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Foreword

The purpose of this document is not for certifying against but instead as a compliment to NSF/ANSI 455-3 Good Manufacturing Practices for Cosmetics. The information in this guidance is not all inclusive; however, it reflects the most current approach to achieving compliance with the standard requirements.

This edition of the ARG contains the updates made to NSF/ANSI 455-3-2021.

Suggestions for improvement of this guidance are welcome. This guidance is maintained on a continuous maintenance schedule and can be opened for comment at any time. Comments should be sent to Chair, Joint Committee on GMP for Cosmetics at standards@nsf.org, or c/o NSF International, Standards Department, PO Box 130140, Ann Arbor, Michigan 48113-0140, USA.
Audit Requirements Guideline
for NSF/ANSI 455-3 – 2021:

Good Manufacturing Practices for Cosmetics

1 General

1.1 Purpose

This Audit Requirements Guidance (ARG) document is intended to compliment NSF/ANSI 455-3: Good Manufacturing Practices for Cosmetics. It will assist auditors and manufacturers to understand and interpret the requirements of NSF/ANSI 455-3 in order to prepare, evaluate, and achieve compliance. The information in this guidance is not all inclusive however reflects the most current approach to achieving compliance with the standard requirements. Readers of this document should reference ISO 22716 as well as the complete NSF/ANSI 455-3 standard to ensure that they have complied, in full, with all relevant sections. Interpretations are denoted in italics.

2 Normative references

See NSF/ANSI 455-3 Good Manufacturing Practices for Cosmetics.

3 Definitions


4 Audit requirements

4.1 Context of the organization

4.1.1 Manufacturers, packers, and distributors of cosmetic products that are in commercial distribution shall be registered with the regulatory agency in the country of manufacture or sale, if required by the relevant jurisdiction(s).

4.1.2 The organizational structure is defined so that the organization and functions of the staff are understandable and logical. [ISO 22716:2007 3.2.1.1]

4.1.2.1 Relevant to entire organization.

4.1.2.2 Check for an organization chart with clear reporting relationships and functional structure.

4.1.3 The organization chart shows the independence of the quality unit, including quality assurance (QA) and quality control (QC) activities, from other areas of the plant. [ISO 22716:2007 3.2.1.3]

4.1.3.1 A clear organization chart shall be available that is current and up to date.
4.1.3.2 Organizational structure should show appropriate separation between the Quality Unit and production. The Quality Manager shall not report directly to the Production Manager to ensure that quality decisions can be made independent of production decisions. Consideration may be given for very small plants where individuals have multiple organizational responsibilities.

4.1.3.3 The key point to look for throughout the audit regarding this audit criteria is met whenever there is a conflict or difference of opinion between quality and production, the quality management decision should not be able to be overruled by management or production.

4.1.4 Hygienic practices have been established to include appropriate garments, personal hygiene, hand washing and sanitization, etc. prior to starting work and at any time personnel can become soiled / contaminated. [ISO 22716:2007 3.5.1.1 & 3.5.1.2]

4.1.4.1 A written dress code shall exist and be current stating appropriate protective attire for workers, supervisors, managers, visitors, and contractors to all parts of the production, storage, packaging, and testing facilities.

4.1.4.2 Outer garments shall be donned prior to entering the facility and shall not be worn outside the production facility. Therefore, proper changing areas are required. Outer garments shall have long sleeves and have secured fasteners. Above waist pockets (or carrying items in pockets) should be avoided.

4.1.4.3 Gowning areas shall be located at the entrance to required production areas and should be designed to prevent entrance or exit without gown changing.

4.1.4.4 Outer garments shall not be worn into restroom and appropriate hooks should be provided.

4.1.4.5 A written procedure shall exist and be current describing hand washing requirements including methods and frequencies. The procedure shall also cover glove use and hand sanitizers if used.

4.1.5 Procedures have been established for use of impermeable gloves, hairnets, caps, beard covers, etc. in areas where product contamination could occur. Procedures have been established to prevent contamination from extraneous sources and unhygienic practices. [ISO 22716:2007 3.5.1.3]

4.1.5.1 A written procedure shall exist and be current describing the use of personal protective equipment such as hairnets, goggles, gloves, and beard covers in areas where product is exposed.

4.1.5.2 A written procedure shall exist and be current describing wearing of jewelry and cosmetic makeup. Jewelry, if allowed, must be secured to prevent product adulteration.

4.1.6 Procedures have been established to prevent eating, drinking, chewing, smoking or the storage of food, drink, or smoking materials or personal medication in the production, control, and storage areas. [ISO 22716:2007 3.5.1.4]

4.1.6.1 A written procedure shall exist and be current excluding the use of tobacco products, consumption of food, gum, drink or medicine from production areas.

4.1.6.2 A written procedure shall exist and be current describing what types of items cannot be taken into production areas including personal effects or clothing. The procedure should cover the prevention of personal care products from entering production.

4.1.6.3 Areas where eating, drinking, or smoking are allowed are clearly identified and controlled.

4.1.7 Procedures have been established to ensure medical conditions, open lesions, or infected wounds are reported to a supervisor and ensure that personnel do not pose a threat of contamination in

4.1.7.1 A written procedure shall exist and be current stating that personnel with medical conditions such as open lesions or infected wounds will be removed from the manufacturing process to prevent product adulteration during manufacturing or storage. The procedure shall state that such health conditions will be reported to supervision.

4.1.7.2 Inspection verifies that such workers are not in areas where adulteration could occur.

4.1.7.3 Personnel shall be trained on the written procedure and knowledgeable of the disease control policies.

4.2 Leadership

4.2.1 Management supports the organization through an established quality policy, provision of adequate resources (human, financial, materials, facilities, and equipment) and communicates achievements. [ISO 22716:2007 3.3.1.1]

4.2.1.1 There is published quality policy statement.

4.2.1.2 There is management review of quality key performance indicators.

4.2.1.3 Resources are provided for training, facilities, and equipment for cosmetic GMP.

4.2.1.4 Management communicates and shares achievements of key performance indicators and successes.

4.2.2 Access to areas by authorized personnel is defined, communicated, and controlled. [ISO 22716:2007 3.3.1.3]

4.2.3 A visitor policy is implemented to control access to secure areas, and visitors are provided information to assure safety and personal hygiene. [ISO 22716:2007 3.6]

4.3 Planning

4.3.1 Current finished product samples as well as retained product samples are tested for adequacy of preservation against microbial contamination under reasonable conditions of storage and use. [US FDA Cosmetic GMP guidance]

4.3.1.1 Cosmetic products are tested to assure adequacy of preservation using appropriate test methods such as a Preservative Effectiveness Test (PET).

4.3.1.2 Challenge test methods include BAM Chapter 23 <www.fda.gov/Food/FoodScienceResearch/LaboratoryMethods/ucm073598>.

4.3.1.3 Methods for challenge testing of wipes, atypical, and water-miscible products can be found in the CTFA Microbiology.

4.3.2 Changes that could affect the quality of product are approved and performed by authorized personnel and supported by data. [ISO 22716:2007 15]

4.3.2.1 The change control process defines the roles and responsibilities of those involved in change management, and assigns responsibility for authorization and approval.
4.3.2.2 The change control process should evaluate which departments / functions are affected, and thus who (in addition to Quality) needs to review and approve the change.

4.3.2.3 The effectiveness of the change is monitored through metrics and data.

4.3.3 A procedure has been established to manage any change associated with the production of a cosmetic product, such as changes to specifications, formulations, raw material suppliers, equipment, process, physical plant, etc. The procedure shall describe how to document and effectively communicate changes to applicable parties in order to secure the necessary approvals prior to implementation of the change. [ISO 22716:2007 15]

4.3.3.1 There is a procedure for change control that evaluates the impact of changes to materials, equipment, process, and procedures.

4.3.3.2 The evaluation assesses the impact of the change on the quality of the product, and the risk of contamination or adulteration.

4.3.3.3 The change control process should evaluate which other documents and/or processes are affected, e.g., SOP’s, specifications, training, etc. (as well as any relevant validations).

4.3.3.4 Records of change control show appropriate follow-up for all affected departments, functions, documents, and processes.

4.3.3.5 The change management process incorporates operations with contractors.

4.4 Support

4.4.1 A master site plan or facility diagram / floor plan shall be on file reflecting the current layout of the building.

4.4.2 Staffing levels are adequate for the scope, diversity, and type of production. [ISO 22716:2007 3.2.1.2]

4.4.2.1 Staffing is provided for support areas (quality, maintenance, administration) as well as production areas.

4.4.2.2 The number of employees is adequate to conduct the business.

4.4.2.3 Where the operation operates more than one shift, all shifts are adequately staffed.

4.4.2.4 Staffing is adequate for the number and types of products, technologies, or processes.

4.4.3 Premises are located, designed, constructed and utilized to ensure protection of the product, permit efficient cleaning, sanitizing and maintenance, and to minimize the risk of mix-up of products, raw materials, and packaging materials. [ISO 22716:2007 4.1.1]

4.4.3.1 The physical plant is designed and built to prevent contamination of the equipment and materials for the range of products.

4.4.3.2 Adequate area is provided around equipment to permit cleaning and sanitization processes.

4.4.3.3 Adequate space is provided for the storage and inventory of materials and products. Areas are labeled as to use.

4.4.3.4 Product stored in warehouse facilities shall be enclosed in suitable racking.
4.4.3.5 Elevated platforms or catwalks shall be cleanable and designed to prevent contamination into processes located below the platforms.

4.4.3.6 The maintenance shop area shall be kept in a clean and orderly manner. The shop should be physically separated from production areas so contamination cannot occur.

4.4.3.7 Temperature and humidity controlled areas shall be qualified and monitored, including storage areas.

4.4.3.8 No product shall be stored on the floor for prolonged periods. All materials (packaging materials, raw materials, finished products, etc.) shall be stored at least 6 inches off the floor (at least at pallet height). All racking should be at a minimum 12 inches from perimeter and interior walls to facilitate cleaning.

4.4.3.9 Roads, docks, parking lots, and yards shall be clean, be in good repair, and minimize dust.

4.4.3.10 Standing water shall not be evident around plant’s perimeter.

4.4.4 The following areas have been clearly defined or separated: receiving, storage, QC, hand washing stations, and restrooms. [ISO 22716:2007 4.2]

4.4.4.1 Functional areas are physically separated or arranged to provide adequate space for the operation.

4.4.4.2 Functional areas are so designated, either through physical means or electronic means.

4.4.4.3 During the inspection, assure adequate control between areas that have restrictions and unrestricted areas.

4.4.4.4 Doors and gates that are used to separate productions areas shall be kept closed.

4.4.5 Facilities are of adequate size, construction, and design for their intended use such as receipt, storage, and production. [ISO 22716:2007 4.3]

4.4.5.1 The physical plant is designed and built to provide adequate space for the equipment and operations for production of the range of products.

