1. **Purpose:** To describe how Quality is controlled in Giles' manufacturing facility where FDA recognized Continuous Flow process is used rather than a Batch process. This discussion serves as the premise for defining Giles' sampling process to meet the intent of the CFR.

2. **Scope:** The Continuous Process philosophy will apply to the Manufacturing process and be used to explain why the Continuous Process philosophy is acceptable from a compliance standpoint.

3. **Policy: Quality through Continuous Process Control**

The manufacturing process for magnesium sulfate heptahydrate is performed in a continuous manner and operates consistently 24 hours per day. It begins with the continual metering of approved magnesium oxide and sulfuric acid to the primary digesters from raw material storage. The process continues through the additional stages of manufacturing without any defined stop or start points which could be used to define a specific batch of material. Briefly, the processes in sequence are made up of Secondary Digesters, Mud tanks, Filter Press, Brine storage and feed, Crystallization, Centrifugal dewatering, Drying and Cooling, transport and packaging. It is due to the nature of this particular product and process that quality cannot be appropriately controlled via batch methodologies. It must be viewed as a continuous chain where quality is controlled and or built at each step of the process ensuring final compliance to specifications.

The process by which this is accomplished is driven by statistical process control of critical parameters throughout the manufacturing process. Each of these critical parameters has been selected based upon their potential to impact the final product meeting specifications. This selection has been confirmed via risk assessment and validation.

The control mechanism for the critical parameters follows commonly accepted rules for statistical process control in determining normal and acceptable process measurements and variability as within control and distinguishing this level of variability from abnormal or out of control. An out of control condition can be caused by a single data point outside of established limits or certain defined trends within established limits. Either of these situations will cause the need for a documented response by the responsible operator. The procedure for both determinations of when a response is necessary and what that response should be are clearly documented for each critical parameter.

The control process is tracked over time throughout manufacturing via process control charts. The charts will typically graph the actual data readings of critical parameters against control limits established one, two, and three standard deviations from the normalized process readings. These charts are monitored by both production and Quality Assurance personnel. The charts and established limits will be updated any time that a true process change is detected and validated to deliver the target finished product specifications.

This stage by stage control of quality is obviously designed to ensure compliance with all finished product specifications. Finished product specifications are the ultimate control point for this operation.

4. **Change Information:** New document