Cosmetics Good Manufacturing Practice Regulations

Announced Date: Aug 13th, 2019

1. Promulgated by the Ministry of Health and Welfare Order Wei-Shou-Shi-Tzu No.1081103973, on August 13th, 2019; The Regulations shall be effective on July 1st, 2019.

Chapter 1 General Provisions

Article 1

These regulations are formulated in accordance with the Paragraph 4, Article 8 of the Cosmetic Hygiene and Safety Act (hereinafter referred to as the Act).

These regulations are formulated in reference to the ISO 22716: Cosmetics-Good manufacturing practices (GMP)-Guidelines on good manufacturing practices issued by International Organization Standardization.

Article 2

The definition of terms used in this regulation are defined as follows:

1. Acceptance criteria: the acceptable amount, range, or other suitable measurement methods according to the test result.
2. Auditing: systematic and independent examination to determine whether quality activities and related results comply with planned arrangements and whether these arrangements are implemented effectively and are suitable for achieving objectives.
3. Batch: the certain produce amount of raw materials, packaging materials, or products from a single or series of manufacturing process.
4. Batch number: The identification of certain batch of products which contains numbers, alphabets, or symbolic combinations.
5. Bulk product: any product that is completed the manufacturing process, but without the final packaging process.
6. Calibration: Under a certain condition, to establish the operation methods and procedures with the known standard reference values to ensure the result values and material testing values of the measurement equipment or measurement system.
7. Control: verification that acceptance criteria are met.
8. Change control: To ensure all manufacturing, packaging, process control and storage of the products to meet the defined acceptance criteria. The amendment plan conducted by the internal organizations and responsible units related to good manufacturing practice.
9. Cleaning: all operations that ensure a level of cleanliness and appearance, consisting of separating and eliminating generally visible dirt from a surface

by means of the following combined factors, in variable proportions, such as chemical action, mechanical action, temperature, duration of application.

10. Complaint: external information claiming a product does not meet the defined acceptance criteria.
11. Contamination: occurrence of any undesirable matter such as chemical, physical and/or microbiological matter in the product.
12. Consumables: materials such as cleaning agents and lubricants that are used up during cleaning, sanitization or maintenance operations.
13. Contract acceptor: person, company or external organization to enforce an operation on behalf of another person, company or organization.
14. Deviation: internal organization and responsibilities relative to the authorization to deviate from specified requirements due to a planned or unplanned and, in any case, temporary situation concerning one or several activities covered by the Good Manufacturing Practices.
15. Finished product: cosmetic product that has undergone all stages of production, including packaging in its final container, for shipment.
16. In-process control: controls performed during production in order to monitor and, if appropriate, to adjust the process to ensure that the product meets the defined acceptance criteria.
17. Internal audit: systematic and independent examination made by competent personnel inside the company, the aim of which is to determine whether activities covered by these guidelines and related results comply with planned arrangements and whether these arrangements are implemented effectively and are suitable for achieving objectives.
18. Major equipment: equipment specified in production and laboratory documents, which is considered essential to the process.
19. Maintenance: any periodic or unplanned support and verification operations designed to keep premises and equipment in proper working condition.
20. Manufacturing operation: set of operations from the weighing of raw materials to the making of the bulk products.
21. Out-of-specification: examination, measurement or test result that does not comply with the defined acceptance criteria.
22. Packaging operation: all packaging steps including filling and labeling, which a bulk product has to undergo in order to become a finished product.
23. Packaging material: any material employed in the packaging of a cosmetic product, excluding any outer packaging used for transportation. Packaging

materials are referred to as primary or secondary according to whether or not they are intended to be in direct contact with the product.

