[Rev. 11/22/2013 9:46:21 AM--2013]
[NAC-585 Revised Date: 4-12]

CHAPTER 585 - DRUGS AND COSMETICS

COSMETICS

NAC 585.700 Definitions. (NRS 585.210, 585.245) As used in NAC 585.700 to 585.840, inclusive, unless the context otherwise requires:

1. "Batch" means a specific quantity of a cosmetic which has a uniform character and quality within specified limits and is produced according to a single manufacturing order during a cycle of manufacture.
2. "Control number" means any distinctive combination of letters or numbers, or both, from which the complete history of the manufacturing, control, packaging and distribution of a lot can be determined.
3. "Licensee" means a person who is licensed by the Commissioner to manufacture, process or package cosmetics.
4. "Lot" means a batch or any portion of a batch of a cosmetic or, if the cosmetic is produced in a continuous process, any amount of the cosmetic produced in a unit of time or quantity in a manner that ensures its uniformity.

[Comm'r of Food & Drugs, Cosmetics § 2, eff. 12-16-82]

NAC 585.705 Use, inspection of equipment. (NRS 585.210, 585.245) A licensee may use precision, automatic or electronic equipment to manufacture, process or package cosmetics if the licensee adequately inspects and checks the equipment to ensure its proper performance.

[Comm'r of Food & Drugs, Cosmetics § 3, eff. 12-16-82]

NAC 585.710 Qualifications of employees. (NRS 585.210, 585.245) A licensee shall ensure that:

1. Employees who are responsible for directing the manufacture and control of a cosmetic have sufficient education, training and experience, or a combination thereof, to ensure that the cosmetic will have the safety, identity, quality and purity that it purports or is represented to possess.
2. Employees must have capabilities which are commensurate with their assigned duties, a thorough understanding of the manufacturing or control operations they perform, the appropriate training or experience and adequate information concerning the reasons for statutes and regulations relating to the manufacture of cosmetics.

[Comm'r of Food & Drugs, Cosmetics § 4, eff. 12-16-82]

NAC 585.715 Exclusion of persons with illness or open lesions. (NRS 585.210, 585.245) A licensee shall exclude from direct contact with any cosmetic any person shown at any time, either by medical examination or supervisory observation, to have an apparent illness or open lesion that may adversely affect the safety or quality of the cosmetic until the condition is corrected.

[Comm'r of Food & Drugs, Cosmetics § 5, eff. 12-16-82]

NAC 585.720 Report on adverse effects. (NRS 585.210, 585.245) A licensee shall instruct all of his or her employees to report to their supervisor any conditions that may have an adverse effect on any cosmetic.

[Comm'r of Food & Drugs, Cosmetics § 6, eff. 12-16-82]

NAC 585.725 Buildings used to manufacture cosmetics: Condition; size, construction, location; separate rooms. (NRS 585.210, 585.245)

1. A licensee shall maintain in a clean and orderly condition the buildings used to manufacture cosmetics. The buildings must be of suitable size, construction and location to facilitate adequate cleaning, maintenance and proper operations in the manufacturing, processing, packing, labeling and storage of a cosmetic.
2. The licensee shall provide any separate rooms which are necessary to prevent a cosmetic product from being contaminated by another.

[Comm'r of Food & Drugs, Cosmetics § 7, eff. 12-16-82]

NAC 585.730 Buildings used to manufacture cosmetics: Space. (NRS 585.210, 585.245) A licensee shall use buildings to manufacture cosmetics which have adequate space for:

1. The orderly placement of equipment and materials to minimize the risk of contamination and confusion between different components, materials in process, packaging materials or labeling materials.
2. The storage of components, containers, packaging materials and labeling materials.

3. Any manufacturing and processing operation.
4. Any packaging or labeling operation.
5. The storage of finished products.
6. The control of production and laboratory operations.

[Comm'r of Food & Drugs, Cosmetics § 8, eff. 12-16-82]

NAC 585.735 Buildings used to manufacture cosmetics: Lighting, facilities; water; sewage disposal. (NRS 585.210**,** 585.245**)** A licensee shall provide in a building used to manufacture cosmetics:

1. Adequate lighting of at least 50 foot-candles, and ventilation and screening, if necessary, to:

(a) Minimize the contamination of products by extraneous adulterants, including the cross-contamination of one product by dust or particles or ingredients arising from the manufacture, storage or handling of another product;

(b) Minimize the dissemination of micro-organisms from one area to another; and

(c) Maintain suitable conditions for the storage of components, materials in process and finished cosmetics.