4.4.5.2 A current facility diagram/floor plan or process flow diagram should be available. Review the diagram during the inspection.

4.4.5.3 Plant design in areas where product is routinely open, shall have cleanable surfaces. Painted and/or wood surfaces should not be used in areas of product or equipment contact.

4.4.5.4 Ledges in product contact areas shall be minimized to prevent dust accumulation.

4.4.5.5 Gowning areas shall be located at the entrance to required production areas and should be designed to prevent entrance or exit without gown changing.

4.4.6 There is adequate space for performing all operations and to prevent mix-ups, contaminations, and cross-contaminations during manufacturing, packaging, labeling, or holding. Flow of materials, products, and personnel is defined to prevent mix-ups. [ISO 22716:2007 4.4]

4.4.6.1 The production and packaging areas are organized and clean.

4.4.6.2 Staging areas are provided in compounding and blending areas for materials.
4.4.6.3 Proper storage areas for transfer hoses and small equipment are provided. Hoses are stored off the floor.

4.4.6.4 Raw materials are stored off the floor on pallets or racks.

4.4.6.5 Unused materials are stored in closed containers and returned to inventory.

4.4.6.6 Materials from prior product runs are removed from the packaging and labeling area.

4.4.6.7 Procedures and controls must be in place to ensure no cross-contamination occurs between cosmetic products and any other products that are produced or handled at the same facility.

4.4.7 Walls, floors, ceilings, and windows can be adequately cleaned and are kept in good repair. [ISO 22716:2007 4.5]

4.4.7.1 All rooms where product contact occurs shall have walls, ceilings, floors, and work surfaces that can be cleaned and sanitized. Seams should be minimized in wall and ceiling coverings.

4.4.7.2 Floor to wall joints shall be sealed with concave or cove baseboards or bumpers.

4.4.7.3 Ceilings are constructed of smooth, nonporous, nonabsorbent, cleanable material. Acoustic tile ceilings are not to be used in product contact rooms, the panels shall be FRP or HDPE grade or equivalent material. Grid system ceilings shall be on a cleaning schedule.

4.4.7.4 Floors in product contact areas shall be sealed and not have exposed aggregate, cracks, peeling coating, or broken areas. Floors shall be impervious and kept clean and dry.

4.4.7.5 Ceiling and wall penetrations shall be sealed.

4.4.7.6 Interior wall and ceiling surfaces are free from signs of moisture, damage, insects / pests, mold / mildew, etc.

4.4.8 Hand washing facilities are constructed and located in appropriate areas to ensure proper hand washing of personnel. [ISO 22716:2007 4.6]

4.4.8.1 Hand washing facilities furnished with tempered water shall be located where employees are required to wash hands.

4.4.8.2 Hand washing facilities should have hands-free faucets. Hands free can be foot operated, sensor operated or have long handles that can be controlled with the arm or wrist.

4.4.8.3 Air dryers or single use sanitary towels shall be provided.

4.4.8.4 Liquid or single use soap shall be provided.

4.4.8.5 Signs shall be posted instructing employees to wash hands before returning to work.

4.4.8.6 Bathroom shall be available to all workers, well lit, functional, and stocked.

4.4.8.7 Bathrooms must have signs directing employees to wash hands before returning to work.

4.4.8.8 Bathroom doors shall be self-closing and not open into operation areas where product is exposed.

4.4.8.9 Bathrooms shall vent mechanically to the outside.
4.4.9  Bathrooms and wash facilities are kept clean and are not a potential source of contamination to components, products, contact surfaces, etc. [ISO 22716:2007 4.6]

4.4.9.1  Routine documented cleaning of bathrooms and hand wash facilities takes place.

4.4.9.2  Hand washing facilities are not used to clean utensils or equipment.

4.4.9.3  Change rooms, if needed, should be orderly and clean. Procedures cover cleaning of change rooms.

4.4.10  Adequate lighting is provided in all production areas, examination areas, where equipment is cleaned and examined, etc. [ISO 22716:2007 4.7.1]

4.4.10.1  The number and intensity of light sources provides sufficient illumination for the activities conducted.

4.4.10.2  Areas where visual examination of labels, products, and samples are critical.

4.4.10.3  Lighting must be provided for confirmation of cleaning processes inside of vessels and tanks.

4.4.11  Lighting that is suspended or located above areas where materials or equipment are exposed is of adequate construction or lighting type to prevent contamination and enable ease of cleaning. [ISO 22716:2007 4.7.2]

4.4.11.1  All lighting in areas with exposed product shall be shatter proof. Shatterproof includes plastic bulbs or glass bulbs fitted with plastic shields (use of safe-lights, fixtures, etc.).

4.4.11.2  Light fixtures/fittings should be designed and installed to avoid buildup of dust / product.

4.4.12  Adequate ventilation and airflow, including appropriate filtration and bacteriological controls, are provided in all areas of the facility. [ISO 22716:2007 4.8]

4.4.12.1  Heating and ventilation systems shall be provided to maintain sanitary conditions and prevent cross-contamination. Condensation on walls or ceilings shall be prevented.

4.4.12.2  A PM program is in place for all HVAC units. HVAC systems shall be qualified to conform as fit for purpose.

4.4.12.3  HVAC systems are designed and installed to prevent cross-contamination or adulteration of product.

4.4.12.4  Vents, fans and gratings in product contact areas are on a cleaning schedule.

4.4.12.5  Excessive dust buildup from powdered materials or products should be minimized by dust collection.

4.4.12.6  Documented systems exist to ensure dust collection fines and or vacuum fines shall not be recycled into finished goods.

4.4.12.7  Dust collection systems shall be part of cleaning schedule. Dust hoods or hoses directly above or adjacent to product shall be maintained clean at all times and not provide a source of cross contamination.

4.4.12.8  Windows used for ventilation open outward and are properly screened.
4.4.13  Plumbing is of adequate size and design for intended usage. Pipework, drains, and ducts shall be installed so that drip or condensation does not contaminate products. [ISO 22716:2007 4.9]

4.4.13.1  Piping and plumbing materials are to be compatible with the materials it contains.

4.4.13.2  Ancillary piping should be labeled as to contents to prevent wrong connections.

4.4.13.3  Water piping shall be of appropriate materials of construction and so configured that it does not become a source of contamination (elimination of dead-end piping and proper drainage).

4.4.13.4  Piping and plumbing throughout the facility shall not be leaking or damaged.

4.4.13.5  Drip legs should be piped into floor drains (allowing for siphon breaks). Drip legs shall not drip onto the floor.

4.4.13.6  Standing water shall not be evident within the manufacturing facility.

4.4.13.7  Piping, joists, and bracing shall be free of dust and contaminants.

4.4.14  Floor drainage is adequate (immediate and continuous drainage, no pooling, proper drain covers, etc.). [ISO 22716:2007 4.9.1]

4.4.14.1  Areas requiring wet cleaning should have adequate floor drains.

4.4.14.2  Drains are covered with grating and be free of debris.

4.4.14.3  Drains are part of cleaning procedures and be odor free.

4.4.14.4  Drains shall drain properly and not back up or contain standing water.

4.4.14.5  Drains are not permitted in defined sterile processing rooms.

4.4.15  Backflow and cross-connection prevention is in place. [ISO 22716:2007 4.9.2]

4.4.15.1  Plumbing should be appropriately trapped to prevent back flow.

4.4.15.2  The city water or water supply to the plant shall have a backflow prevention device at the plant’s connection point.

4.4.15.3  An annual PM (Preventative Maintenance) is required for checking the backflow system.

4.4.15.4  Hose drops or points of use where product siphoning could occur shall have backflow prevention.

4.4.16  In areas where open vessels are used, there is adequate protection against contamination, e.g., use of protective coverings, physical location, use of skimming equipment, use of screening, etc. [ISO 22716:2007 5.2.2]

4.4.16.1  Tanks and hoppers are equipped with lids or covers of appropriate construction materials. Tanks and hoppers shall be covered when not actively being filled.

4.4.16.2  If open vessels must be used, an alternate form of product protection must be defined, and used.

4.4.17  Premises are maintained in a clean and sanitary condition. [ISO 22716:2007 4.10]
4.4.17.1 The production facility and premises are visible clean.

4.4.17.2 There are waste receptacles located throughout the facility; these are routinely emptied.

4.4.17.3 There is an absence of trash, filth, and debris on floors, windows, ceilings, walkways, piping, storage racks, and equipment.

4.4.18 Procedures shall be established and implemented for cleaning of the plant areas, facilities, and equipment. [ISO 22716:2007 4.10.4 & 5.3.1]

4.4.18.1 Cleaning procedures should cover plant areas such as offices, production areas, storage areas, laboratories, warehouses, toilets, changing areas, maintenance areas, and grounds.

4.4.18.2 Cleaning and sanitization procedures, including verification and documentation thereof, should cover utensils and equipment.

4.4.18.3 The procedures shall describe the cleaning methods, solutions, and frequency of cleaning.

4.4.18.4 The sanitation program should be designed to prevent cross contamination due to product / formula changes, sensitivities / allergies, colorants, and micro contamination.

4.4.18.5 Cleaning logs or reports documenting compliance to the procedure should be maintained.

4.4.18.6 Periodic internal audits / checks of sanitary practices shall be conducted at a minimum on a monthly basis.

4.4.19 Cleaning and sanitizing compounds have been established for cleaning the facility. These agents are safe and effective under the conditions of use. [ISO 22716:2007 4.10.3]

4.4.19.1 A written procedure outlines the purchasing policy for cleaning and sanitizing chemicals, lists approved chemicals, and describe chemical usage guidelines (including concentrations and areas where chemicals can be used).

4.4.19.2 Cleaning compounds are compatible with the materials of construction and the products produced.

4.4.20 Cleaning and sanitizing agents, pesticide chemicals, and fungicides have been identified, used, held and stored in a manner that protects against adulteration of raw materials and in-process or finished products, and against contamination of processing equipment, utensils, and packaging materials. [ISO 22716:2007 4.10.2 & 5.5.2]

4.4.20.1 All chemicals shall be stored in labeled containers and used for their intended purpose only.

4.4.20.2 All chemicals shall be stored away from product and equipment to prevent contamination through spills. All spills should be cleaned up immediately.

4.4.20.3 All chemicals shall be stored with like substances. Cosmetic materials should not be stored with nonfood grade chemicals.

4.4.21 Premises are maintained in a good state of repair. [ISO 22716:2007 4.11]

4.4.21.1 Facilities used for the production of cosmetic products are maintained in a good state of repair. The building, floors, windows, washrooms, and laboratories are visually in good condition.

4.4.21.2 Walls do not exhibit holes or peeling paint or coatings.
4.4.21.3 Floors are free from cracks or missing components.
4.4.21.4 Foundations and exterior surfaces are sound and free from cracks or structural defects.
4.4.21.5 Repairs to premises are made in a timely manner.