24. Plant: location for production of cosmetic products.
25. Premises and Facilities: physical location, buildings and supporting structures used to conduct receipt, storage, manufacturing, packaging, control and shipment of product, raw materials and packaging materials.
26. Production: manufacturing and packaging operations.
27. Quality assurance: all those planned and systematic activities necessary to provide confidence that a product satisfies the defined acceptance criteria.
28. Raw material: any substance going into or involved in the manufacturing of a bulk product.
29. Recall: decision made by a company to call back a product batch that has been put on the market.
30. Reprocessing: re-treatment of all or part of a batch of finished product or a bulk product of an unacceptable quality from a defined stage of production so that its quality may be rendered acceptable by one or more additional operations.
31. Return: sending finished cosmetic products which may or may not present quality defect back to manufacturing premises.
32. Sample: one or more representative elements selected from a set to obtain information about that set.
33. Sampling: set of operations relating to the taking and preparation of samples.
34. Sanitization: operation, used to reduce undesirable micro-organisms on inert contaminated surfaces depending on the objectives set.
35. Shipment: set of operations relative to the preparation of an order and its putting in a transport vehicle.
36. Waste: any residue of a production operation, transformation or use, any substance, material, product that its holder intends for disposal.

Article 3

The cosmetics manufacturing premises shall be regulated according to the public announced cosmetics categories listed in Paragraph 2 Article 8 of the Act.

Chapter 2 Management and Personnel

Article 4

The personnel in the cosmetics manufacturing premises shall have an

appropriate training to comply the quality of production, control and product storage operation.

Article 5

The personnel in the cosmetics manufacturing premises shall establish the organization according to the following:

1. Regulate the organization and to establish an organization chart to ensure the division of labor and competency according to the scale and diversity of its product of the manufacturing premises.
2. To ensure there are adequate staffing levels and well-trained as well as sufficient personnel in the different scope of activity according to its diversity of products.
3. The quality assurance unit and quality control unit shall be independent to other departments. The responsibility of quality assurance and quality control can be undertaken by a separate quality assurance unit and quality control unit or a single unit accordingly.

Article 6

The cosmetics manufacturing premises shall regulate the key responsibilities as follows:

1. Management level:
   (1) The organization shall be supported by the top management of the company to ensure the enforcement of these regulations.
   (2) To monitor the participation and commitment of the personnel at all level in the manufacturing premises for the following these regulations.
   (3) Management shall categorize the areas in which the authorized personnel are allowed to access.
2. Personnel in each department and each level:
   (1) To ensure the position and department in the organizational structure.
   (2) To ensure the scope of responsibilities.
   (3) To obtain the related documents within the scope of responsibilities, and follow the regulations indicates in the documents.
   (4) Comply with personal hygiene requirements according to Article 8.
   (5) To report the irregularities and other non-conformities.
   (6) To receive adequate educational training and skills to perform the activities and responsibilities.

Article 7

Personnel of the cosmetics manufacturer involved in production, control, storage and shipment shall acquire the appropriate abilities of working experience and training according to the responsibilities.

1. Appropriate training related to the activities in this regulation shall be provided to all personnel.
2. To ensure training needs of different levels and qualification of the personnel, and to conduct and enforce its related training program.
3. The training program shall be considered and developed according to the expertise, experience, and the scope of responsibilities of the personnel.
4. The cosmetics manufacturer may outsource to a professional group, if necessary, to develop and enforce training program according to the training needs and manufacturing premises resources.
5. The personnel shall receive training normally and continually, and the training content and program shall be updated regularly.
6. Newly recruited personnel shall receive theory and practical training related to this regulation, and specific training according to the duties assigned to them.
7. The effectiveness of receiving the training shall be evaluated during the training process or afterwards.

Article 8

The cosmetics manufacturer shall control the hygiene and health of the personnel, and the following regulation shall apply:

1. To establish and to adapt the need of a hygiene program, these requirements shall be understood and followed by all personnel who entered in the production, control and storage area.
2. Personnel shall be instructed to the hand washing facility.
3. Ensure the personnel who enter production, control and storage to wear appropriate clothing and protection outfit to avoid the contamination of cosmetic products.
4. Avoid the personnel from eating, drinking, chewing, smoking, or to store foods, drinks, smoking products or personal drugs in the production, control, and storage area.
5. Prohibit all the unhygienic practice in the production, control, storage area or in any other area where the product may be adversely affected.
6. Any person affected by an apparent illness or having open wound, a measurement shall be taken to be excluded from direct contact to the products until the condition is corrected or determined by medical personnel that the quality of cosmetic products will not be compromised.

Article 9

Visitor or untrained personnel shall be prohibited to enter production, control and storage area. However, if there is any necessity to enter these areas, they

shall be given related precaution in advance, including rules about personal hygiene and the prescribed protective clothing, and closely supervised.