2. Adequate lockers and facilities near working areas with soap and hot and cold water for washing hands.

3. An adequate supply of potable water under continuous positive pressure in a plumbing system which is free of defects that could cause or contribute to the contamination of any cosmetic. Drains must be of adequate size and, where connected directly to a sewer, must be equipped with traps to prevent back siphonage.

4. For the safe and sanitary disposal of sewage, trash and other refuse within and from the building and immediate premises.

[Comm'r of Food & Drugs, Cosmetics § 9, eff. 12-16-82]

NAC 585.740 Equipment. (NRS 585.210**,** 585.245**)**

1. A licensee shall maintain in a clean and orderly condition all equipment used in the manufacturing, processing, packaging, labeling, holding, testing or controlling of cosmetics. The equipment must be of a suitable design, size, construction and location to facilitate cleaning, maintenance and operation for its intended purpose.

2. Any equipment must:

(a) Be constructed so that all surfaces which come into contact with a cosmetic are not reactive, additive or absorptive in a way which alters the safety, quality or purity of the cosmetic;

(b) Be constructed and installed to facilitate adjustment, disassembly, cleaning and maintenance and to ensure uniformity of production and the exclusion from the cosmetics of contaminants from previous and current operations that might affect the safety and quality of the cosmetics; and

(c) Be of a suitable type, size and accuracy for any testing, measuring, mixing, weighing or other processing or storage.

[Comm'r of Food & Drugs, Cosmetics § 10, eff. 12-16-82]

NAC 585.745 Submission, approval of plan to construct, remodel plant. (NRS 585.210**,** 585.245**)**

1. If, after December 16, 1982, a plant for manufacturing cosmetics is constructed or extensively remodeled, or an existing structure is converted for such a use, an applicant must submit plans to the Commissioner for his or her approval before the work is begun.

2. The plans must include:

(a) The layout and arrangement of the plant;

(b) The materials to be used in construction; and

(c) The location, size and type of any fixed equipment and facilities.

3. The Commissioner's approval of a plan does not constitute his or her final approval of the facility. An actual inspection of the completed facility must be made before a final approval will be given to the applicant. Until such inspection is made and final approval of the facility is granted, the Commissioner will not issue a license.

[Comm'r of Food & Drugs, Cosmetics § 11, eff. 12-16-82]

NAC 585.750 Procedures for production and control. (NRS 585.210**,** 585.245**)**

1. The procedures for the production and control of cosmetics which are adopted by a licensee must include all reasonable precautions, including those contained in this section, to ensure that the cosmetics which are produced will have the safety and quality which they purport or are represented to possess.

2. Each significant step in the manufacturing process, such as the selection, weighing or measuring of components, the addition of ingredients during the process and the determination of the finished yield, must be performed by a competent and responsible person. If these steps are controlled by precision, automatic, mechanical or electronic equipment, the proper performance of the equipment must be adequately checked by at least one competent and responsible person.

3. Each container, line and piece of equipment used during the production of a batch must be properly identified at all times to show accurately and completely its contents and, when necessary, the stage of the processing of the batch.

4. To minimize contamination and prevent confusion, all equipment, utensils and containers must be thoroughly and appropriately cleaned and properly stored. The identification marking for the previous batch must be removed between batches or at suitable intervals during a continuous production.

5. A licensee shall establish appropriate procedures:

(a) To minimize the cross-contamination of cosmetics while they are being manufactured or stored.

(b) For the review and approval of all records concerning production control, including those for packaging and labeling, before the release or distribution of any batch.

[Comm'r of Food & Drugs, Cosmetics § 12, eff. 12-16-82]

NAC 585.755 Components: Storage, handling; conformance with specifications. (NRS 585.210, 585.245**)**

1. A licensee shall store and handle in a safe, sanitary and orderly manner, all components and other materials used in the manufacturing, processing and packaging of cosmetics and all materials necessary for the maintenance of the buildings and equipment.

2. A licensee may not use any component until it has been identified and examined for conformance with the specifications of the product.

[Comm'r of Food & Drugs, Cosmetics § 13, eff. 12-16-82]

NAC 585.760 Components: Examination; testing. (NRS 585.210, 585.245**)** A licensee shall:

1. Visually examine each container of components before the components are used to detect any damage or contamination.

2. Appropriately examine samples of components which are susceptible to contamination by filth, insects or other extraneous contaminants.

3. Subject the final product to microbiological tests. The product shall not contain microorganisms that are objectionable.

4. Handle and store approved components in such a manner as to guard against their contamination by other cosmetics or components.

[Comm'r of Food & Drugs, Cosmetics § 14, eff. 12-16-82]

NAC 585.765 Containers. (NRS 585.210, 585.245**)** The containers which are used by the licensee for his or her products and their components must not be reactive, additive or absorptive so as to alter the safety or quality of the cosmetic. The containers must provide adequate protection against any element which can cause the deterioration or contamination of the cosmetic.