4.4.22 Controls have been established to prevent entrance to the facility by pests and animals, including screens and barriers, rodent traps, insect traps or lights, etc. [ISO 22716:2007 4.13.1]

4.4.22.1 Exterior openings (windows, ventilation, etc.) are screened or sealed to protect against pests. Windows in production areas should be non-opening.
4.4.22.2 Exterior doors are kept closed when not in use. Exterior doors are self-closing.
4.4.22.3 Exterior doorways shall have traps.
4.4.22.4 Insect traps or lights should be installed adjacent to large openings (overhead doors).

4.4.23 Pest control procedures are established. Controls scheduled and planned for the appropriate use of any insecticides, fungicides, fumigants, rodenticides, etc. [ISO 22716:2007 4.13.2]

4.4.23.1 It is required that a licensed pest control agent provides pest control. The up-to-date license, contract and insurance shall be on file. If internal personnel are used to perform any of the pest control activities, appropriate training shall be provided and documented.
4.4.23.2 The licensed agent is expected to provide aggressive support to plant pest control, housekeeping, sanitation, and maintenance programs as they relate to potential pest harborage or conditions susceptible to pest infestations.
4.4.23.3 Any conditions noted by the pest agent, shall have documented corrective action implementation. Company personnel shall review the reports.
4.4.23.4 Any pesticides used shall be registered with, and used in accordance with, the U.S. Federal Insecticide, Fungicide and Rodenticide Act.
4.4.23.5 MSDS’s for all applied chemicals shall be kept.
4.4.23.6 The pest control agency should provide the rationale used in developing the placement of traps and the logic used in creating the pest control program.
4.4.23.7 The pest control system shall include, at a minimum, bait traps (only located outside of buildings), interior pest traps (glue boards or other nonchemical means) and insect lights. Other methods can be used. A map of the lights and traps shall be kept up to date.
4.4.23.8 Exterior doorways shall have traps.
4.4.23.9 All traps shall be marked or fixed to a location to prevent movement.
4.4.23.10 Pest traps and lights shall be monitored for activity. The activity shall be reported in a written document including where the activity occurred, what type of activity occurred and any corrective actions taken. If activity warrants, frequency may be increased. Traps shall be checked at least monthly. High activity may warrant more frequent checks.
4.4.23.11 Use of chemical sprays is undesirable inside production facilities. If chemical means are needed because of pest infestations, then procedures shall exist outlining that production shall cease and all product be stored in a means to prevent adulteration. Production records shall reflect adherence
to this policy during chemical applications. Logs of applied chemicals shall be kept.

4.4.24 Grounds have been properly maintained to prevent attracting or harboring pests (e.g., through removal of litter and waste, cutting of grass and weeds adjacent to the plant, providing adequate drainage, etc.) [ISO 22716:2007 4.13.3]

4.4.24.1 No harborage areas exist and facility is tidy and orderly.

4.4.24.2 No areas of clutter shall exist around the plant’s perimeter that could be pest harborage areas.

4.4.24.3 Vegetation around the outside perimeter of the facility shall be kept to a minimum. Individual situations shall be evaluated based on pest control system.

4.4.24.4 Standing water shall not be evident around the perimeter of the plant.

4.4.25 Laboratory and production measuring instruments shall be accurate and precise, calibrated where necessary, and maintained. There is a calibration and preventive maintenance (PM) program. [ISO 22716:2007 5.4]

4.4.25.1 Instruments (laboratory and production operations) shall be part of a calibration and/or PM program. Ancillary gauges, instruments, etc. are appropriately installed for function and calibrated where identified as having a product quality impact.

4.4.25.2 Calibration records shall include:

- identity of instrument or control;
- date calibration is performed;
- identity and certification of compliance of any reference standard;
- calibration procedure that was used including the calibration limits or specifications;
- calibration readings or readings found;
- recalibration method and readings found (if required); and
- initials of the person performing the calibration.

4.4.25.3 Calibration of operational equipment, measuring and metering devices such as thermometers, scales, flow meters, timers, speed controls, HPLC, GC, AA, metal detectors, etc. shall be properly completed on a justified regular basis to assure their accuracy. Equipment shall be calibrated on a frequency that is justified by data, taking into account the type of equipment in question and the required accuracy and precision.

4.4.25.4 Scales and balances shall be calibrated by a certified individual at least annually.

4.4.25.5 Scales and balances shall be evaluated at appropriate weights prior to use. These checks (recording the observed weights) shall be documented.

4.4.25.6 Test weights shall be calibrated by a certified contractor at least annually, or whenever the weights are dropped or damaged. Records shall be available. Test weights shall be stored properly off the floor. They should be stored in cabinets or shelves where they are protected against water or potential damage.

4.4.25.7 Checks of intermediate thermometers against NIST-traceable standards (primary standard) shall be performed at a frequency commensurate with the use of the intermediate thermometer (secondary standard), on a justified regular basis. Full documentation of the calibration of the intermediate thermometers shall be available.
4.4.26 Measuring instruments with out-of-calibration results are removed from service; the condition is investigated to determine if there is any impact to product quality with appropriate corrective action. [ISO 22716:2007 5.4.2, 5.4.3]

4.4.26.1 When calibration shows an instrument to be out of calibration, the instrument is to be repaired or removed from service.

4.4.26.2 Measurements or test results from the instrument are to be reviewed from the point in time the instrument was last found in calibration.

4.4.26.3 If investigation determines a negative impact to product quality due to the calibration issue, corrective action is to be taken with the product or material (e.g., rework, recall).

4.4.27 An adequate number of trained personnel are provided to meet the activities of ISO 22716. [ISO 22716:2007 3.2.2]

4.4.27.1 Employees are trained in cosmetic Good Manufacturing Practices (GMP) requirements; the training is documented.

4.4.27.2 The number of employees is sufficient to conduct cosmetic GMP requirements.

4.4.27.3 Where specialized skills or knowledge is required, staff is provided to cover all contingencies (e.g., illness, absenteeism, vacations).

4.4.28 Personnel understand their role in the organizational structure, know their defined responsibilities and activities, have access to and comply with documents relevant to their responsibilities, and comply with hygiene requirements. [ISO 22716:2007 3.3.2]

4.4.28.1 Personnel shall have written job descriptions, which include job requirements and reporting structure. Job descriptions should follow good documentation practices including revision control and appropriate sign offs.

4.4.28.2 Employees have been trained in their roles and understand their responsibilities. Look for employee knowledge of their job descriptions.

4.4.28.3 Employees are provided relevant documentation such as policies and procedures.

4.4.28.4 Employees demonstrate knowledge of hygiene requirements such as personal protective equipment, appropriate dress such as hairnets, gloves, uniforms, and personal cleanliness.

4.4.29 Personnel, both permanent and temporary, shall be qualified and have adequate training, experience, or education, or both, necessary to perform job functions. [ISO 22716:2007 3.4.1]

4.4.29.1 Personnel have education, training, and experience, or a combination thereof, to perform their job responsibilities, and such qualifications are documented.

4.4.29.2 Individual qualification may be documented through a Curriculum Vitae (CV).

4.4.29.3 There is a training and qualification program for job skills and GMP.

4.4.29.4 The training program assesses and identifies the training needs of all personnel.

4.4.29.5 The training program should include training topics and frequencies as well as forms or electronic records for documenting training.

4.4.29.6 Training and procedures shall be available in appropriate languages.
4.4.29.7 Training documentation shall include a roster of who attended, date of training, subject matter taught, and the name of the trainer.

4.4.29.8 Qualifications of the trainer to conduct are documented (e.g., in their CV).

4.4.29.9 Training is a continual process.

4.4.30 Personnel are trained in GMP defined in ISO 22716. [ISO 22716:2007 3.4.2]

4.4.30.1 All personnel including management shall receive at minimum annual GMP training and education to perform their assigned functions.

4.4.30.2 Training comprehension for GMP training is required. Comprehension can be shown in a number of ways, e.g., written test, by routine questioning of employees, to determine understanding of GMPs as they relate to their job function, etc.

4.4.30.3 Temporary workers shall receive documented basic GMP training prior to beginning work and/or entering production areas.

4.4.30.4 Contractors shall receive GMP training appropriate to the work they are performing prior to entering production areas.

4.4.30.5 Training documentation shall include a roster of who attended, date of training, subject matter taught, and the name of the trainer.

4.4.31 Newly hired personnel are trained in the duties assigned to them and the theory and practice of GMP. [ISO 22716:2007 3.4.3]

4.4.31.1 A written procedure shall exist and be current outlining the training policy and program for new hires. The procedure shall include how training for cosmetic GMP is conducted for new hires.

4.4.31.2 The new hire training is to be completed prior to the employee engaging in activities covered by cosmetic GMPs.

4.4.31.3 Training comprehension for cosmetic GMP training is required. Comprehension can be shown in a number of ways, e.g., written test, by routine questioning of employees, to determine understanding of GMPs as they relate to their job function, etc.

4.4.31.4 Training documentation shall include a roster of who attended, date of training, subject matter taught, and the name of the trainer.

4.4.32 Personnel are evaluated during and after training. [ISO 22716:2007 3.4.4]

4.4.32.1 The effectiveness of the training shall be assessed and documented.

4.4.32.2 Competency in job skills and knowledge is assessed through an on-going evaluation and review process.

4.4.32.3 Training comprehension training is required. Comprehension can be shown in a number of ways, e.g., written test, by routine questioning of employees, to determine understanding of GMPs as they relate to their job function, etc.

4.4.32.4 There is a process to re-train employees who demonstrate deficiencies in performance. Alternatively, there is a process to disqualify underperforming employees to prevent them from engaging in cosmetic GMP activities.
4.4.33 A system has been established and maintained for creation, control, editing, and archiving documents such as procedures, instructions, specifications, protocols, reports, methods, and records appropriate to cosmetic GMP. [ISO 22716:2007 17.1]

4.4.33.1 A document control process is developed and implemented. The process may be manual or electronic.

4.4.33.2 The document control procedure should describe the format, content sections, and approval procedure of controlled documents.

4.4.33.3 The process includes initial generation of controlled documents, revision procedure, distribution / access, and archiving / retention schedules.

4.4.33.4 A master list of documents should be maintained.

4.4.33.5 The document control system applies to the following types of documents:

- standard operating procedures;
- standard sanitation operating procedures;
- manufacturing instructions / master batch records;
- specifications for chemical raw materials, packaging materials, in-process product, and finished product;
- protocols such as validation processes, supplier qualification processes, material qualification processes, and audits;
- test methods; and
- reports, records, and forms relevant to cosmetic GMP.

4.4.33.6 The quality management program for quality should be consolidated into a quality manual. The recommended format follows ISO9001 requirements. ISO9001 requires a quality manual that includes the scope of the quality management system, documented procedures established for the quality management system, and a description of the interaction between the processes of the quality management system.