Chapter 3 Premises and Facilities

Article 10

The location, design, construction, and use of the cosmetics manufacturing premises shall be regulated as follows:

1. To make sure the produces are protected.
2. May enforce effective cleaning. Sanitizing and maintenance shall be enforced when necessary.
3. To minimize the risk and control of mix-up of products, raw materials, and packaging materials.

The design of the premises mentioned in the preceding paragraph shall consider the type of the cosmetic product produced, existing condition, cleaning, sanitizing, and other necessary measures.

Article 11

The storage, production, quality control, ancillary, washing and toilets of the cosmetics manufacturing premises shall be separated of identified clearly.

Article 12

There shall be sufficient space to enforce operations such as receiving, storage, production or other related operations in the cosmetics manufacturing premises.

Article 13

The flow of the materials, products, and personnel through the building or between the buildings shall be planned properly to avoid any mix-ups in the cosmetics manufacturing premises.

Article 14

The design and construction of the cosmetics manufacturing premises shall be regulated as follows:

1. The design and construction of floors, walls, ceilings and windows of the production area, shall be implemented with smooth surfaces to tolerate cleaning agents and sanitizers. They shall be easy to clean and sanitized to maintain in a good condition.
2. The windows shall be non-opening design, except if there is insufficient ventilation in the buildings, shall set up with push out casement windows with screens.

Article 15

Sufficient and clean washing and toilet facilities shall be provided in the

cosmetics manufacturing premises. The facilities shall be separated from production area. Sufficient shower and clothes changing facilities shall be provided when necessary.

Article 16

The lighting of the cosmetics manufacturing premises shall be regulated as follows:

1. Sufficient lighting facilities shall be installed to provide the needs for operation.
2. The lighting facilities shall be installed properly or other measures be taken to make sure there will not be any fragments from potential breakage to contaminate the products.

Article 17

There shall be sufficient ventilation, or other specific measures to be taken to protect the products in the cosmetics manufacturing premises alternatively.

Article 18

The pipework, drains and ducts in the cosmetics manufacturing premises shall be regulated as follows:

1. Shall be installed properly to avoid any drip and condensation to contaminate the materials, products, equipment, and facilities.
2. Drains shall be kept flowing smoothly and without any back flow.
3. Exposed overhead rood beams, pipes and ducts shall be avoided. Exposed pipes shall be suspended by brackets or separated and not touch the walls for easy cleaning.
4. Specific measures to be taken to protect the products when necessary.

Article 19

The cleaning and sanitation of the facilities of the cosmetics manufacturing premises shall be regulated as follows:

1. To conduct a specific cleaning and sanitation plan for each area, and to keep it in a clean condition.
2. To enforce cleaning and necessary sanitation to ensure the products are not contaminated.
3. To identify the specific kinds of the cleaning agents and sanitizers, and to ensure they work effectively.

Article 20

The cosmetics manufacturing premises and facilities shall be repaired and maintained properly.

Article 21

The cleaning agents and lubricants cosmetics manufacturer used to clean,

sanitize or maintain premises and facilities shall not affect the quality of the products.

Article 22

The pest control in the cosmetics manufacturing premises shall be regulated as follows:

1. The design, construction, and maintenance of the premises shall be effective to avoid any insects, birds, pests, rodents and other vermin.
2. A pest control plan shall be conducted.
3. Measures shall be taken to prevent attracting pests at the exterior of the premises.

Chapter 4 Equipment

Article 23

Equipment in the cosmetics manufacturing premises shall meets the intended uses, and easy to clean, sanitize, and maintain if necessary.

Article 24

The equipment design in the cosmetics manufacturing premise shall meet the requirements as follows:

1. The production equipment shall be designed to prevent the products from being contaminated.
2. The container for bulk products shall come with the protection to avoid dusts, moisture and other air contaminants.
3. Transfer hoses and accessories shall be cleaned and sanitized if necessary, kept dry and protected properly from dusts, splash or other contamination.
4. The material of the equipment shall be compatible with the products, cleaning agents, and sanitizer.

Article 25

The installation of the equipment shall be regulated as follows:

1. The design and installation of the equipment shall be easy to drain in order to clean and sanitize.
2. The placement for the equipment shall consider the movement of materials, movement of mobile equipment, and personnel flow, not to pose a risk to the quality.
3. Appropriate access space under, inside and around the equipment shall be provided for cleaning and sanitizing.
4. The major equipment shall be easy to identify.

