitted to the laboratory provided with the appropriate information.
14.4	The laboratory shall document the review of the request form and document the visual inspection of the sample on receipt.
14.5	The laboratory shall register the sample with an assigned unique registration number and the sample shall be legibly labeled.
14.6	Samples should be appropriately stored and storage areas should be monitored for the environment.
14.7	The examination of a sample should not be started before the relevant test

request has been received.

14.8 The sample should be properly stored until all relevant documentation has been received.

14.9 A request for analysis may be accepted verbally only in emergencies. All details should immediately be placed on record pending the receipt of written confirmation.

14.10 Unless a computerized system is used, copies or duplicates of all documentation should accompany each numbered sample when sent to the specific unit.

15. Analytical Worksheets and Laboratory Notebooks

Clause	Requirement
15.1	The information about the sample, test procedure, calculations and the results of testing should be recorded in worksheets or notebooks and should be complemented by the raw data obtained in the analysis.
15.2	The record should provide sufficient information to confirm that the sample was tested in accordance with the requirements or support an OOS result.
15.3	There should be a separate record for each sample.
15.5	The record should provide the following information:

(a) the registration number of the sample;

(b) page numbering;

(c) the date of the test request;

(d) the date on which the analysis was started and completed;

(e) the name and signature of the analyst;

(f) a description of the sample received;

(g) references to the specifications and a description of test method;

(h) the identification of the test equipment used;

(i) the identification number of any reference substance and the lot No's of the reagents used;

(j) if applicable, the results of the system suitability test;

(k) the identification of reagents and solvents used;

(l) the results obtained;

(m) the interpretation of the results and the final conclusions;

15.6 The record should be completed contemporaneously.

15.7 All the results obtained should be appropriately checked by a second analyst and signed and appropriately signed, approved and authorized.

15.8 Errors should be appropriately corrected.

15.10 Current versions of the relevant pharmacopeias and European Standards Publications of Cosmetics should be used in the laboratory.

15.11 Analytical records should be appropriately archived.

16. Validation of analytical procedures

Clause	Requirement
16.1	The laboratory should perform appropriate validation or verification procedures for the analytical methods employed for testing.
16.2	The laboratory should have a written process describing all elements of method validation.
16.3	The SOP should describe which analytical performance characteristics need to be verified for the various types of analytical procedures.
16.4	The laboratory should perform system suitability testing, where appropriate.
16.5	A major change to the analytical procedure or composition of the product requires revalidation of the method.

17. Testing and Reporting

Clause	Requirement
17.1	Samples should be tested according to an approved or authorized plan where any deviations should be adequately recorded. During analysis samples should be stored securely.
17.2	All deviations from the provided method should be adequately documented

and explained.

18. Evaluation of test results Reports and Certificates of Analysis

Clause	Requirement
18.1	An SOP is required to describe the review and evaluation of test results and describe: (a) Where statistics should be employed; (b) The confirmation of compliance with the specification; (c) How doubtful or atypical results are investigated, and definition of decision rules; (d) The investigation of OOS; (e) Trend analysis.
18.2	An SOP is required for describing the investigation when a doubtful result (suspected OOS result) has been identified.
18.3	The final analytical test report should compile the results and provide a conclusion of the examination of a sample and based on the analytical worksheet.
18.4	If a report requires any amendments a new corrected document should be issued.
18.5	The analytical report should provide the following content:

(a) The laboratory registration number of the sample.

(b) The laboratory test report number;

(c) The laboratory testing the sample;

(d) The originator of the request for analysis;

(e) Full details of the sample;

(f) The purpose of the investigation;

(g) A reference to the specifications employed or the test methods used;

(h) The results of all the tests obtained;

(i) A discussion of the results obtained;

(j) A conclusion as to whether or not the sample complied with the specification;

(k) The date on which the test(s) was (were) completed;

(l) The signature of the head of the laboratory or authorized person;

(m) The name and address of the original manufacturer and, if applicable, those of the re-packer and/or trader;

(n) The date on which the sample was received;

(o) The expiry date or retest date;

(p) A statement indicating that the analytical test report, or any portion thereof, cannot be reproduced without the authorization of the laboratory.

19. Certificates of analysis

Clause	Requirement

19.1 The COA should contain the following information:

(a) The registration number of the sample.

(b) Date of receipt;

(c) The name and address of the laboratory testing the sample;

(d) The name and address of the originator of the request for analysis;

(e) The name, description and batch number of the sample;

(f) The name and address of the original manufacturer;

(g) The reference to the specification used for testing the sample;

(h) The results of all tests performed;

(i) a conclusion as to whether or not the sample was found to be within the limits of the specification;

(j) Expiry date or retest date if applicable;

(k) Date on which the tests were completed;

(l) The signature of the head of laboratory or another authorized person.