4.4.33.7 Documents should be reviewed for adequacy on a scheduled basis and revised if necessary.

4.4.33.8 The current revision status of documents must be available to avoid use of invalid or obsolete documents.

4.4.33.9 Obsolete documents maintained for historical purposes must be clearly identified.

4.4.33.10 The need for training should be considered when documents are changed.

4.4.34 Documents describe in appropriate detail operations that shall be carried out, precautions that shall be taken, and measures that shall be applied. Documents are written in a legible and comprehensive way, approved, signed and dated by authorized persons, accessible to appropriate personnel, and removed and destroyed when out-of-date. [ISO 22716:2007 17.3.1]

4.4.34.1 Documents are written in sufficient detail and clarity so they can be used as stand-alone documents.
4.4.34.2 The operational steps are fully detailed. Safety precautions or operational notes are included to provide further information or clarity.

4.4.34.3 Documents are available to personnel who need and use them, regardless of day of week and/or shift or time of day.

4.4.34.4 Only approved, current, and controlled copies of documents should be in use.

4.4.34.5 Documents are removed from the job area and destroyed if they are outdated. No out-of-date documents are observed during the audit.

4.4.35 Procedures describe GMP recordkeeping practices, e.g., permanent ink, identification of “who” and “when” for entries, and procedures for correcting entries (sign, date, explain, and not obliterate the original entry). [ISO 22716:2007 17.3.4]

4.4.35.1 Records relevant to the control of the process or evaluation of product quality will be:

— recorded on a timely basis with the applicable date and time;
— recorded in permanent ink (preferably blue or black), not pencil;
— complete with no missing data;
— signed and dated by the author; and
— indexed and easily retrievable.

4.4.35.2 Batch records are initialed by the operator and verified by a second person.

4.4.35.3 Errors are corrected by striking with a single line and initialed, and notated with the reason for the correction. The initial entry remains legible. Correcting fluid (“White-Out”) is not used.

4.4.36 Revision control is used for up-dated documents, with revision numbers and reason for the revision. [ISO 22716:2007 17.4]

4.4.36.1 A system of revision control is used when updating or revising documents.

4.4.36.2 The revision control scheme is described in the document control procedure.

4.4.36.3 Documents include a document history / revision section that details date of revision, and what was revised or reason for revision.

4.4.37 Procedures have been established that describe the requirements for record retention. Original documents are archived for a defined duration under secured storage. [ISO 22716:2007 17.5]

4.4.37.1 A written records retention procedure is in place and includes definitions of original records and copies.

4.4.37.2 The records retention procedure specifies the retention period, storage conditions, and disposition following the retention period for each type of record.

4.5 Operation

4.5.1 Equipment and utensils are of appropriate design so as to not contaminate components, products, or contact surfaces with lubricants, fuel, coolants, metal or glass fragments, filth or any extraneous materials, contaminated water, or other contaminants. [ISO 22716:2007 5.2]

4.5.1.1 Pumps and agitators do not leak lubricants into materials or products.

4.5.1.2 Utensils and tools should be impervious and non-shedding.
4.5.1.3 If tools must be used on equipment during production, then the tools shall be clean and prevent cross contamination. Tools are not to be stored on top of equipment, ledges or electrical boxes but should be stored in cabinets or outside of product contact areas.

4.5.1.4 Storage of cleaned equipment and utensils shall preclude adulteration from other activities in the area or airborne contamination.

4.5.2 Bulk product containers are protected from air contaminants such as dust and moisture. [ISO 22716:2007 5.2.2]

4.5.2.1 Bulk product containers are to be covered or sealed.

4.5.2.2 Enclosed tanks should have domed tops to minimize condensation.

4.5.2.3 Supersacks or big bags are to be tied shut.

4.5.2.4 Portable bulk storage containers are stored inside, and away from dust sources.

4.5.3 Transfer hoses and accessories that are not in use are cleaned, sanitized, kept dry, and protected from dust, splash, or other contamination. [ISO 22716:2007 5.2.3]

4.5.3.1 Water or air hoses shall be stored off the floor.

4.5.3.2 Product transfer hoses shall be drained, stored off the floor, and capped.

4.5.3.3 Bulk unloading hose systems shall be labeled, capped, and secure.

4.5.3.4 A cleaning and, where appropriate, disinfection schedule shall exist for equipment used for loading / unloading (e.g., bulk unloading hoses, transfer hoses).

4.5.4 Equipment and utensils are corrosion resistant, made of nontoxic materials, and are compatible with products and the cleaning and sanitizing agents. [ISO 22716:2007 5.2.4]

4.5.4.1 Equipment and utensils that contact product contact shall be smooth, inert, impervious, nontoxic and corrosion resistant.

4.5.4.2 No wood-handled or wood-part utensils are to be used (including mops, squeegees, and brooms).

4.5.4.3 Noncleanable materials such as cardboard and tape should not be used in production areas.

4.5.5 Equipment is designed and installed to ease drainage in order to facilitate cleaning and sanitization, and provide access under, inside and around equipment for maintenance and cleaning. [ISO 22716:2007 5.3]

4.5.5.1 Drains are provided under mixing tanks and fillers.

4.5.5.2 The space around production equipment provides access for cleaning and maintenance.

4.5.6 Major equipment has been identified and tagged or labeled. [ISO 22716:2007 5.3.4]

4.5.6.1 Equipment including bulk raw material storage tanks, mixing tanks, bulk product storage tanks, packaging line, fillers, cappers, case packers, and palletizers / unitizers are identified such as with a number. The identifier is used in the manufacturing batch record and for maintenance tracking.

4.5.6.2 Automated control and test equipment is similarly identified for maintenance purposes.
4.5.7 Equipment, instruments, utensils, contact surfaces etc. are cleaned and sanitized as necessary. [ISO 22716:2007 5.5]

4.5.7.1 Documentation of major equipment cleaning must be kept. Documentation should include, date, reference cleaning methods, the person(s) who performed the cleaning, and effectiveness checks.

4.5.7.2 Cleaning procedures shall be verified, and equipment inspected. If visual inspection is difficult or impossible then supplement bioluminescence or microbial testing should be used. Deficiencies and corrective action shall be documented and followed up. Final rinse water for tanks or large vessels should be evaluated to determine if chemical residue has been effectively flushed (water clarity, pH, odor).

NOTE — Once formal cleaning validation studies are performed, this routine testing / verification may be reduced or even eliminated as long as the validated system does not change.

4.5.7.3 A final (or pre-start up) sanitizing step on product contact surfaces is required. Reusable towels should not be used during the sanitizing step.

4.5.7.4 Equipment and utensils shall be cleaned prior to contact with different products where cross-contamination could occur. For example, scoops are cleaned during weigh up to prevent cross-contamination in bulk containers.

4.5.7.5 Cleaning of equipment and utensils shall be conducted to prevent contamination from chemical residue.

4.5.7.6 All equipment taken out for maintenance shall have documented cleaning and sanitizing steps prior to putting back in service.

4.5.7.7 Equipment and utensil status must be clearly indicated.

4.5.7.8 Storage of cleaned equipment must preclude contamination.

4.5.8 Equipment, instruments, utensils, contact surfaces, etc., are maintained and inspected at routine intervals for signs of wear, damage, etc. [ISO 22716:2007 5.6]

4.5.8.1 Equipment shall be maintained and not show signs of excessive wear. If excessive wear is seen, then a maintenance program shall be established to ensure product is not adulterated.

4.5.8.2 Inspect the equipment interior for damage, rusting, rouging (in stainless steel equipment), pitting or gouging, stains, un-cleanliness, etc. Interior surfaces should be clean, smooth (seamless), and in good condition.

4.5.8.3 Inspect the equipment exterior for damage, peeling paint, debris, dust, oils, spilled chemicals/materials, etc. Exterior surfaces should be well maintained, clean, and should not be a source of possible contamination.

4.5.8.4 Inspect hatch covers, exposed gaskets, etc. for damage, cleanliness, etc.

4.5.9 Defective equipment is identified and excluded from use or isolated. [ISO 22716:2007 5.6.3]

4.5.9.1 Defective equipment is not to be used for production.

4.5.9.2 Defective equipment is identified as such via prominent signage or labels.
4.5.9.3 Defective equipment is to be physically removed from service or electrically locked to prevent use.

4.5.10 Consumables and process gases that are used and which contact cosmetic products, components, and contact surfaces shall be controlled so as not to cause contamination (e.g., filters). [ISO 22716:2007 4.2 & 5.7]

4.5.10.1 Process gases (e.g., compressed air) are supplied through a filter. The filter / filtering mechanism is part of the PM program.

4.5.10.2 Food grade (as specified on the label or accompanying documentation) chemicals and lubricants are to be used in product contact applications.

4.5.11 Equipment or automated systems used in production and control are accessed and used only by authorized personnel. [ISO 22716:2007 5.8]

4.5.11.1 A procedure is implemented to assure authorization of personnel to restricted access areas, equipment, and control systems.

4.5.11.2 Password protection is implemented for controlled processes.

4.5.11.3 Passwords are secure and changed according to a defined schedule.

4.5.11.4 Internal audits challenge the security and authorization procedure.

4.5.12 Back-up systems are available for systems which need to be operated in the event of a failure or breakdown. [ISO 22716:2007 5.9]

4.5.12.1 Back-up systems for critical process controls are used (e.g., mirrored IT systems).

4.5.12.2 Redundant or installed back-up production equipment is used for critical processes.

4.5.12.3 Back-up electrical systems (e.g., generators) are available in the event of an emergency.

4.5.12.4 There are contingency plans for business continuity in the event of major incidents such disruption to key services (water, energy, staff availability), and events such as flood, fire, and natural disaster.

4.5.13 Specifications have been established for raw materials, labels, and packaging materials. [ISO 22716:2007 6.1]

4.5.13.1 Written specifications describe quality requirements for chemical raw materials, labels, and packaging materials.

4.5.13.2 Such specifications include parameters, specification limits, COA requirements, and test methods.

4.5.13.3 Chemical raw materials typically include an identity specification.

4.5.14 Suppliers of raw materials and packaging materials are evaluated, selected, and formal relationships are established for technical clauses, acceptance criteria, defect actions, and audit. [ISO 22716:2007 6.2]

4.5.14.1 There is a process to choose and qualify suppliers. The approval and monitoring procedure shall contain clear assessment criteria such as: audits, certificates of analysis, supplier reliability and complaints, as well as required performance standards.
4.5.14.2 There is an approved supplier list or identifier (e.g., on the specification).

4.5.14.3 The contract includes language addressing specifications, quality, audits, and returns.

4.5.14.4 There is a qualification / trial procedure for materials.

4.5.14.5 Supplier performance is reviewed periodically for compliance to expectations.

4.5.15 Receiving, sampling, testing, release procedures have been established. [ISO 22716:2007 6.3, 6.4, 6.5]

4.5.15.1 A procedure for receiving chemicals and packaging materials is in place. The procedure describes quarantine, sampling protocols, quality control requirements (COA and testing), and release processes.