Article 26

The equipment calibration in the cosmetics manufacturing premises shall be regulated as follows:

1. Laboratory and production measuring instruments related to production quality shall be calibrated regularly.
2. If calibration results of measuring instruments do not meet the acceptance criteria, those shall be identified specifically and removed from service.
3. The condition set forth in the preceding subparagraph shall be investigated to confirm the impact to the production quality and to take appropriate measures afterwards according to the investigation result.

Article 27

The cleaning and sanitation of the equipment in the cosmetics manufacturing premises shall be regulated as follows:

1. All equipment shall be cleaned adequately. A Sanitation plan shall be established if necessary.
2. Cleaning agents and sanitizers shall be specifically identified and work effectively.
3. Where equipment is assigned for continuous production or production of successive batches of the same products, that equipment shall be cleaned and if necessary, a sanitizing period can be established to carry out.

Article 28

The equipment maintenance of the cosmetics manufacturing premises shall be regulated as follows:

1. The equipment shall be maintained regularly.
2. Maintenance operation shall not affect the quality of the products.
3. The defective equipment shall be identified accordingly and excluded from use and isolated, except for any unavoidable condition.

Article 29

The consumable uses for equipment in the cosmetics manufacturing premises shall not affect the quality of the products.

Article 30

The equipment or automated system in the cosmetics manufacturing premises used in production and control shall be access and used by authorized personnel.

Article 31

The cosmetics manufacturer shall prepare an adequate alternative back-up plan for operation system breakdown or failure.

Chapter 5 Raw Materials and Packaging Materials

Article 32

Raw materials and packaging materials purchased by the cosmetics manufacturer shall meet the acceptance criteria.

The acceptance criteria in the preceding paragraph shall be established based on the finished products quality requirements.

Article 33

Raw materials and packaging materials are purchased from the cosmetics manufacturer shall consider the following requirements:

1. The selection and evaluation of the supplier.
2. The establishments of technical clauses such as type of selection to be conducted, acceptance criteria, measures to take in the case of defect or modification, transport conditions or other related items.
3. Setting of the relations and interactions between the company and supplier such as questionnaire, assistance, and audit or other related items.

Article 34

The receiving of the raw materials and packaging materials of the cosmetics manufacturer shall be regulated as follows:

1. The records of the purchase order, the deliver notes and the receiving materials shall all match.
2. The integrity of the raw materials and packaging materials shall be checked. Transportation data shall be inspected if necessary.

Article 35

The raw materials and packaging materials identification and status in the cosmetics manufacturing premises shall be regulated as follow:

1. Shall be labelled in order to identify the material and batch information.
2. The raw materials and packaging materials shows defects that may affect the product quality shall be suspended hold for further decision.
3. The raw materials and packaging materials shall be identified and separated according to its status, such as accepted, rejected or quarantined. Those can be identified by using physical system of identification or others methods that can ensure the same level of identification.

The identification of the raw materials and packaging materials mentioned in the preceding paragraph shall include the following information:

1. Name of the product indicated on the delivery note.
2. Name of the products given by the company. If different from the name or code number given by the supplier, shall be indicated clearly.

3. Batch reference provided by the supplier and the one given at the receipt shall all be presented if there is any difference.
4. Name of the supplier.
5. Date and number of the receipt, if necessary.

Article 36

The release of the raw materials and packaging materials in the cosmetics manufacturing premises shall be regulate as follows:

1. To establish physical or other alternative system to ensure only released raw materials and packaging materials are used.
2. The release of the raw materials shall be enforced by authorized personnel who are responsible for the quality.
3. The analysis certificates provided by the supplier can be accepted as the acceptance criteria, only if the supplier possess the sufficient technology, experience and knowledge, and agree with the test methods adopted by the company, as well as the appropriate inspection and audit conducted by the company.

After measurement, when there are remaining released raw materials mentioned in the preceding paragraph, they shall be contained in a sealed container, labelled adequately and stored properly in the storage.