20. General Safety Rules

Clause	Requirement
20.1	ALL staff members should be provided with appropriate, documented safety training.
20.2	The laboratory should have procedures and enforce “Good Practice” regarding the following:

(a) Use of safety data sheets (MSDS);

(b) Smoking, eating and drinking in the laboratory;

(c) Use of fire-fighting equipment;

(d) Wearing protective clothing and eye protection;

(e) Use and handling highly potent, infectious or volatile substances;

(f) Use and handling of highly toxic substances;

(g) Use of warning labels on all containers of chemicals;

(h) Spark proofing of solvent stores;

(i) Rules on safe handling of cylinders of compressed;

(j) Rules regarding working alone;

Instructing staff in first-aid techniques and emergency care and availability of first-aid materials, including safety showers and eye wash stations.

20.3 The laboratory should have rules regarding:

(a) Mouth pipetting;

(b) Safe handling of glassware, corrosive reagents and solvents;

(c) Warnings provided regarding exothermic reactions;

(d) Use of oxidizing agents;

(e) Disposal of chemicals;

(f) Use of known carcinogens and mutagens as reagents.

Clause	Requirements
	Microbiology GLP Check-List of Cosmetic
	1- Principles
1.1	The laboratory should be a legal entity licensed from EDA, or a defined part of a legal entity licensed from EDA, that is legally responsible for its laboratory activities.
1.2	Principles described for personnel, premises, equipment and documentation should apply to the quality control laboratory.
	2-Personnel
2.1	Current job descriptions for all personnel involved in any activity in the laboratory including tests and/ or calibrations,
2.2	Microbiological testing should be either performed or supervised by an experienced person, qualified to degree level in microbiology or equivalent.
2.3	Staff should have basic training in microbiology and relevant practical experience before being allowed to perform work covered by the scope of testing (Training evidence or records should be documented).
2.4	If the laboratory includes opinions and interpretations of test results in reports, this shall be done by authorized personnel with suitable

experience

3–Premises

3.1 The microbiology laboratory should be separated from production area and restricted to authorized personnel only.

3.2 Microbiology laboratories should be designed to suit the operations to be carried out in them. There should be sufficient space for all activities to avoid mix ups, contamination and cross-contamination (dedicated area for each activity)

3.3 Laboratories should be appropriately designed (smooth surfaces) to enable appropriate cleaning, disinfection and minimize the risks of contamination.

3.4 Temperature and humidity controls and records should be in place for microbiological laboratories.

3.5 In general, laboratory equipment should not be routinely moved between areas of different cleanliness class or used outside the microbiology area, unless there are specific precautions in place to prevent cross-contamination.

4- Cleaning, disinfection and hygiene

4.1 There should be a documented cleaning and disinfection program**.**

4.2 Adequate hand-washing and hand-disinfection facilities should be available**.**

4.3 Swing doors should open to the high-pressure side and be provided with self-closers.

4.4 False ceilings should be sealed to prevent contamination from the void space above them.

4.5 Airlock doors should not be opened simultaneously. An interlocking system and a visual and/or audible warning system should be operated to prevent the opening of more than one door at a time.

4.6 Adjacent rooms of different grades, if present, should have a pressure differential of approximately10-15 Pascal (guidance value). Particular attention should be paid to the protection of the zone of greatest risk, i.e. the immediate environment to which the product and the cleaned components in contact with it are exposed.

4.7 If the lab contains classified areas; indicators of pressure differentials should be fitted between areas where this difference is important, and the pressure differentials should be regularly recorded and failure alarmed.

5-Test methods

5.1 The laboratory should use all test methods necessary to confirm that the product complies with acceptance criteria.

5.2 Standard (European Standards Publications of Cosmetics) test methods are considered to be validated.

5.3 Test methods not based on compendial or other recognized references should be validated before use.

6-Equipement

6.1 Each item of equipment, instrument or other device used for testing, verification and calibration should be uniquely identified.

6.2 The microbiological lab. Should be of the following qualified minimum instrument requirements:

- One Autoclave (SOP of 2 activities time separation is required)

- Two Laminar air flow units in controlled room (with air locked duple doors)

-Fridge

- three incubators

-Microscope

- Balance

6.3 Qualification

Equipment, instruments and other devices should be designed, constructed, adapted, located, calibrated, qualified, verified and maintained as required by the operations to be carried out in the local environment.

6.4 Incubators, water-baths and ovens

The operating temperature of this type of equipment should be monitored and records retained.

6.5 Autoclaves

Autoclaves should be capable of meeting specified time and temperature tolerances; monitoring pressure alone is not acceptable.

The effectiveness of autoclave operation may be checked by the use of chemical or biological indicators for sterilization or decontamination purposes.