4.5.15.2 The procedure describes responsibilities for each of the activities.

4.5.15.3 Transportation inspections are conducted and storage conditions are appropriate for the component. Components are controlled during transport (tamper evident seals). Components are not subject to adverse conditions during transport or storage.

4.5.15.4 Incoming materials that require special storage and handling conditions (e.g., specified temperature range) have such documented proof of acceptable storage and handling.

4.5.15.5 Written procedures describe operational flow of goods and how/where goods are stored and segregated. Segregation is adequate throughout the facility.

4.5.16 Procedures are established and implemented for checking the integrity of shipping containers is checked, and verifying the purchase orders, delivery notes, and delivered materials match. [ISO 22716:2007 6.3.1]

4.5.16.1 A procedure is implemented to assure the material matches the order.

4.5.16.2 Prior to accepting the shipment of materials or packaging, the shipping container is visually examined for damage and/or contamination.

4.5.16.3 The material is checked and verified against the delivery paperwork accompanying the shipment (bill of lading [BOL]) and purchase order.

4.5.16.4 The procedure includes acceptance requirements and rejection / return criteria.

4.5.17 Containers of raw materials and packaging materials are labeled with the name of the material, date of receipt, supplier name, batch reference, or control number, or both, and material status. [ISO 22716:2007 6.4.4]

4.5.17.1 Containers are properly labeled with complete information.

4.5.17.2 Methods for controlling status of goods are used which may include physical or computerized inventory systems.

4.5.17.3 Where used for status, the label includes a clear indicator of material status (e.g., Sampled, Released, Hold, Rejected).

4.5.18 Materials are released prior to use in production by authorized personnel responsible for quality. Raw materials and packaging components meet defined specifications. [ISO 22716:2007 6.5]
4.5.18.1 Materials are tested and approved prior to use.

4.5.18.2 Materials meeting quality requirements are released for use in production.

4.5.18.3 There should be no materials in the production area that are under test, held pending disposition, or rejected.

4.5.18.4 Documented controls for materials used prior to completion of testing are in place to prevent shipment of finished goods prior to successful completion of testing.

4.5.18.5 The material status of release should be evident from labeling or computer control.

4.5.19 If a certificate of analysis (COA) is used to confirm the component, the supplier shall be qualified and documentation shall be maintained for this qualification. [ISO 22716:2007 6.5.3]

4.5.19.1 The use of COA as the primary quality control system must be justified by audit and qualification of the supplier.

4.5.19.2 COA’s may be used for confirming specifications except identity. COA’s must include description of the test used, limits and actual results.

4.5.19.3 An audit sampling of receipts should be performed to confirm the COA values on frequency of no less than once per year.

4.5.20 Raw materials and packaging materials are stored and handled to maintain their quality, e.g., containers are closed and stored off the floor. [ISO 22716:2007 6.6]

4.5.20.1 Bags and drums of chemical raw materials are covered, closed, or tied shut.

4.5.20.2 Boxes of packaging materials are closed.

4.5.20.3 Hazardous chemicals are not stored near ingredients, components, or finished goods.

4.5.20.4 Containers are stored off the floor on pallets or racks.

4.5.20.5 When raw materials and packaging materials are repacked, they should carry the same labeling as at origin.

4.5.21 Specific storage condition requirements are controlled and monitored. [ISO 22716:2007 6.6.3]

4.5.21.1 Any incoming materials that require special storage and handling conditions (e.g., those requiring documentation of cold chain under specified temperature ranges) have such documented proof of acceptable storage and handling. These records should be retained.

4.5.21.2 Materials that require defined storage conditions such as temperature and/or humidity are stored in a controlled environment.

4.5.21.3 Temperature and humidity should be monitored in areas where components, in-process materials, or finished product is handled or stored.

4.5.21.4 Temperature mapping studies should be available for large areas such as warehouse storage areas.

4.5.21.5 Acceptable ranges shall be established and documented corrective actions implemented if temperature or humidity deviates from the accepted range.
4.5.21.6 Such devices shall be part of calibration or PM programs.

4.5.22 Stock turnover and rotation procedures are implemented, e.g., first in, first out (FIFO). [ISO 22716:2007 6.6.7]

4.5.22.1 Materials are controlled for age. FIFO (first in, first out) is practiced for chemical raw materials and packaging materials.

4.5.22.2 Approved raw materials shall be rotated so that the oldest approved stock is used first. These should also include procedures for periodic assessment of the inventory to assure that no adverse conditions exist.

4.5.22.3 There should be a written procedure describing the stock rotation program.

4.5.23 Periodic inventory is performed to ensure stock reliability. [ISO 22716:2007 6.6.8]

4.5.23.1 Inventory of materials is taken on a defined schedule to assure stock quantities and age of stock.

4.5.23.2 Over-age materials are removed from approved stock until evaluated a disposition is made.

4.5.24 A system of re-evaluation is implemented to determine suitability of use after a defined period of storage. [ISO 22716:2007 6.7]

4.5.24.1 There is a procedure to establish “use-by” or expiry periods for chemical raw materials and packaging materials.

4.5.24.2 The procedure identifies materials nearing their use-by date, and provides a process to re-test and disposition those materials. The procedure includes a method to extend the use-by date, if warranted.

4.5.24.3 Out of specification materials are quarantined for rejection or disposal.

4.5.24.4 In no case should materials past their use-by date be used for production.

4.5.25 The quality of water used in production is specified, and the quality is verified by testing or monitoring of process parameters. [ISO 22716:2007 6.8]

4.5.25.1 Source water (town, well, etc.) should be monitored for micro/chemical quality to establish normal quality and seasonal limits.

4.5.25.2 Diagrams of the system should be maintained and change controlled.

4.5.25.3 There is a specification for water used in the production of cosmetic products.

4.5.25.4 Water used in production of cosmetic products is routinely sampled at the point of use and tested for chemical and microbiological purity.

4.5.25.5 Additional sample points such as treatment ports, storage tanks, etc. may sampled and tested.

4.5.25.6 The design of the water permits sanitization.

4.5.26 Water sources do not act as a potential source of contamination of the cosmetic products, either due to water purity or due to the configuration and construction of the water delivery system. [ISO 22716:2007 6.8.4]
4.5.26.1 Routine maintenance and sanitation processes should exist for the water system.

4.5.26.2 The water distribution system is devoid of dead legs.

4.5.26.3 The water system is mapped. Water system piping is labeled with grade of water and direction of flow. Facility Plumbing and Water Line Diagrams should be available.

4.5.26.4 Recycled water that is used in the process shall not pose a contamination risk. Related records of testing shall be available.

4.5.27 Rejected components, packaging, labeling, and in-process and finished products are appropriately quarantined and dispositioned. [ISO 22716:2007 6.6.6 (for raw materials and packaging materials)].

4.5.27.1 Rejected materials are quarantined - physically segregated and identified as rejected.

4.5.27.2 There is a process to disposition rejected materials - return to vendor, dispose of, etc.

4.5.27.3 The process does not allow rejected materials to accumulate for lengthy periods of time.

4.5.28 Relevant documentation is available at each stage of manufacturing operations; documentation includes suitable equipment, formula for the product, raw material list, and detailed manufacturing operations such as addition of raw materials, temperatures, mixing speeds and times, sampling, cleaning, sanitizing, and bulk product transfer. [ISO 22716:2007 7.2.1]

4.5.28.1 Mixing and blending Master Manufacturing Records (MMRs) or Master Batch Records (MBRs) must include all processing steps from production.

4.5.28.2 Required parts of the MMR:

- name of the cosmetic product to be manufactured;
- strength, concentration, weight, or measure of each chemical raw material for each batch size;
- a complete list of all chemical raw materials;
- an accurate statement of the weight or measure of each chemical raw material;
- a statement of any intentional overage amount of a chemical raw material;
- written instructions, including specifications at each control point;
- sampling procedures and a cross-reference to tests or examinations;
- specific actions to perform and verify critical control steps (places for initials/signatures on each critical step for the performer and verifier);
- any special notations or precautions and corrective actions if specifications are not met;
- references to appropriate SOPs, specifications, etc. if needed;
- appropriate review and approval signatures.

4.5.28.3 Good documentation procedures have been established and are being followed.
4.5.28.4 Required parts of batch records:

- the batch, lot, or control number(s) that ensure traceability;
- identification of equipment and process lines that were used in the production;
- if not recorded in log books, then date and time of cleaning, sanitizing and maintenance operations;
- the lot number of each chemical raw material used;
- identity and weight or measure of each chemical raw material used;
- optional: A statement of actual yield and a statement of theoretical yield at the appropriate stages (if yield is out of allowable variances then investigation and results);
- actual results of any monitoring operations;
- results of any in process testing or examinations (or cross-references to the results);
- the date and initials of each person performing and verifying steps (weighing and addition steps need verification);
- the results of finished bulk tests or examinations;
- quality examinations of finished bulk;
- quality review of the Batch Record documented at the time of performance;
- quality review of all monitoring operations, test results and examinations;
- Quality Control approval or rejection of any reprocessing;
- documentation of any material reviews and disposition decisions; and
- Quality Control approval or rejection of the batch.

4.5.29 Start-up checks are made prior to production to ensure that all relevant documentation is available, raw materials are available and released, equipment is available for use, in working order, clean and sanitized, and material from other products is cleared from the area. [ISO 22716:2007 7.2.2]

4.5.29.1 A startup check and inspection shall be documented.

4.5.29.2 The records include the documentation (batch record, etc.), equipment cleaning and sanitization log, area clearance check, chemical raw material availability, release, and approval.

4.5.30 Batch numbers or unique identification schema are used. [ISO 22716:2007 7.2.3]

4.5.30.1 Each batch is traceable by unique identification.

4.5.30.2 The batch numbering procedure is captured in an SOP.

4.5.31 Containers of materials used in production, equipment, and bulk product are identified with name, batch number, status, and date. [ISO 22716:2007 7.2.4]
4.5.31.1 Containers of chemical raw materials are properly labeled with name, batch number, and status.

4.5.31.2 Mixing or batching equipment is identified with the product being made, batch number, and status.

4.5.31.3 Bulk product in storage is identified with the product name, batch number, and status.

4.5.32 In-process controls and specifications have been established for in-process material and batches during production, and such tests and controls are performed. [ISO 22716:2007 7.2.5]

4.5.32.1 In-process controls (mix times, temperatures, pH) are defined and documented in the batch record.

4.5.32.2 Written specifications describe in-process product and bulk product requirements.

4.5.32.3 In-process product and bulk product are sampled and tested according to the specification.

4.5.33 A system has been established to determine if all specifications have been met for in-process materials and batches during production. [ISO 22716:2007 7.2.5.2]

4.5.33.1 There is a procedure for review of quality control tests and that the test results meet specification prior to release.