Article 37

The storage of the raw materials and packaging materials in the cosmetics manufacturing premises shall be regulated as follows:

1. Storage condition shall be set up properly to fit each raw materials and packaging materials. Monitoring and control measures shall be taken to maintain the specific storage if necessary.
2. The raw materials and packaging materials shall be stored and handled properly according to its characteristics.
3. The container of the raw materials and packaging materials shall be sealed and stored off the floor.
4. When repacking the raw materials and packaging materials, the content on the labels shall be identical to the original labels.
5. When raw materials and packaging materials are rejected or quarantined, they shall be stored at a certain location, or use other methods to ensure they can be identified.
6. To establish measures to ensure stock turnover, and stock rotation shall follow the rules of first in, first out.
7. Periodic inventory shall be performed to ensure the inventory information is correct. Any significant discrepancy shall be investigated and corrected.

Article 38

In order to prevent the misuse of materials after the defined period of storage, the cosmetics manufacturer shall establish a re-evaluation system for those materials to determine the suitability for use.

Article 39

The quality of water used in production shall be regulated as follows:

1. The water treatment system shall supply a defined quality of water.
2. The water quality shall be monitored or verified through water quality testing or process parameters.
3. The water treatment system shall permit sanitation.
4. The material used for the water treatment equipment shall be selected to ensure the water quality is not affected; the settlement of the water treatment equipment shall avoid any water stagnation or the risk of contamination.

Chapter 6 Production

Article 40

At each stage of manufacturing production, measures shall be taken to ensure the finished products meet the defined specification.

Article 41

The cosmetics manufacturer, according to the need of every manufacture operation stage, relevant documents and data shall be prepared and available. The documents are:

1. Equipment documents.
2. Formula for the products
3. List of all raw material with the quantities and identified batch numbers.
4. Detailed manufacturing process for each stage, including the addition of the raw materials, temperature, speeds, mixing time, sampling, cleaning, necessary sanitizing, transfer of bulk products and other related items.

Before starting any manufacturing process mentioned in the preceding paragraph, these items have to be ensure:

1. All the relevant documents related to manufacturing and all raw materials are prepared, available and released.
2. Equipment is able to use properly and has been through appropriate cleaning and sanitizing.
3. Operation area is cleaned to prevent from mixing any materials from the previous manufacturing operations.

The identification of the manufacturing operation mentioned in paragraph 1 shall be regulated as follows:

1. All raw materials measured and weighted according to the formula, and placed in a labelled, cleaned and suitable container, or directly put into the manufacturing equipment.
2. Major equipment, raw material containers, and bulk product containers shall be identified easily at any time.
3. The identification on the bulk product container shall include: Name or identification code, batch number and storage condition when such information is critical to assure the quality of the products.

Manufacturing process mentioned in the preceding paragraph shall be regulated as follows:

1. Establish a manufacturing process control plan includes acceptance criteria and to enforce it.
2. To enforce the plan mentioned in the preceding sub-paragraph. Any result does not meet the acceptance criteria shall be and reported and investigated according to the procedure.

Article 42

Every batch of manufactured bulk products shall be assigned a batch number. When the batch number is different from the numbers on the finished products, it shall be easy to identified and related to each other.

The storage of the bulk products mentioned in the preceding paragraph shall be regulated as follows:

1. Use the proper container for to store, and to place it at a specific location with adequate condition.
2. Set up a defined period of storage.
3. Bulk products shall be re-evaluated and not allowed to use when passed the defined period of storage.

Article 43

The cosmetics manufacturer, According to the needs for every stage of packaging operations, the following relevant documentations and data shall be available:

1. Equipment documents.
2. Lists of packaging materials.
3. Operation details in every stages including filling, sealing, labeling, coding or other items.

Before starting any packaging operation mentioned in the preceding paragraph, it shall be ensure that:

1. Prepare the documentations and data listed in the preceding paragraph.
2. Equipment is able to use properly and has been through appropriate cleaning and sanitizing.
3. Operation area is cleaned to prevent from mixing any materials from the previous manufacturing operations.
4. Finishing the establishment of the numbering for product identification information.

Every batch of manufactured bulk products shall be assigned a batch number. When the batch number is different from the numbers on the finished products, it shall be easy to identified and related to each other.