- Clear operating instructions should be provided based on the heating profiles determined for typical uses during validation/revalidation.
- Records of autoclave operations, including temperature and time, maintained for every cycle.
- Monitoring of autoclave may be achieved by one of the following:
- using a thermocouple and recorder to produce a chart or printout.
- direct observation and recording of maximum temperature achieved and time at that temperature.

6.6 Weights and balances

Weights and balances shall be calibrated traceably at regular intervals (according to their intended use) using appropriate standard weights **traceable** to certified standard weights.

6.7 Volumetric equipment

- For “single-use” disposable volumetric equipment, laboratories should obtain supplies from companies with a recognized and relevant quality system.
- If the supplier does not have a recognized quality system, laboratories should check each batch of equipment for suitability.

7- Reagents, solutions, reference standards, culture media

7.1 Reagents, solutions, reference standards, culture media, etc. should be

identified by the following information: a) the name; b) its strength or concentration, when appropriate; c) expiration date, when appropriate; d) the name and/or signature of the person who prepared it, when appropriate; e) opening date; f) storage conditions, when appropriate.

7.2.1 **Media**

- Media should be prepared in accordance with any manufacturer's instructions, taking into careful account specifications such as time and temperature for sterilization.
- Growth promotion and, if appropriate, other suitable performance tests should be done on all media on every batch and on every shipment.

7.2.2 Microwave devices should not be used for the melting of media due to the inconsistent distribution of the heating process.

7.2.3 Batches of media should be identifiable and listed, their conformance with quality specifications documented (e.g. growth promotion and inhibitory properties.

The suitable performance of culture media, diluents and other suspension fluids should be checked, with regard to:

—Recovery of 50–200% (after inoculation of not more than 100 colony-forming units (CFU) should be demonstrated;

— inhibition or suppression of non-target organisms;

— Other appropriate properties (e.g. pH, volume and sterility).).

7.2.4 Media should be stored under appropriate conditions recommended by the manufacturer, e.g. cool, dry and dark.

7.2.5 Water of a suitable microbiological quality and which is free from bactericidal, inhibitory or interfering substances, should be used for preparation unless the test method specifies otherwise**.**

8 -Reference cultures

8.1 Reference cultures are required for establishing acceptable performance of media (including test kits), for validating methods and for assessing/evaluating ongoing performance.

To demonstrate traceability, laboratories must use reference strains of microorganisms obtained **directly** from recognized national or international collections

8.2 Reference strains may be sub-cultured once to provide reference stocks.

It is recommended to store reference stocks in aliquots either deep-frozen or lyophilized. If reference stocks have been thawed, they must not be refrozen and reused.

8.3 Working stocks should not normally be sub-cultured, usually not more

than **five passages** from the original reference strain.

9-Sampling and sample handling

9.1
- Sampling should only be performed by trained personnel (documented training).
- It should be carried out aseptically using sterile equipment, appropriate precautions should be taken to ensure that sample integrity is maintained through the use of sterile sealed containers for the collection of samples where appropriate.

9.2
- The laboratory should have procedures that cover the delivery of samples and sample identification.

9.3
- Samples should be identified by: a) the name or identifying code; b) the batch number; c) the date of sampling; d) the container from which the sample was taken; e) the sampling point, if applicable.

9.4 Samples should be stored (retained) until the test results are obtained, or longer if required

10-Disposal of contaminated waste material

10.1
- The procedures for the disposal of contaminated materials should be designed to minimize the possibility of contaminating the test environment or materials.
- It is a matter of good laboratory management and should conform

to national/international environmental or health and safety regulations.

11-Testing procedures

11.1 Testing should normally be performed according to procedures described in the national, regional and international standard methods and reported in SOPs for documentation.

11.2 Alternative testing procedures may be used if they are appropriately validated and equivalence to official methods has been demonstrated.

12-Test reports

12.1 If the result of the enumeration is negative, it should be reported as “not detected for a defined unit” or “less than the detection limit for a defined unit”. The result should not be given as “zero for a defined unit” unless it is a regulatory requirement.

12.2 Qualitative test results should be reported as “detected/not detected in a defined quantity or volume”.

Annex **3: Documents required to be delivered in paper**

3Annex

Documents required to be delivered in paper

- **Original receipt for payment for the service for both (application for obtaining an accreditation certificate, application for accreditation for tests for the main groups of cosmetics provided)**
- **The original delegation letter mentioned in the application form.**
- **The original application form signed by the authorized person.**
- **An undertaking from the laboratory that it will provide all instruments, reference materials, and chemicals necessary to conduct all tests required for approval.**
- **In the event that some tests are analyzed in a laboratory at a government agency, a stamped and signed pledge must be submitted from the laboratory submitting the request.**