4.5.33.2 The review and approval process may be performed by operations or the quality unit.

4.5.34 Procedures and controls have been established for investigation and handling of in-process materials that do not meet specification requirements. [ISO 22716:2007 7.2.5.3]

4.5.34.1 Procedures have been established and are followed for handling OOS results or product deviations. The FDA guidance document on OOS may be used for reference.

4.5.34.2 The OOS procedure should not permit “testing into compliance”.

4.5.34.3 Rejected bulk product has not been used. Exceptions may apply for reprocessed materials. Exceptions must follow deviation procedures and be approved by the quality unit.

4.5.35 Bulk product is stored in suitable containers under appropriate conditions, and with defined maximum storage duration. In-process materials requiring specific holding conditions (temperature, humidity etc.) are stored appropriately. [ISO 22716:2007 7.2.6]

4.5.35.1 Bulk product held and stored in containers constructed of compatible materials. Containers are covered or shut.

4.5.35.2 Bulk product containers are stored in the facility in a manner to prevent contamination.

4.5.35.3 Maximum storage times are defined for bulk product, and there is a process to monitor the storage time.

4.5.35.4 If controlled storage conditions (e.g., temperature, humidity) are required, the storage conditions must be documented and have action limits beyond which corrective actions are needed.

4.5.35.5 Equipment shall be maintained and not show signs of excessive wear. If excessive wear is seen, then a maintenance program shall be established to ensure product is not adulterated.

4.5.35.6 Inspect the equipment interior for damage, rusting, rouging (in stainless steel equipment),
pitting or gouging, stains, uncleanliness, etc. Interior surfaces should be clean, smooth (seamless), and in good condition.

4.5.35.7 Inspect the equipment exterior for damage, peeling paint, debris, dust, oils, spilled chemicals / materials, etc. Exterior surfaces should be well maintained, clean, and should not be a source of possible contamination.

4.5.35.8 Inspect hatch covers, exposed gaskets, etc. for damage, cleanliness, etc.

4.5.36 Unused raw materials returned to stock are properly closed, identified, and stored. [ISO 22716:2007 7.2.7]

4.5.36.1 Raw materials that are left over from production may be returned to inventory if they are not contaminated.

4.5.36.2 Returns must be properly stored in closed containers with identification the same as the original container / label.

4.5.36.3 Returns are to be stored off the floor on pallets or racks.

4.5.36.4 Returns are to be inventory controlled including the use-by date.

4.5.37 Relevant documentation is available at each stage of packaging operations; documentation includes suitable equipment, packaging material list, and detailed packaging operations such as filling, closing, labelling, and coding. [ISO 22716:2007 7.3.1]

4.5.37.1 Filling and packaging Manufacturing Master Records (MMRs) or Master Batch Records (MBR) must include all processing steps from production.

4.5.37.2 Required parts of the MMR:

— name of the cosmetic product to be manufactured;
— quantity of bulk product for each batch size (net fill weight);
— a complete list of all bulk product, packaging components, labels, and associated components (inserts, hangtags, etc.);
— written instructions, including specifications at each control point;
— sampling procedures and a cross-reference to tests or examinations;
— specific actions to perform and verify critical control steps (places for initials/signatures on each critical step for the performer and verifier);
— any special notations or precautions and corrective actions if specifications are not met;
— references to appropriate SOPs, specifications, etc. if needed;
— appropriate review and approval signatures.

4.5.37.3 Good documentation procedures have been established and are being followed.

4.5.37.4 Required parts of batch records:

— the batch, lot, or control number(s) that ensure traceability;
— identification of equipment and process lines that were used in the production;
— if not recorded in log books, then date and time of cleaning, sanitizing and maintenance operations;
— the batch / lot number of the bulk product used;
— a description of packaging and a representative label (or a cross-reference to the physical location of the actual or representative label);
— optional: A statement of actual yield and a statement of theoretical yield at the appropriate stages (if yield is out of allowable variances then investigation and results);
— actual results of any monitoring operations;
— results of any in process testing or examinations (or cross-references to the results);
— the results of packaged product bulk tests or examinations;
— quality examinations of packaged product;
— quality review of the Batch Record documented at the time of performance;
— quality review of all monitoring operations, test results and examinations;
— quality control approval or rejection of any reprocessing;
— documentation of any material reviews and disposition decisions;
— quality control approval or rejection of the batch.

4.5.37.5 Documentation of packaging and labeling operations at time of performance including the unique identifier for packaging and labels used.

4.5.37.6 Controls of packaging and labels have been established which include visual examination, review of paperwork, sampling of each unique lot, quality testing and review, and quarantine and release. Controls should include defect action levels for large bulk shipments.

4.5.37.7 Packaging components are lot tracked to ensure traceability throughout the supply chain.

4.5.37.8 Label controls extend to labels printed in-house, labels printed externally, and labels (or label copy) provided by customers.

4.5.38 Start-up checks are made prior to packaging to ensure that all relevant documentation is available, packaging materials are available and released, equipment is available for use, in working order, clean and sanitized, coding for the product is defined, and material from other products is cleared from the area. [ISO 22716:2007 7.3.2]

4.5.38.1 A system, procedure, or document is in place to ensure that all previous materials have been removed.

4.5.38.2 A startup check and/or first article inspection shall be documented.

4.5.38.3 The records include the documentation (packaging record, etc.), equipment cleaning and sanitization log, area clearance check, packaging and label availability, release, and approval.
4.5.38.4 Materials are segregated, status controlled, and held to prevent contamination or mix-up. Labels of different UPCs are held separately and controlled.

4.5.38.5 Products shall be protected from metal and extraneous material inclusion. Metal detection or metal magnets are acceptable for powders. Filters or traps are acceptable for liquids. Magnets shall be cleaned and inspected prior to use. Metal detectors shall be calibrated for the product and its orientation prior to use. Metal detectors shall have documented challenges performed prior to startup.

4.5.39 Batch / lot numbers or unique identification schema are used on each unit of packaged product. [ISO 22716:2007 7.3.3]

4.5.39.1 Each unit of production is traceable by unique identification.

4.5.39.2 The batch numbering procedure is captured in an SOP.

4.5.39.3 Inspection of the final product and/or its packaging shall be documented to show that correct lot number and expiration dating (if applicable) or PAO (period after opening) was used.

4.5.40 Packaging line, the name or identifying code of the finished product, and batch number are identified. [ISO 22716:2007 7.3.4]

4.5.40.1 The filling and packaging line bears identification.

4.5.40.2 The packaging record documents equipment used (e.g., filling and packaging line), the finished goods product number and name, and the associated lot or batch number(s).

4.5.41 Procedures and program shall be established maintaining and calibrating equipment to include online controls. [ISO 22716:2007 7.3.5]

4.5.41.1 The PM program should include auxiliary equipment such as HVAC units, dust collectors, boilers, air compressors and water treatment systems that may have direct or indirect product quality impact. On-line equipment such as metal detectors, on-line scales, outage meters, etc., should be included.

4.5.41.2 Equipment should be designated with unique identifiers (equipment numbers).

4.5.41.3 The program should outline what activities should be completed for the preventive maintenance and the frequency the maintenance should occur. The system can be paperless, but adequate records should show that the maintenance was completed as scheduled based on the established frequency.

4.5.41.4 Records should demonstrate that on-line control equipment is in calibration.

4.5.41.5 When on-line control equipment is out of calibration, the equipment should be either immediately removed from service or repaired. Production should not run without functioning on-line control equipment.

4.5.41.6 Investigations should be made to determine the impact of prior production when on-line equipment is found to be out of calibration.

4.5.42 In-process controls and specifications have been established for in-process materials and products during packaging, and such tests and controls are performed. [ISO 22716:2007 7.3.6]

4.5.42.1 In-process controls (net weights, torques, date/lot coding) are defined and documented in the packaging record.
4.5.42 Written specifications describe filling and packaging requirements.

4.5.42.3 In-process product is sampled and tested according to the specification.

4.5.43 A system has been established to determine if all specifications during packaging operations have been met. [ISO 22716:2007 7.3.6.1]

4.5.43.1 There is a procedure for review of quality control tests and that the test results meet specification prior to release.

4.5.43.2 The review and approval process may be performed by operations or the quality unit.

4.5.44 Procedures and controls have been established for investigation and handling of packaging operations and products that do not meet specification requirements. [ISO 22716:2007 7.3.6.3]

4.5.44.1 Procedures have been established and are followed for handling OOS results or product deviations. The FDA guidance document on OOS may be used for reference.

4.5.44.2 Rejected components, finished product or bulk product has not been used or distributed. Exceptions may apply for reprocessed materials. Exceptions must follow deviation procedures and be approved by the quality unit.

4.5.44.3 Rejects are identified, segregated, status controlled, and held to prevent contamination.

4.5.45 Unused packaging materials returned to stock are properly closed, identified, and stored. [ISO 22716:2007 7.3.7]

4.5.45.1 Packaging materials that are left over from production may be returned to inventory if they are not contaminated.

4.5.45.2 Returns must be properly stored in closed containers with identification the same as the original container and identifier.

4.5.45.3 Returns are to be stored off the floor on pallets or racks.

4.5.45.4 Returns are to be inventory controlled including the use-by date, if applicable.

4.5.46 Specifications have been established for finished products, and finished product meets the defined acceptance criteria. [ISO 22716:2007 8.1,8.2.1]

4.5.46.1 All finished product shall be tested to assure the product meets specifications.

4.5.46.2 Customer specific requirements are reflected in the specification.

4.5.46.3 Specification for finished product and packaged finished product may be the same.

4.5.46.4 Categories of products or components may have the same specifications.

4.5.46.5 Specifications must have documented test methods and limits.

4.5.46.6 Identity, purity, strength and composition of the finished product must be established by either in-process specifications or finished product specifications.

4.5.46.7 Representative samples are tested against the written specifications. The finished product meets specifications prior to release to the trade.
4.5.46.8 Finished product shall be tested, as necessary, to ensure freedom from objectionable microorganisms.

4.5.47 The theoretical yield for a production batch is compared with the actual yield. [US FDA Cosmetic GMP guidance]

4.5.47.1 The actual yield of a cosmetic product batch is compared to the theoretical yield, accounting for spillage, waste, and rework.

4.5.47.2 Measurements of yield may include: (1) quantity of cosmetic product in pounds, kilograms, or other suitable units, and (2) label usage and reconciliation.

4.5.47.3 Limits on the difference between the actual yield and theoretical yield are specified. Investigations are initiated and completed when the difference exceeds the limits.

4.5.48 Product release is conducted by authorized personnel for quality. [ISO 22716:2007 8.2.2]

4.5.48.1 A written procedure shall be established and followed that outlines the criteria for releasing product. Quality shall have final authority on releasing product.