[Comm'r of Food & Drugs, Cosmetics § 15, eff. 12-16-82]

NAC 585.770 Laboratory controls. (NRS 585.210, 585.245**)** A licensee shall include in his or her laboratory controls, provisions for:

1. The establishment of scientifically sound and appropriate specifications and testing procedures to ensure the quality of the finished cosmetic.

2. Verifying the reliability and accuracy of the laboratory testing procedures and instruments which are used.

3. The retention of a properly identified sample of each finished cosmetic. The sample must be stored in a container which is identical to the container in which the cosmetic is marketed. The sample must contain at least twice the quantity necessary to perform all tests performed, except for net weight content, to ensure quality. The licensee shall retain the sample for at least 2 years.

4. The retention of complete records of all laboratory data relating to each lot for at least 1 year after the distribution of the lot is completed.

[Comm'r of Food & Drugs, Cosmetics § 16, eff. 12-16-82]

NAC 585.775 Packaging and labeling. (NRS 585.210, 585.245**)**

1. A licensee shall control his or her packaging and labeling operations to:

(a) Ensure that only cosmetics which meet the standards and specifications established in the master record of production and control are distributed;

(b) Prevent confusion during filling, packaging and labeling operations;

(c) Ensure that correct labels and labeling materials are used; and

(d) Identify each finished product with a control number that permits the determination of the history of the manufacture and control of the batch.

2. The licensee may use a code for the day or for the shift as a number for cosmetics which are manufactured or processed by equipment which is used in continuous production.

3. The licensee may not use labels for containers and package labeling until they have been reviewed and proofed against an approved final copy by a competent and responsible person. The person shall ensure that they are accurate regarding identity and content and in conformity with the approved copy before they are released for distribution. The licensee shall establish a suitable system for ensuring that only current labels for containers and package labeling are retained and that obsolete labels and package labeling are destroyed.

[Comm'r of Food & Drugs, Cosmetics § 17, eff. 12-16-82]

NAC 585.780 Master record of production and control. (NRS 585.210, 585.245)

1. To ensure the uniformity of batches, a licensee shall prepare a master record of production and control for each cosmetic and each batch.

2. The record must be dated and signed or initialed by a competent and responsible person and must include:

(a) The name and weight or measure of each ingredient.

(b) A complete list of ingredients, designated by names or codes which are sufficiently specific to show any special characteristic of quality, including statements concerning:

(1) Any calculated amount of excess of an ingredient;

(2) The theoretical weight or measure at the various stages of processing; and

(3) The theoretical yield.

(c) A description of the containers, closures and packaging of finished materials.

(d) The instructions regarding manufacturing and control, and the procedures, specifications, and special notations and precautions to be taken.

[Comm'r of Food & Drugs, Cosmetics § 18, eff. 12-16-82]

NAC 585.785 Records of batches. (NRS 585.210, 585.245)

1. A licensee shall prepare a record which is readily available containing complete information concerning the production and control of each batch which he or she produces.

2. The licensee shall retain the record for at least 2 years after the distribution of the batch has been completed.

3. The record must:

(a) Identify the specific labeling and control numbers used on the batch; and

(b) Note the number that identified all of the documents concerning the production, control and history of the batch and all other control numbers associated with the batch.

[Comm'r of Food & Drugs, Cosmetics § 19, eff. 12-16-82]

NAC 585.790 Records of distribution of lots. (NRS 585.210, 585.245)

1. A licensee shall include in the procedures for the control and distribution of finished goods, a record system by which the distribution of each lot can be readily determined to facilitate the recall of a cosmetic, if necessary. The records must contain the name and address of the consignee, the date of each shipment, the quantity shipped and the lot or control number of the cosmetic. The licensee shall retain these records for at least 2 years after the distribution of the cosmetic has been completed.

2. The licensee shall establish a system whereby the licensee's oldest approved stock is distributed before newer stock is distributed, whenever possible.

[Comm'r of Food & Drugs, Cosmetics § 20, eff. 12-16-82]

NAC 585.795 Records of complaints. (NRS 585.210, 585.245) A licensee shall maintain records of all written and oral complaints he or she receives regarding each product and shall notify the Commissioner immediately upon the receipt of any such complaint.

[Comm'r of Food & Drugs, Cosmetics § 21, eff. 12-16-82]

NAC 585.800 Qualifications of applicant for license. (NRS 585.210, 585.245) The Commissioner will not issue a license pursuant to NRS 585.245 unless the applicant has satisfied the Commissioner that the applicant is competent and has adequate business experience to conduct the activity for which the application for a license is made.

