

NOTICE OF VIOLATION

Smithkline Beecham Clinical Laboratories
Waltham, Massachusetts

Docket No. 030-04721/96-001
License No. 20-12707-01

During an NRC inspection conducted on October 29, 1996, violations of NRC requirements were identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," (Enforcement Policy), NUREG 1600, the violations are listed below:

Condition 16 of License No. 20-12707-01 requires that licensee's conduct their program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures submitted.

1. Item 3., "Training Program," in a letter dated June 21, 1994 states: "As an added measure, we will institute annual re-training."

Contrary to the above, as of October 29, 1996, adequate annual training was not conducted in calendar years 1994, or 1995, as required. While meetings which were intended to meet this requirement were conducted on July 22, 1994 and August 4, 1995, the minutes of meetings indicate they were brief discussions of radiological topics not adequate for annual re-training sessions.

This is a Severity Level IV violation (Supplement VII).

2. Item 8.3) in the section entitled "Environmental and personnel monitoring," submitted with the letter dated June 31, 1995 states: "Using a survey meter, readings of the work areas will be taken weekly."

Contrary to the above, as of October 19, 1996, weekly surveys were not performed in June or August of 1992, and weekly surveys were not performed from October 1 through December 31, 1993.

This is a Severity Level IV violation (Supplement VII).

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Pursuant to the provisions of 10 CFR 2.201, SmithKline Beecham Clinical Laboratories is hereby required to submit a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555, with a copy to the Regional Administrator, Region I, within 30 days of the date of the letter transmitting this Notice of Violation (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each violation: (1) the reason for the violation, or, if contested, the basis for disputing the violation, (2) the corrective steps that have been taken and the results achieved, (3) the corrective steps that will be taken to avoid further violations, and (4) the date when full compliance will be achieved. Your response may reference or include previous docketed correspondence, if the correspondence adequately addresses the required response. If an adequate reply is not received within the time specified in this Notice, an order or a Demand for Information may be issued as to why the license should not be modified, suspended, or revoked, or why such other action as may be proper should not be taken. Where good cause is shown, consideration will be given to extending the response time.

Because your response will be placed in the NRC Public Document Room (PDR), to the extent possible, it should not include any personal privacy, proprietary, or safeguards information so that it can be placed in the PDR without redaction. However, if you find it necessary to include such information, you should clearly indicate the specific information that you desire not to be placed in the PDR, and provide the legal basis to support your request for withholding the information from the public.

If personal privacy or proprietary information is necessary to provide an acceptable response, then please provide a bracketed copy of your response that identifies the information that should be protected and a redacted copy of your response that deletes such information. If you request withholding of such material, you must specifically identify the portions of your response that you seek to have withheld and provide in detail the bases for your claim of withholding (e.g., explain why the disclosure of information will create an unwarranted invasion of personal privacy or provide the information required by 10 CFR 2.790(b) to support a request for withholding confidential commercial or financial information). If safeguards information is necessary to provide an acceptable response, please provide the level of protection described in 10 CFR 73.21.