4.5.48.2 Quality conducts a material review and make a disposition decision, including when:

- specifications are not met;
- a batch deviates from the MMR;
- there is an unexpected occurrence that could lead to adulteration or mislabeling; and
- calibration or failure of an instrument occurs that could affect batch quality.

4.5.49 Finished product is stored in a designated area under appropriate conditions and under a defined maximum storage time. [ISO 22716:2007 8.3.1]

4.5.49.1 Finished goods are stored in the facility in a manner to prevent contamination.

4.5.49.2 Maximum storage times are defined for finished goods, and there is a process to monitor the storage time.

4.5.49.3 If controlled storage conditions (e.g., temperature, humidity) are required, the storage conditions must be documented and have action limits beyond which corrective actions are needed.

4.5.49.4 Warehouse facilities shall be devoid of dust and debris and free from pest indications.

4.5.49.5 Hazardous chemicals shall not be stored near ingredients, components, or finished goods.

4.5.50 Finished goods stock turnover and rotation procedures are implemented, e.g., FIFO. [ISO 22716:2007 8.3.5]

4.5.50.1 Finished goods are controlled for age. FIFO (first in, first out) is practiced for finished goods.

4.5.50.2 There should be a written procedure describing the stock rotation program.

4.5.50.3 Examine date codes of finished goods in the warehouse vs. the date codes of product being shipped.

4.5.51 Periodic inventory is performed to ensure inventory accuracy, acceptance criteria are met, and overage stock is addressed. [ISO 22716:2007 8.3.6]
4.5.51.1 There is a schedule of finished goods inventory, and records support compliance to the schedule.

4.5.51.2 Limits are established for accuracy, and deviations are investigated and documented.

4.5.51.3 Overage stock identified in the inventory is segregated and dispositioned.

4.5.51.4 Discrepant product (rejects, held product) is included in the inventory control process.

4.5.52 Shipment records and conditions are defined, e.g., correct product, batch number, temperature control, as appropriate. Distribution of product occurs under conditions that protect against contamination and deterioration. [ISO 22716:2007 8.4]

4.5.52.1 Shipment records include product name, identifier (product number), quantity, and batch number to provide traceability.

4.5.52.2 Documented inspection of transport vehicles is required for ensuring stable environmental conditions during transport. Before loading transport vehicles, their condition (e.g. absence of strange smells, high dust load, adverse humidity, pests, mold) shall be checked and action taken, if necessary.

4.5.52.3 Product must be sealed with tamper evident seals and shipped in containers that protect against physical, chemical, or microbial contamination or deterioration.

4.5.52.4 Any products that require special storage and handling conditions (e.g., documentation of cold chain under specified temperature ranges) have such documented proof of acceptable storage and handling.

4.5.53 Procedures have been established for the handling of returned cosmetic product. [ISO 22716:2007 8.5]

4.5.53.1 There is a written procedure describing how to handle returned finished goods. The procedure describes receipt, handling, examining, and testing requirements for returned goods.

4.5.54 Returned cosmetic products have been appropriately quarantined, evaluated and dispositioned. [ISO 22716:2007 8.5.2, 8.5.3]

4.5.54.1 Returns are segregated from shippable product.

4.5.54.2 Returned goods are examined and/or sampled and tested to verify correctness and quality of the product.

4.5.54.3 A disposition to place returned goods into shippable inventory is supported by the quality unit via disposition.

4.5.54.4 Returned product adheres to the lot/batch coding schema.

4.5.54.5 Product that does not meet specifications, is returned unsealed, or has been subject to improper storage conditions, is to be destroyed.

4.5.54.6 Records must include reason and date of return and ultimate disposition of the product. Returns for any quality reason or because of a customer complaint shall be reviewed by quality and investigated if appropriate.

4.5.55 Laboratory facilities used are adequate for testing of components, in-process materials, and cosmetic products. This includes any outside contracted laboratories. [ISO 22716:2007 9.1]
4.5.55.1 Laboratory facilities are adequate in size to conduct testing for materials and products. The labs are not cluttered nor do they present a safety hazard due to insufficient space.

4.5.55.2 Labs are condition controlled (e.g., HVAC).

4.5.55.3 Labs have adequate lighting.

4.5.55.4 Labs are equipped with appropriate safety equipment (e.g., fume hoods, eye wash stations, safety shower, first aid kit).

4.5.55.5 Microbiological test labs are physically segregated from other test labs.

4.5.55.6 Provision is made for hazardous material and compressed gas storage.

4.5.55.7 Lab test equipment is adequate and maintained. Typical lab test equipment consists of analytical balances, scales, ovens and/or incubators, water baths, IR spectrometer, HPCL, GC, titrators (manual and/or automated), colorimeters and/or spectrometers, pH meters, specific gravity meters or density meters.

4.5.55.8 In-house lab facilities are clean and orderly. In full operation, there should be adequate personnel to ensure that interruption of critical steps, within testing methods, does not occur in order to accommodate other testing that may be run in parallel.

4.5.55.9 Contract laboratories must be qualified against defined and documented selection criteria, and periodically reviewed for their performance. Contract laboratories must meet the same criteria as in-house laboratories.

4.5.55.10 Contract laboratories shall provide documented results including actual results, methods used, reference standards used if applicable, names and dates.

4.5.56 Solid waste and trash are disposed of appropriately and not allowed to accumulate. [ISO 22716:2007 11.1]

4.5.56.1 Refuse, garbage, waste, and debris from all areas are removed promptly and adequately.

4.5.56.2 Refuse receptacles in restrooms and production areas shall be containers designated only for refuse. Modified product or raw material containers shall never be used for refuse.

4.5.56.3 Receptacles shall prevent pest harborage and be covered.

4.5.57 Solid waste and trash does not provide a potential source of contamination to components, products, contact surfaces, etc. [ISO 22716:2007 11.3]

4.5.57.1 Waste and trash are segregated from product and manufacturing equipment.

4.5.57.2 There is no evidence of waste, build-up, or trash accumulation in production areas and material storage areas.

4.5.58 Hazardous waste is properly controlled so as not to provide a potential source of contamination to components, products, contact surfaces, etc. [ISO 22716:2007 11.3]

4.5.58.1 Hazardous waste is stored in appropriate containers and segregated.

4.5.58.2 Hazardous waste is disposed of in accordance with regulatory requirements.
4.5.59 Containers of waste are properly identified as to contents and other appropriate safety / hazard information. [ISO 22716:2007 11.4]

4.5.59.1 Waste collection containers are clearly marked, suitably designed, in good state of repair, easy to clean, and disinfected where necessary.

4.5.59.2 Containers of waste are identified as to their contents. Waste labels include hazard information.

4.5.60 A written contract or agreement is established and mutually confirmed between the contract giver and contract acceptor. [ISO 22716:2007 12.1]

4.5.60.1 Contracted operations (contract manufacturing, external laboratory, contracted maintenance operations, pest control) are governed by a written contract.

4.5.60.2 The contract spells out products or services provided, and expected outcomes.

4.5.60.3 The contract is signed or approved by both the contracting company and the contractor.

4.5.61 The contract giver has assessed the contract acceptor's ability, capacity, and means to conduct the contracted operations. The contract giver has assessed the contract acceptor's ability to comply with cosmetic GMP. [ISO 22716:2007 12.3.1]

4.5.61.1 There is a process to evaluate and qualify contractors.

4.5.61.2 The assessment includes evaluation of the contractors technical and process capability.

4.5.61.3 Where applicable, the contractor must meet the requirements of cosmetic GMPs.

4.5.61.4 Contractor performance is reviewed against expectations periodically to assure capability.

4.5.62 A documented system of communication, documentation, deviation reporting, decision making, data exchange, and change control with a subcontractor has been implemented. [ISO 22716:2007 12.5]

4.5.62.1 Procedures have been established for the exchange of information and documentation.

4.5.62.2 The process and requirements for handling discrepant material and deviations are clearly defined.

4.5.62.3 Roles and responsibilities for decision making are clearly defined.

4.5.62.4 A procedure is in place describing how changes are communicated, executed, and confirmed. The contractor shall not initiate changes on their own volition.

4.6 Performance evaluation

4.6.1 Procedures have been established for laboratory operations. [ISO 22716:2007 9.1.2]

4.6.1.1 Procedures have been established and are being followed for laboratory operations including sample handling, results reporting, release/rejection procedures, reference standard programs, and OOS result investigations. Skip lot programs if used are defined and justified.

4.6.1.2 All laboratory procedures have been approved by the Quality Unit.

4.6.1.3 Procedures have been established for the operation, maintenance, calibration, and where necessary, cleaning of laboratory equipment.
4.6.1.4 Procedures have been established for creating specifications.

4.6.1.5 Procedures must exist and be current for receipt, sampling, testing, and release of chemical raw materials, packaging materials, and bulk goods to be packaged.

4.6.1.6 There is a documented process for training and qualification of laboratory personnel in test methods.

4.6.2 QC responsibilities for laboratory test methods and examinations used to test specification requirements have been defined and are being followed. Proper testing procedures or programs have been established to determine if in-process and finished product specifications have been met. [ISO 22716:2007 9.2, 9.3]

4.6.2.1 Test methods shall exist and be current following good documentation practices for all laboratory methods used. Methods must be an accurate representation of the actual test performed. Methods should reference source, reference standards, and reagents used.

4.6.2.2 Control procedures for chromatographic procedures shall include system suitability checks.

4.6.2.3 Personnel conducting the testing and examination have documented at the time of performance the laboratory methods that were used. Test data and results are documented.

4.6.2.4 Finished product assays must be completed on the finished product form of the product.

4.6.2.5 Tolerance limits shall be established. Corrective actions shall be made on trends and major deviations from control limits. Control charts may be used.

4.6.3 Scientifically valid test methods are used for testing of components, packaging materials, in-process materials, and final products. [ISO 22716:2007 9.2]

4.6.3.1 Scientifically valid methods are used for establishing that specifications have been met.

4.6.3.2 Compendial methods may be used.

4.6.3.3 If methods are validated, USP or ICH criteria for method validation should be followed.

4.6.3.4 Method transfer protocols, with pre-determined acceptance criteria, are defined and followed whenever a test method is to be used that was developed and validated at a different laboratory.

4.6.4 All results are reviewed and used to make a decision of approval, rejection, or pending. [ISO 22716:2007 9.4]

4.6.4.1 The quality unit reviews test results.

4.6.4.2 The review is used to make a disposition decision of the material or product.

4.6.5 Out of specification (OOS) results are reviewed by authorized personnel according to a standard procedure, and decision made in terms of deviation, rejection, or pending. [ISO 22716:2007 9.5]

4.6.5.1 There is a written OOS procedure.

4.6.5.2 Responsibility is assigned for conducting the OOS procedure and the personnel authorized to make decisions regarding such material.

