

NOV 4 1977

Docket No. 30-6990

Ethicon, Incorporated
Manufacturing Division
ATTN: Dr. Charles Artandi
Vice President for Research
Route 22
Somerville, New Jersey 08876

Gentlemen:

Subject: Inspection 77-01

This refers to the inspection conducted by Mr. C. Stearns of this office on October 21, 1977, of activities authorized by NRC License No. 29-02786-03 and to the discussions of our findings held by Mr. Stearns with Messrs. Kendra and Foerst of your staff at the conclusion of the inspection, and to a subsequent telephone discussion between Mr. Stearns and yourself on October 27, 1977.

The inspection was an examination of activities conducted under your license as they relate to radiation safety and to compliance with the Commission's rules and regulations and the conditions of your license. The inspection consisted of selective examinations of procedures and representative records, interviews with personnel, measurements made by the inspector, and observations by the inspector.

Within the scope of this inspection, no items of noncompliance were observed.

From the discussions conducted during the inspection, it is our understanding that you are presently conducting a review of your irradiator safety systems to assure that they meet the new requirements published in the Proposed Rule Making, 10 CFR 20.203(c)(6). You are advised that all new or revised procedures which you propose to use as a result of this review should be submitted to the USNRC, Radioisotope Licensing Branch, Washington, D.C. 20555, with a request to amend your license to include these procedures.

In accordance with Section 2.790 of the NRC's "Rules of Practice," Part 2, Title 10, Code of Federal Regulations, a copy of this letter will be placed in the Public Document Room.

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No reply to this letter is required; however, should you have any questions concerning this inspection, we will be pleased to discuss them with you.

Sincerely,

Robert O. McClintock, Chief
Materials Radiological Protection
Section

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