

NOTICE OF VIOLATION

Lisega GmbH
Zeven, Germany

Docket No. 99901235
Report No. 93-01

During a U.S. Nuclear Regulatory Commission (NRC) inspection conducted September 28 through October 1, 1993, a violation of NRC requirements was identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C (1992), the violation is listed below:

Section 21.21(a) of Part 21 of Title 10 of the Code of Federal Regulations, (10 CFR 21.21(a)), "Reporting of Defects and Noncompliance," requires, in part, that each individual, corporation, or entity subject to the regulations in this part adopt appropriate procedures to ensure the proper evaluation of deviations and failures to comply and report defects and failures to comply related to a substantial safety hazard to a director or responsible officer in accordance with specified time requirements and that an interim report be made to the NRC if the evaluation cannot be completed in the required time.

Contrary to the above, as of September 29, 1993, Revision 0 of Lisega GmbH's "Procedural Guidelines Quality: Quality Assurance Program" (Verfahrensbeschreibung Qualitätssicherungsprogramm, or VQSP) VQSP 34, "State of Product-Information and Report" (Berichtswesen über Produktverhalten), dated April 1989, would not, as written, ensure proper evaluation and reporting in accordance with the version of 10 CFR Part 21 that became effective on October 29, 1991. Specifically, the procedure had not been updated to include the new provisions in 10 CFR 21.21(a) that (1) limit the time for evaluating deviations or failures to comply to not more than 60 days from discovery, (2) require an interim report to the NRC within the 60 days if this evaluation cannot be completed within the 60 days, and (3) limit the time for informing a director or responsible officer of Lisega GmbH of the defects or failures to comply associated with a substantial safety hazard to 5 working days from completion of the evaluation. (93-01-01)

This is a Severity Level V Violation (Supplement VII).

Pursuant to the provisions of 10 CFR 2.201, Lisega GmbH 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 Chief, Vendor Inspection Branch, Division of Reactor Inspection and Licensee Performance, Office of Nuclear Reactor Regulation, within 30 days of the date of the letter transmitting this Notice of Violation. This reply should be clearly marked as a "Reply to a Notice of Violation" and should include the following: (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. Where good cause is shown, consideration will be given to extending the response time.

Dated at Rockville, Maryland
this 2nd day of March, 1994