9. Design Control

a. Design activities (completed) will be carried out in a planned, controlled and orderly manner.

b. Measures have been established to correctly translate applicable regulatory requirements and design bases into specifications, drawings, written procedures, and instructions.

(Note: Design specifications are as outlined in para. 178.194 - 1 through 7.)

c. Quality standards are specified in the design documents, and deviations and changes from these standards are controlled.

d. The design is reviewed to assure that design characteristics can be controlled, inspected and tested, and inspection and test criteria are identified.

e. The design specifications are as outlined in para 178.194-1 through 7, and do not require verification by Isomedix.

f. Individuals within this organization are not designated for design verification, per para. e. above.

g. Design and specification changes, if required, will be subject to the same design controls and procedures applicable to the original design.

h. Groups (which may be designated at a later time) responsible for design review or verification activities, with their applicable authority and responsibilities, will be identified and controlled by written procedures.

SUPPLEMENT #1 to Isomedix

"QA PROGRAM FOR THE CONTROL AND SHIPMENT OF 20WC-5 SHIPPING CONTAINERS"

Effective Date: June 25, 1979

(Identified as page 5, para. 9, to basic document of May 15, 1978).

Concur by _____ 6-25-79
General Manager

Concur by _____ 6-25-79
Quality Assurance

Approved by _____ 6-25-79
President

June 25, 1979