[Comm'r of Food & Drugs, Cosmetics § 22, eff. 12-16-82]

NAC 585.805 Application for license. (NRS 585.210, 585.245)

1. Any person who desires to operate a plant for the manufacture of cosmetics must submit to the Commissioner an application for a license.

2. The applicant must provide the Commissioner with complete information regarding the ownership of the plant and report promptly all significant changes in its ownership.

3. A corporate applicant must provide the Commissioner with the name and address of each of its officers and managers. An applicant who is not a corporation must provide the Commissioner with the name and address of each of the applicant's managerial employees. Each applicant must notify the Commissioner of any change in this information.

4. The applicant must:

(a) State the proposed hours of operation of the plant and notify the Commissioner of any change in the hours of operation.

(b) Submit the formula of the cosmetic he or she intends to manufacture, including all components, to the Commissioner for review and approval.

(c) Satisfy the Commissioner of his or her ability to meet the requirements of NAC 585.700 to 585.740, inclusive, of this regulation before the Commissioner will issue any license.

[Comm'r of Food & Drugs, Cosmetics § 23, eff. 12-16-82]

NAC 585.810 Denial, suspension, revocation of license. (NRS 585.210, 585.245)

1. The failure or refusal of an applicant or a licensee to comply with any applicable statutes or regulations is a ground for the denial, suspension or nonrenewal of a license.

2. The Commissioner will include in the notice of any denial, suspension, revocation or nonrenewal of a license the legal authority and reasons for the action. The Commissioner will send the notice to the applicant or licensee by certified mail within 10 days after the action is taken.

[Comm'r of Food & Drugs, Cosmetics § 24, eff. 12-16-82]

NAC 585.815 Fees; renewal of license. (NRS 585.210, 585.245)

1. An applicant must pay an initial licensing fee of $300 to the Commissioner before a license will be issued. The Commissioner will prorate an initial licensing fee for the period from the date of the issuance of the license until the end of the fiscal year.

2. A license is effective until June 30 of the fiscal year in which it is issued and must be renewed by July 1 of each year. The renewal fee is $300. In certain cases, the Commissioner may prorate a renewal fee for part of a fiscal year. An application for the renewal of a license must be received by the Commissioner at least 30 days before the expiration of the license.

3. The fees collected pursuant to this section will not be refunded.

[Comm'r of Food & Drugs, Cosmetics § 25, eff. 12-16-82]

NAC 585.820 Inspections. (NRS 585.210, 585.245)

1. The Commissioner will make an initial inspection of an applicant's plant before a license is granted and will make such an inspection at least annually. The Commissioner will make such additional inspections as he or she deems necessary for the enforcement of chapter 585 of NRS and this regulation.

2. The Commissioner will give to the licensee a written report of the findings of any inspection the Commissioner makes at the licensee's factory, warehouse or plant.

[Comm'r of Food & Drugs, Cosmetics § 26 + part § 27, eff. 12-16-82]

NAC 585.825 Examination of records. (NRS 585.210, 585.245) A licensee shall permit the Commissioner to examine the records of the establishment to obtain information which is pertinent to the licensee's operation.

[Comm'r of Food & Drugs, Cosmetics part § 27, eff. 12-16-82]

NAC 585.830 Federal regulations adopted by reference. (NRS 585.210, 585.245) Parts 700 to 740, inclusive, of Title 21 of the Code of Federal Regulations, as those regulations existed on April 1, 1982, are hereby adopted by reference. A copy of the volume containing these parts may be obtained by mail from the Superintendent of Documents, U.S. Government Printing Office, P.O. Box 979050, St. Louis, Missouri 63197-9000, or by telephone at (866) 512-1800, for the price of approximately $6.

[Comm'r of Food & Drugs, Cosmetics § 28, eff. 12-16-82]

NAC 585.835 Exemptions. (NRS 585.210, 585.245)

1. A licensee may petition the Commissioner for an exemption from a particular provision of NAC 585.700 to 585.840, inclusive.

2. The petition must contain:

(a) The section for which the licensee requests the exemption; and

(b) Facts sufficient to show the Commissioner that, because of the harmless nature of the cosmetic the licensee manufactures, the section should not apply.

3. A decision by the Commissioner is final and may not be appealed.

[Comm'r of Food & Drugs, Cosmetics § 29, eff. 12-16-82]

NAC 585.840 Severability. (NRS 585.210**,** 585.245**)** If any provision of NAC 585.010 to 585.840, inclusive, or any application thereof to any person, thing or circumstance is held invalid, the Commissioner intends that the invalidity not affect the remaining provisions or applications to the extent that they can be given effect.

[Comm'r of Food & Drugs, Cosmetics § 30, eff. 12-16-82]