

4.1 INTRODUCTION:

The following information provides the essence of what Good Manufacturing Practices (GMP) are all about; i.e., conducting manufacturing operations in such a manner that protects all products produced from contamination or from the potential of becoming contaminated.

To meet these principles, it will take the interest, cooperation, and alertness of all employees. Operators, shippers, maintenance personnel, managers, and staff must work together to assure that GMP requirements are met.

4.2 OPERATING PROCEDURES:

Each production unit shall maintain standard operating procedures (SOP's). Operators shall be familiar with these instructions and observe the requirements thereof. These procedures should include specific reaction details (e.g. quantities, control parameters, etc.), operating instructions of major equipment/systems (Initial startup, normal operations, normal shutdown, temporary operations, and start up after normal , emergency and turnarounds),, process flow diagrams, raw material handling instructions, and product specifications. Revisions should be issued periodically reflecting any changes or improvements in the daily operating procedures.

4.3 SAFETY POLICIES AND PROCEDURES:

Specific safety policies and procedures shall be maintained to ensure the safe conduct of all employees. Each individual has an obligation to comply with these policies and procedures to provide the maximum, reasonable level of safety and health within the plant.

Appendix 4.0 contains plant safety requirements, policies and procedures.

4.4 PROCESS AND CONTROLS:

All operations should comply with adequate operating practices to guard against product contamination.

Appropriate quality control measures shall be employed to determine that raw materials and products are suitable for their intended usage.

Raw materials, other ingredients and rework material should be properly labeled and held in vessels (with lids) suitable to protect against contamination.

All equipment used to handle, process or hold raw materials, work-in-process, or finished products should be constructed in such a manner that protects against contamination.

Contaminated product or raw materials shall be disposed of in a manner that does not affect other materials.

4.5 CLEANING OPERATIONS:

Plant facilities shall be maintained in a good condition to prevent product contamination.

Cleaning substances used should be free of contamination, safe for use, and adequate to do the job. Effective measures to guard against product contamination by pests shall be taken.

Product-contact surfaces and work implements shall be cleansed as necessary to prevent product contamination.

4.6 PEST CONTROL:

The pest control program shall be administered by the Regulatory Department. A pest control contractor licensed by the State of New York shall perform the pest control duties. The contractor shall use Catchalls, Glue Boards, and Exterior Bait stations to control pests. The contractor shall report his findings to the Manager of Quality Assurance & Regulatory Affairs on a monthly basis. The Regulatory Department will use this information to assess the pest control status.

4.7 WAREHOUSING AND DISTRIBUTION:

Storage and transportation of finished products shall be done under conditions that protect product from physical, chemical, or pest contamination.

Approved products shall be properly identified and stored away from rework or contaminated material (also properly labeled).

4.8 GLASS & BRITTLE PLASTIC

Niacet Corporation maintains a Glass and Brittle Plastics Policy that is consistent with Good Manufacturing Practices. The purpose of the program is to control any risks that are associated with the use of glass and brittle plastics that cannot be effectively protected or replaced with alternative materials, and are therefore required in the plant environment. Such items may include thermometers, site glass, windows, signal lights, glassware used for chemical tests, etc.

Niacet's policy includes the following elements:

- *Identification of glass and brittle plastic materials in the plant.*
- *Elimination or adequate protection of materials.*
- *Inventory and inspection of materials that cannot be protected.*
- *Action plan to handle any breakage that may occur*
- *Prevention of employees or contractors bringing materials into our facility*
- *Universal authority for reporting glass/brittle plastic breakage incidents.*
- *Defined authority for managing the program*
- *Audit and review of the program for effectiveness during Monthly Unit Safety Training meetings.*

4.9 CLOTHING & JEWELRY POLICY

- 1.) *Safety shoes with steel toe or equivalent protection must be worn while working in the plant.*
- 2.) *Hard hat, Safety glasses with side shields, Hearing protection, Respiratory protection, and any other applicable PPE must be worn in designated areas or when performing designated activities. Safety glasses with dark or tinted lenses are not permitted indoors or in low light conditions.*
- 3.) *Facial hair (such as a beard), and long side burns are not permitted on employees who work in the plant where such conditions interfere with proper fit of a respirator face piece, or presents a food safety concern, Long hair must be maintained in a safe manner to avoid an entanglement hazard, or presents a food safety concern.*
- 4.) *Protective clothing issued by Niacet shall be worn at work and must be changed regularly. Clean uniforms must be kept separate from street clothes. Protective clothing such as uniforms must not be worn off site and kept in good condition. Soiled clothing and hard hats, loose clothing, shorts, sleeveless shirts, ripped or torn clothing is prohibited.*
- 5.) *Jewelry with the exception of wristwatches and rings without stones are not permitted in production areas. False eyelashes, false or painted fingernails are not allowed.*
- 6.) *It is prohibited to carry writing implements behind the ear or anywhere else where they may fall. Washing hands thoroughly and maintaining adequate personal cleanliness are examples of hygienic practice. This be conformed to while working in contact with food chemicals*
- 7.) *Lockers may be inspected at any time. No food may be stored in the lockers. Plant clothes lockers must be kept free of street clothes or any personal items which may contribute to any contaminants entering the plant. Keep street clothes and plant clothes in separate lockers. Keep personal items in the street locker.*