During the packaging operation, according to the actual process, Identification information shall be placed on each operation line; the information includes:

1. Name and identification code of the packaging operation line.
2. Name and identification code of the finished products.
3. Batch number.

The unused packaging materials shall be placed in a sealed container and labelled properly. Then it can be restored to the storage.

When filling and labelling operation does not complete at once, measures such as quarantine and identification shall be taken to avoid mix-up or mislabeling.

Article 44

The packaging mentioned in the preceding article, the in-process control shall be regulated as follows:

1. To establish an in-process control plan including acceptance criteria, and to enforce it.
2. Any result does not meet the acceptance criteria shall be and reported and investigated according to the procedure.

The control mentioned in the preceding paragraph, including those who use on-line control equipment shall be checked regularly according to the established period, items and content.

Chapter 7 Finished Products

Article 45

The finished products of the cosmetics shall meet the acceptance criteria.

The cosmetics manufacturer shall use proper storage, shipment and return methods to ensure the quality of the finished products.

Article 46

The release of finished products shall be regulated as follows:

1. Before releasing to the market, all finished products shall be controlled to make sure to meet to acceptance criteria according to the established test methods.
2. The release of the finished products shall be enforced by authorized personnel who are responsible for the quality.

Article 47

The storage of the finished products shall be regulated as follows:

1. The finished products shall be stored in a specific area in a systematic method according to the storage condition and duration. They shall be monitored and controlled, if necessary.
2. The finished products shall be categorized into release, quarantine or reject and they shall be stored at a certain location, or other ways to ensure they can be identified.
3. The identification of the finished products shall include:
   (1) Name or identification code, batch number and quantity.
   (2) The critical storage condition to assure the quality of the finished products.
4. To establish measures to ensure stock turnover, and stock rotation shall follow the rules of first in, first out.
5. Periodic inventory shall be performed to ensure the list of inventory and quantities are complying with the inventory acceptance criteria. Any significant discrepancy shall be inspected and corrected.

Article 48

Cosmetics manufacturer shall adopt the proper protective measures of shipping methods in order to maintain the quality of the finished products during the shipping process.

Article 49

Cosmetics manufacturer shall handle the returned products according to following the regulations:

1. To identify in a proper way and to store in a specific area.
2. To decide the handling method according to the established evaluation standard.
3. For resale products, shall be handled according to the release procedure.
4. To establish measures to effectively distinguish the reprocessing return, to avoid re-distribution without going through the release procedure.

Chapter 8 Quality Control Laboratory

Article 50

Quality control laboratory shall apply mutatis mutandis to regulations of Chapter 2 Management and Personnel, Chapter 3 Premises and Facilities, Chapter 4 Equipment, Chapter 11 Contracting, Chapter 16 Documentation.
Quality control laboratory mentioned in the preceding paragraph shall enforce sampling and testing to the cosmetics materials and the finished products. When conducting sampling, testing or other related activities, related control shall be enforced in order to make sure the materials for use complies with the defined acceptance criteria. Packaging and shipping may be approved when the finished products are complying with the defined acceptance criteria.

Article 51

The test methods mentioned in Paragraph 2 of the preceding article shall be clear, appropriate and workable.
The acceptance criteria mentioned in Paragraph 2 of the preceding article shall be defined and established according to types the raw materials, packaging materials, bulk products, and finished products from Quality control laboratory.

Article 52

Test results conducted from quality control laboratory mentioned in the preceding 2 articles shall be reviewed. Decisions of approval shall be made when results complies with the relevant provisions after review; However, rejection or pending shall be made when results does not complies with the relevant provisions after review according to the rules regulated in Article 53.

Article 53

Out-of-specification shall be regulate as follows:

1. Out-of-specification results shall be reviewed and investigated properly by the responsible personnel. Re-testing shall not be performed except with a sufficient and legitimate reason.
2. After the review mentioned in the preceding subparagraph, the decisions shall be made according to the previous article after reviewed as deviation or not.

Article 54

Reagents, solutions, reference standards and culture media shall, at least, be labelled identification information such as name and opening date. If necessary, shall include strength or concentration, storage condition, expiration date, and the name or signature of the person who prepared.

Article 55

The cosmetics manufacturing premises shall perform sampling operation by authorized personnel according to the established sampling operation plan.

