

641—154.49(124E) Requirements of a manufacturer.

154.49(1) *Assuming costs.* A manufacturer shall assume the costs for all laboratory testing pertaining to verification studies on new products, the cost of standard testing protocols as outlined in a Laboratory Acceptance and Criteria Document and other tests as requested by the department. A manufacturer shall provide any necessary reference materials to the laboratory at no cost.

154.49(2) *Obtaining approval for sampling protocols.* A manufacturer shall obtain approval from the department for the manufacturer's sampling protocols prior to submitting samples for laboratory testing related to content and contamination.

154.49(3) *Obtaining approval for stability-testing procedures.* A manufacturer shall obtain approval from the department for the manufacturer's stability-testing procedures prior to submitting samples for laboratory testing related to stability testing and product-expiration-date studies.

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