



UNITED STATES
NUCLEAR REGULATORY COMMISSION

REGION IV

611 RYAN PLAZA DRIVE, SUITE 400
ARLINGTON, TEXAS 76011-8064

March 5, 1997

Martin Goldstein, Laboratory Director
Department of Health and Human Services
Food & Drug Administration
Laboratory Branch (HFR-SE460)
4298 Elysian Fields Avenue
New Orleans, Louisiana 70122-3896

SUBJECT: TELEPHONE CONTACT AND NOTICE OF VIOLATION

Dear Mr. Goldstein:

This letter and the enclosed Notice of Violation refer to the telephone contacts conducted on January 14 and 16, 1997. The purpose of the telephone contacts was to review with you 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 the license. The contacts consisted of discussions with you and your staff regarding the status of the Food & Drug Administration (FDA) laboratory in New Orleans, Louisiana. A telephonic exit briefing was conducted with you on January 16, 1997.

As a result of our discussions with you, certain of your activities appeared to be in violation of NRC requirements as specified in the enclosed Notice of Violation (Notice). The violation described in the Notice involved the failure to amend your license to designate a new radiation safety officer (RSO) following the departure of your former RSO in 1994.

As discussed with you during the telephonic exit briefing, although your program poses minimal potential for significant radiation safety concerns, there are license commitments which must be met, along with requirements for general oversight and control of licensed activities. The RSO is the individual tasked with these responsibilities. Because individuals designated to serve as RSOs hold a significant role with respect to licensed activities, the NRC has established certain training and experience requirements which a prospective RSO must meet. Therefore, the NRC requires that licensees request amendment of their NRC license before they designate an individual to serve as the RSO. The NRC requires amendment of the license to designate a new RSO even if the individual proposed to serve as the RSO was identified as an alternate RSO, as in your case, in earlier correspondence with the NRC. Since the NRC does not recognize alternate RSOs, a review of the alternate's credentials would not have been conducted.

During the telephone contact on January 14, you stated that your laboratory is scheduled to close in February 1998. Because of this, the inspector discussed the timing of notifications required under the NRC's Decommissioning Timeliness Rule. 10 CFR 30.36(d) requires that a licensee must provide notification to the NRC in writing within 60 days of the licensee's decision to cease principal licensed activities at the specified site. You are encouraged to review the requirements and must provide the specified notification. Your

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written notification should be sent to: U.S. Nuclear Regulatory Commission, Region IV, Nuclear Material Licensing Branch, 611 Ryan Plaza Drive, Suite 400, Arlington, Texas 76011.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. In your response, you should document the specific actions taken and any additional actions you plan to prevent recurrence. Your response may reference or include previous docketed correspondence, if the correspondence adequately addresses the required response. For your consideration and convenience, NRC Information Notice 96-28, "SUGGESTED GUIDANCE RELATING TO DEVELOPMENT AND IMPLEMENTATION OF CORRECTIVE ACTION," is enclosed. After reviewing your response to this Notice, including your proposed corrective actions and the results of future inspections, the NRC will determine whether further NRC enforcement action is necessary to ensure compliance with NRC regulatory requirements.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter, its enclosure, and your response will be placed in the NRC Public Document Room (PDR). To the extent possible, your response should not include any personal privacy or proprietary information so that it can be placed in the PDR without redaction.

Should you have any questions concerning this letter, please contact William H. Radcliffe at (817) 860-8151 or Linda L. Howell at (817) 860-8213.

Sincerely,

Charles L. Cary

For Ross A. Scarano, Director
Division of Nuclear Material Safety

Docket: 030-04474
License: 17-09756-01

Enclosures:
1. Notice of Violation
2. NRC Information Notice 96-28

cc w/Enclosure 1:
Louisiana Radiation Control Program Director

Department of Health and
Human Services

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E-Mail report to Document Control Desk (DOCDESK)

bcc to DCD (IE-07)

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*Previously concurred

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Department of Health and
Human Services

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