The operation plan mentioned in the preceding paragraph shall include the following:

1. Sampling methods.
2. Equipment to be used.
3. Number of the samples.
4. Any precautions to be observed to avoid samples from contamination and deterioration.
5. Identification information of sample.
6. Sampling frequency.

Article 56

Identification information of sample mentioned in Subparagraph 5 of Paragraph 2 of the preceding article shall include the following:

1. Name or identification code.
2. Batch number.
3. Sampling date.
4. The container from which the sample was taken.
5. The sampling point, if applicable.

Article 57

The retention sample shall be regulated as follows:

1. The sample of the finished products shall be retained properly in a specific area.
2. The amount of the retain samples of the finished products shall be sufficient enough to enforce analysis.
3. The samples of the finished products shall be retained with the complete packaging, and retain for an appropriate period according to the storage condition.
4. The samples of the raw materials shall be retained according to the regulations of the manufacturing premises or other relevant regulations.

Chapter 9 Treatment of Product that is Out of Specification

Article 58

The treatment of rejected finished products, bulk products, raw materials and packaging materials of the cosmetics manufacturer shall be regulated as follows:

1. Investigation of rejected products or materials shall be conducted by authorized personnel.

2. Decisions from quality control related authorized personnel to be made to determine any further action of the rejected items including destroying or reprocessing.

Article 59

The reprocessing of the finished products and bulk products according to subparagraph 2 of the preceding article shall be regulated as follows:

1. The performance of reprocessing shall be approved by the quality control related authorized personnel.
2. The method for reprocessing shall be approved by the responsible authorized personnel.
3. To enforce control of finished products and bulk products after re-processing and to be reviewed by the authorized personnel in order to ensure to comply with the defined acceptance criteria.

Chapter 10 Waste

Article 60

The cosmetics manufacturer shall dispose the wastes in a proper and sanitary manner.

Article 61

The cosmetics manufacturer shall identify and categorize the type of waste that may affect the product quality clearly according to the information of production and quality control laboratory.

Article 62

The waste disposal shall be regulated as follows:

1. The flow of the waste disposal shall not affect the operation of production and laboratory.
2. Appropriate measures shall be taken concerning collection, transportation, storage and disposal of the wastes.

Article 63

The containers for waste shall be properly identified as to the contents and other information.

Article 64

The cosmetics manufacturer shall dispose the wastes in a proper way with adequate level of control according to subparagraph 2 of Article 62.

Chapter 11 Contracting

Article 65

The cosmetics manufacturer may appoint these items, including manufacture, packaging, analysis, pest control, cleaning and sanitizing of the premises, and maintenance of the equipment and premises and other related items, to agencies, natural persons, schools, institutions, judicial persons or groups.
The contracting mentioned in the preceding paragraph which means the contract giver shall establish a written contract or agreement with the contract acceptor to indicate the objectives, obligations, responsibilities and contract performance management in the written documents, in order to ensure the products being made or the service being provided can meet the requirements from the cosmetics manufacturer.
The contract acceptor shall retain or provide all the information related the contract of the preceding paragraph to the contract giver.

Article 66

When the cosmetics manufacturer conduct the contracting in the preceding article, the contracting should be regulated as follows:

1. To evaluate the performance ability, legal compliance and productivity of the contract acceptor, to ensure they have all the abilities to enforce the contract and to assure all the contracting items can be carried out according to the contract.
2. To provide the contract acceptor with all the necessary information.

Article 67

The contract acceptor shall be regulated as follows:

1. To ensure the method of performance, experience, and personnel abilities are capable to carry out the requirements indicated in the contract.
2. The contract acceptor shall not out-source the items listed in the contract to the third party, except with the approval from the cosmetics manufacturer; with the approval, the contract acceptor and the third party shall conduct another agreement to ensure the cosmetics manufacturer obtain all the operation information according to the original contract or agreement.
3. To cooperate with the cosmetics manufacturer to conduct investigation and to audit according to the contract or agreement.
4. Except with another agreement in addition to the contract or agreement, or with the approval from the cosmetics manufacturer, the contract acceptor cannot make any change to the contract items which may affect the products or service quality.

Chapter 12 Deviation

Article 68

When the cosmetics manufacturer discovers any deviations, the decisions shall be made according to the support of sufficient data.

