A. Policy Statement

Through the Bureau of Inspection and Certification (BIC), OMH has an existing Committee that reviews requests, new equipment, and unique practices. This policy formalizes and augments that process.

New products, equipment and unique practices come to the attention of the Office of Mental Health through a variety of sources, including but not limited to the following:

- Field Office
- Licensing visit
- CRM
- Justice Center
- Commissioner's Correspondence
- Hospital/Service Provider

Note: There is a separate process for restraint requests from OMH State-operated psychiatric centers. Reference PC 701 which dictates that OMG Chief Medical Officer approval is needed for certain deviations from policy.

Review: In all cases that OMH becomes aware of or there is a request for a new product, equipment or unique practice, the Director of the Bureau of Inspection and Certification (BIC) shall request a review of the BIC Safety Committee.

If the requested review includes restraint apparatus, spit mask, or unique practice requests, the Safety Committee shall solicit the input of OMH Executive Staff prior to commencing such review. In addition, Executive Clearance shall be sought under the following circumstances:

- New product or practice requests
- Potentially controversial product or practice request
- Request for use of product or practice in unique manner

B. Related Statutes and Regulations

42 C.F.R. §482.60

42 C.F.R.§482.61

42 C.F.R. §482.62

14 NYCRR 526.4

Mental Hygiene Law 33.04

42 C.F.R. 482.13

P.L. 106-310 (Children's Health Act of 2000)

Reference: The Joint Commission *Comprehensive Accreditation Manual for Hospitals*

C. Body of the Directive:

1. The Safety Committee

    a. Directors of BIC and OQI appoint members of the Safety Committee to include, but not be limited to:

        i. BIC Safety Committee Chair
        ii. BIC Restraint and Seclusion Subject Matter Expert
        iii. Director for Strategic Risk Reduction
        iv. Respective Field Office Representative

2. The Safety Committee's membership shall be reviewed every two years

3. BIC Director to evaluate if clearance is needed based on nature of request, history of product request, and intended use of product

    a. The role of the Committee

        i. Requests come to the committee's attention by providers
        ii. The Safety Committee evaluates requests by reviewing the provider's description of the product or practice, its proposed use, manufacturer guidelines, clinical and operational studies or other literature, pharmacological updates and current evidence base.
        iii. Other sources to be included in evaluating the product or practice may include videos, photos or product samples
        iv. The Committee references patient safety, rights, and quality of treatment standards referred to under Section I, Related Statutes and Regulations
        v. Once the Committee has formulated a recommendation, it is conveyed to the BIC Director for review and final determination.
        vi. Letters, which serve as records for the Committee's decisions, are filed in Share BIC SharePoint Folder
        vii. The Committee's decision will reflect OMH's recommendation back to the community-based provider on the submitted request.

    b. If the Committee rejects the product/treatment/etc.

        i. OMH communicates its objection of the product or practice in writing to the provider. The communication includes a brief rationale for the objection.
        ii. The communication may offer alternatives to the proposed product or practice, along with an invitation to discuss such alternatives by phone or in person
        iii. The communication will advise the provider that proceeding with the product or practice counter to the recommendation of OMH is at their own discretion. However, should they proceed in this manner, the provider is instructed to develop policies and procedures in relation to the use of the product or practice.

    c. If the Committee supports the product/treatment/etc.

        i. OMH communicates its support of the request in writing to the provider
        ii. If the Safety Committee supports the use of a product on a pilot basis, the timeframe, data collection and data review details of the pilot will be communicated and agreed to in writing.

4. **Timeframes**

   a. For routine requests - The committee shall meet no later than 2 weeks following the receipt of the request. Correspondence with a decision shall be issued within 3 weeks of receipt of the request.

   b. For time sensitive/urgent requests - The committee will attempt to meet and issue their decision within one week.

5. The signature of the individual supporting the practice or product shall reflect that of the Commissioner of the Office of Mental Health.