4.6.5.3 The review and decision are documented.
4.6.5.4 The OOS procedure does not permit “testing into compliance.”

4.6.6 Laboratory controls have been established and have been approved by QC (including any outside contracted laboratories). Controls include reagents and standards; calibration of instruments and equipment; sample receipt, handling and traceability; test methods; calculations and data reduction; raw data handling and storage. [ISO 22716:2007 9.6]

4.6.6.1 There is a documented laboratory calibration and control program.

4.6.6.2 Laboratory equipment is calibrated according a written schedule. Results of the calibration are recorded.

4.6.6.3 Microbiological test controls are used, e.g., media control, growth promotion, incubator calibration.

4.6.6.4 Reagents and standards are controlled (e.g., standardization) and assigned an expiration or use-by date. Such controls are recorded.

4.6.6.5 Procedures for sample receipt, labeling, and control are documented.

4.6.6.6 Test methods are written, reviewed, approved, and revision controlled.

4.6.6.7 Laboratory results are recorded such as in laboratory notebooks; such records comply with good laboratory practices.

4.6.7 Procedures have been established for the collection of representative samples for analysis including sampling method, equipment, amounts, precautions, identification, and frequency. [ISO 22716:2007 9.7]

4.6.7.1 Sampling methods and procedures preserve the integrity of the sample material, and do not contaminate the source material.

4.6.7.2 Sampling methods assure representative samples are obtained.

4.6.7.3 Safety considerations are built into the sampling protocols.

4.6.7.4 Samples are labeled with material name, batch/lot code, control number (if applicable), date of sampling, sampled by.

4.6.8 Samples of finished products in their primary package are retained under controlled conditions for a defined time. The sample size allows analysis to be carried out for acceptance criteria. [ISO 22716:2007 9.8.1, 9.8.2, 9.8.3]

4.6.8.1 There is finished product retention program.

4.6.8.2 The program specifies the number and quantity of samples to be retained.

4.6.8.3 Finished goods are retained in their primary package.

4.6.8.4 Retain samples are stored in controlled conditions (e.g., HVAC).

4.6.8.5 The program specifies the retention period (e.g., three years).

4.6.9 Samples of raw materials are retained according to a defined program. [ISO 22716:2007 9.8.4]

4.6.9.1 There is raw material retention program.
4.6.9.2 The program specifies the number and quantity of samples to be retained. The quantity of chemical raw materials is typically three times the amount needed to test for the acceptance criteria.

4.6.9.3 Raw materials are stored in nonreactive containers.

4.6.9.4 Retain samples are stored in controlled conditions (e.g., HVAC) and protected from light.

4.6.9.5 The program specifies the retention period (e.g., one year).

4.6.9.6 Samples of hazardous raw materials need not be retained.

4.6.10 Procedures have been established for cleaning and, as applicable, sanitization, including verification and documentation thereof, of all utensils and equipment. [ISO 22716:2007 5.3.1]

4.6.11 Complaint procedures shall be established, and complaint records shall be maintained.

4.6.11.1 Complaints should be investigated in a timely manner. An escalation process to inform management as the severity or risk increases shall be followed.

4.6.11.2 Complaint information should include the following:
   — name and description of the cosmetic product;
   — batch, lot, or control number (if available);
   — the date of the complaint and the name, address, and telephone number of the complainant, if available;
   — the nature of the complaint and how the product was used;
   — whether a sample was retrieved, and results of testing or investigation of the sample;
   — any reply to the complainant;
   — findings of the investigation and any follow-up actions.

4.6.11.3 Other experts (e.g. Manufacturing, R&D, Medical) should be involved as appropriate.

4.6.11.4 Where adequate information exists to indicate a deficiency in quality or failure to meet specifications, complaints should be investigated. The investigation should include a root cause analysis of the complaint. Corrective action should be implemented and documented.

4.6.11.5 Where an investigation is not conducted, the reason that such investigation was found not to be necessary should be documented.

4.6.12 The investigation for a product complaint is appropriately extended to other batches, products, processes, etc. [ISO 22716:2007 14.2.4]

4.6.12.1 The investigation should include an evaluation if the problem is caused or shared by common materials or processes used in other batches or products.

4.6.12.2 The impact to other batches, products, or processes should be determined and appropriate action taken. The action may be quarantine of materials or products, reworking of products, product withdrawal, or product recall.
4.6.13 Complaints are periodically reviewed for trends or recurrence of a defect. [ISO 22716:2007 14.2.5]

4.6.13.1 There is a routine review process of complaints to identify trends.

4.6.13.2 Complaint trends and metrics are reported to management.

4.6.13.3 Complaint data is used implement ongoing improvements to product quality.

4.6.14 There is a system for investigating, reporting, and follow-up for complaints alleging adverse events involving bodily injury. [US FDA Cosmetic GMP guidance]

4.6.14.1 Complaints alleging adverse events involving bodily injury are investigated and documented.

4.6.14.2 The document contains, at a minimum:

— the kind and severity of each reported injury;
— the body part involved;
— product and code numbers;
— whether medical treatment was sought, and, if so, the nature of the medical treatment and the name of the attending physician or other healthcare professional;
— whether resolution of the event occurred, with or without long-term or persistent effects (If long-term or persistent effects occurred, the nature of those effects);
— the name(s) and location(s) of any poison control center, government agency, physicians group, etc., to whom formula information and/or toxicity data has been provided; and
— whether the company voluntarily reports adverse events to FDA through the MedWatch.

4.6.15 Procedures have been established to define the recall process of a product. The recall process is evaluated through a recall or mock recall exercise at least once a year. [ISO 22716:2007 14.3]

4.6.15.1 Written recall procedures exist and are current. The procedures include and describe roles and responsibilities, communication processes, retrieval processes, reconciliation, and emergency contact lists.

4.6.15.2 Recall procedures identify members of the recall team, responsibilities (including public relations) and contact information (including FDA/regulatory contact information).

4.6.15.3 Recall procedures cover the three classes of recalls outlined by the FDA.

4.6.15.4 Recall procedures should cover finished product recalls and recalls from component, raw material vendors.

4.6.15.5 Mock recalls are conducted at least annually to challenge the procedures and finished goods traceability system.

4.6.16 Designated competent personnel conduct internal audits in an independent manner to monitor the implementation and status of cosmetic GMP. [ISO 22716:2007 16.1]
4.6.16.1 Internal GMP audits shall be conducted at least annually covering all aspects of the quality system / cosmetic GMP program.

4.6.16.2 The scope of the audit includes, but is not limited to, personnel and training, facilities, pest control, housekeeping, sanitation, equipment cleaning, batch records, product manufacturing, packaging operations, preventive maintenance and calibration programs, deviation system, complaint system, recall program, and laboratory and testing records.

4.6.16.3 The audit should cover among other things, the effectiveness of policies, the applicability of procedures and the completeness of corrective action implementation.

4.6.16.4 The audits may be done as one comprehensive audit or as several partial audits conducted throughout the year, but all aspects of the GMP requirements should be audited on a periodic basis.

4.6.16.5 The audit includes a test of the traceability system to ensure traceability can be determined from raw material receipt to finished product and vice versa.

NOTE — This is one area where the audited firm may withhold the specific nonconformances identified during internal audits (to avoid the same conflict of interest issues that led FDA to allow the same privacy of this aspect of a firm’s records). In this case, this audit should confirm that there is a policy / SOP and a current schedule meeting the requirements and that this schedule is being followed.

4.6.17 Audit observations and results are evaluated and shared with appropriate management. [ISO 22716:2007 16.2.2]

4.6.17.1 The audit team shall prepare a report of internal audit findings and evaluate the risk of observed deficiencies or nonconformities.

4.6.17.2 Results of the audit are shared with the audited department(s).

4.6.17.3 Management shall review the results of internal audits.

4.6.18 Corrective actions as a result of internal audits are implemented and evaluated for effectiveness. [ISO 22716:2007 16.3]

4.6.18.1 The audited departments create and implement corrective action plans to address audit findings.

4.6.18.2 Management shall assure corrective action with follow up.

4.6.18.3 Scales shall be evaluated and documented prior to use with at least a single reference weight.

4.6.18.4 Periodic review of the corrective actions is documented to evaluate and assure effectiveness of the plan.

4.6.19 Procedures established for QC laboratory operations shall include OOS procedures. [ISO 22716:2007 9.3]

4.7 Improvement

4.7.1 Investigations of rejected product or materials are performed by authorized personnel according to a standard procedure such as an OOS procedure. [ISO 22716:2007 10.1.1]

4.7.1.1 Procedures have been established and are followed for handling OOS results or product deviations. See FDA guidance document on OOS for more details.
4.7.1.2 Rejected components, finished product or bulk product has not been used or distributed. Exceptions may apply for reprocessed materials. Exceptions must follow deviation procedures and be approved by the quality unit.

4.7.2 Methods for reprocessing are defined and approved. The Quality Unit approves decisions to destroy or reprocess rejected product or materials. [ISO 22716:2007 10.1.2, 10.2.2]

4.7.2.1 Procedures shall be established outlining requirements for disposition (salvage, recovery) decisions. Quality must approve all dispositions.

4.7.2.2 Reprocessing or reworking procedures have been established for production, packaging and labeling operations. These procedures have been reviewed and approved by the quality unit.

4.7.2.3 Procedures shall be established for the methods of destroying or otherwise disposing of any product. Disposal must be documented.

4.7.2.4 Review reprocessing or reworking records (including any repackaging and/or relabeling operations). Verify traceability and controls were in place. Verify quality approved the work prior to commencement. Verify that the completed batch(s) were reviewed for specification compliance and released by quality.

4.7.3 Deviations from specified requirements or written procedures, or both, are authorized with data to support the decision. [ISO 22716:2007 13.1]

4.7.3.1 There is a procedure for handling deviations from cosmetic GMPs. Deviations can arise from discrepant materials, products, operations steps (mixing, blending, packaging), or quality control procedures.

4.7.3.2 The procedure specifies roles and responsibilities for decision making.

4.7.3.3 Written records document the deviation, results of any testing, data analysis, evaluation, decision, and approvals.

4.7.4 Corrective action is taken to prevent recurrence of the deviation (e.g., corrective action preventive action [CAPA]). [ISO 22716:2007 13.2]

4.7.4.1 There is a process for evaluating the case of deviations (e.g., root cause analysis, CAPA).

4.7.4.2 Evaluation of the cause of deviations leads to corrective or preventive action.

4.7.4.3 Cause and solution are communicated to appropriate individuals.

4.7.4.4 The effectiveness of the corrective action or preventive is monitored.
## Standards

The following standards established and adopted by NSF as minimum voluntary consensus standards are used internationally:

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THE HOPE OF MANKIND rests in the ability of man to define and seek out the environment which will permit him to live with fellow creatures of the earth, in health, in peace, and in mutual respect.