

**EVALUATION PROCESS FOR APPROVAL OF
ALTERNATIVE REGULATED MEDICAL WASTE TREATMENT SYSTEMS
SEPTEMBER 2012 (Revised)**

Section 1389 of the Public Health Law requires that methods other than incineration or autoclaving for the treatment of regulated medical waste be approved by the Commissioner of the New York State Department of Health, based on information submitted by the applicant. The Commissioner delegated this responsibility to the Director of Wadsworth Center, who in turn assigned responsibility to the Regulated Medical Waste Program (RMWP). The data provided by the applicant must be obtained in a manner which conforms to recognized scientific principles. To this end, the following procedure has been developed to insure that all requests for RMWP approval of alternative treatment systems are processed in an expeditious and consistent manner:

Stage I. Initial Inquiry

Following receipt of a request by a manufacturer for approval of an alternative treatment system,* a response will be formulated by the Regulated Medical Waste Program Coordinator (Program Coordinator), requiring the applicant to submit a detailed protocol to assess the efficacy of the system. Guidance to development of protocol and efficacy test data acceptable to the Program may be found in the Guidelines for Approval of Alternative Regulated Medical Waste Treatment Technologies (Guidelines).

Stage II. Protocol Evaluation

A. Upon receipt of the efficacy test protocols, copies of the documentation for comprehensive review will be distributed by the Program Coordinator to the Program's Scientific Review Committee (SRC), consisting of scientists from New York State's Wadsworth Center, David Axelrod Institute, and representatives of the Department of Environmental Conservation's Division of Solid and Hazardous Materials.

B. Following evaluation of the SRC review by the Program Coordinator and Division of Laboratory Quality Certification (DLQC) Director, the Program Coordinator will draft recommendations as to the protocols acceptability.

1. If the protocols are unacceptable, the Program Coordinator will outline in a response the factors which contributed to their rejection and note modifications that must be made prior to protocol approval.

*Alternative regulated medical waste treatment systems are defined as any process not already approved as per Section 1389 of the Public Health Law

2. If the protocols are acceptable, an approval letter from the DLQC Director to the applicant will indicate that efficacy studies may begin.

Approval of the test protocols must be received PRIOR to the initiation of efficacy tests.

Stage III. Efficacy Evaluation

A. Efficacy test results will be distributed by the Program Coordinator to the SRC for their comprehensive review.

B. Upon evaluation of the SRC's review by the Program Coordinator and DLQC Director, the Program Project Coordinator will draft a response to the manufacturer, providing recommendations as to the acceptability of the data.

1. If the data is unacceptable, the response from the Program Coordinator will outline the factors which contributed to the rejection of the efficacy studies. Additional efficacy studies may be requested before approval is granted.

2. If the data is acceptable, a recommendation for the approval of the alternative system will be submitted by the Program Coordinator to the Director of Wadsworth Center.

- a. Once approved by the Wadsworth Center Director, the applicant is sent an approval letter.

- b. If disapproved, a response will be drafted by the Program Coordinator indicating the test results were not acceptable, and approval will not be granted until additional studies are performed.