Article 69

The cosmetics manufacturer shall take corrective action to prevent recurrence of the deviation.

Chapter 13 Complaints and Recalls

Article 70

Cosmetics manufacturer shall review, investigate and follow-up on, as appropriate when handling product complaints.

Article 71

Cosmetics manufacturer shall handle product complaints according to the following regulations:

1. To assign authorized personnel to handle complaints.
2. The handling of complaints and all the detailed shall be recorded and preserved.
3. Appropriate follow-up on the concerning batch shall be completed.
4. The investigation and follow-up of the complaints shall include:
    (1) Measures to be taken to prevent any recurrence of defect.
    (2) To check other batch of the products to ensure whether if they are affected.
5. The amount and content of complaints shall be reviewed periodically, to ensure for trends or recurrence of defect.

Article 72

When there is contracting for cosmetics manufacturing, the manufacturer and contract acceptor shall handle the complaints under the established contracts or agreements and not to violate the regulations of the previous 2 articles.

Article 73

Recall of the products shall be regulated as follows:

1. Appropriate measures shall be taken and to enforce the correction according to these regulations.
2. The responsible personnel shall negotiate the recall process.
3. The operation of the product recall shall be initiated promptly and in a timely manner.
4. The related authorities shall be notified of recalls which might cause the impact of consumer safety.
5. The recalled products shall be identified and stored in a safe area.
6. The product recall process shall be reviewed and evaluated periodically.

Chapter 14 Change Control

Article 74

When there is any change to be done which might affect the product quality, the cosmetics manufacturer shall assign authorized personnel to check and approve with sufficient data support.

Chapter 15 Internal Audit

Article 75

The Cosmetics manufacture premises shall enforce internal audit in order to comply with these regulations, and take necessary corrective measures according to the results of internal audit.

Article 76

The enforcement of internal audit mentioned in the preceding article shall be regulated as follows:

1. To assign a responsible competent personnel to conduct internal audit independent and detailed manner, periodically or on demand.
2. Observed results from internal audit shall be evaluated and notify the appropriate management.

Article 77

The cosmetics manufacturer shall ensure the corrective measures mentioned in Article 75 are achieved or implemented.

Chapter 16 Documentation

Article 78

The cosmetics manufacturer shall design, establish, install and maintain its own documentation systems according to its organization structure and the type of the products.

The documentation systems mentioned in the preceding paragraph is an internal part of Good Manufacturer Practices. The documentation shall record all the operation activities according to these regulations to prevent risks of misinterpretation, loss of information, confusions or error.

Electronic systems may be established and managed documents mentioned in the documentation systems in Paragraph 1.

Article 79

The content of documentation systems mentioned in the preceding article shall include: procedures, instructions, specifications, protocols, reports, methods, and records.

The content of the documentation mentioned in the preceding paragraph shall be kept in hard-copy papers or electronic data processing records.

Article 80

All activities in these regulations such as operation details, measures to be taken, and precautions to be taken shall be detailed documented. The title, nature and purpose shall be stated in every document.

Documents mentioned in the preceding paragraph shall be written legibly and comprehensively. The authorized responsible personnel shall sign and indicate the date as approval before the announcement, and update, annul, distribute, and archive accordingly.

The documents mentioned in Paragraph 1 shall be obtained from the appropriate personnel in the company, and to ensure the annulled documents are deleted, destroyed and not being used again.

Article 81

The required hand written records in the documentation mentioned in Paragraph 1 Article 79 shall be regulated to write legibly with permanent ink. The recorder shall sign and indicated the date of the record. Any correction shall require the same consent.

The correction of the written records mentioned in the preceding paragraph shall leave the original entry readable, if necessary, the reason of the correction shall be recorded.

Article 82

The documents shall be updated if necessary. For those are updated, shall indicate the revision number and the reasons for each revision shall be retained.

Article 83

Archiving of the documentation shall be regulated as follows:

1. The controlled copies each revision of the documents mentioned in the preceding articles shall be used, and the original records shall be archived.
2. The duration of archiving original documents shall be defined according to the related regulations.
3. The storage of original documents shall be properly secured.
4. The documents shall be stored electronically or as hard-copy papers, and to ensure their legibility.
5. The documents shall be back-upped regularly and stored in a separated safe location.