



Department of Energy

Washington, DC 20585

January 20, 2010

Mr. Ron Shaffer
President
Isotek Systems, LLC
701 Scarboro Road
Suite 301
Oak Ridge, Tennessee 37830

Dear Mr. Shaffer:

The U.S. Department of Energy's (DOE) Office of Enforcement, within the Office of Health, Safety and Security, conducted an evaluation of the deficiencies described in Noncompliance Tracking System Report NTS-ORO--ISOTEK-3019-2008-0001. Our evaluation included a review of Isotek Systems, LLC (Isotek) causal factors analysis and corrective actions, and other requested documentation, as well as discussions with Isotek senior management and DOE Oak Ridge Office (ORO) personnel. Based on our evaluation, violations of DOE nuclear safety requirements involving 10 C.F.R. Part 830 Subpart A, *Quality Assurance Requirements*, appear to have occurred during the design of the U233 Material Downblending and Disposition Project to be constructed at the Oak Ridge National Laboratory site.

The Noncompliance Tracking System report describes the inadequate implementation of the Burns and Roe Enterprises, Inc. (BREI) quality assurance (QA) program and documentation to support the design work that had been performed. BREI, a member company of Isotek, was responsible for providing engineering, procurement, and construction services and, in January 2004, was selected to perform engineering design work to support the construction of the U233 Material Downblending and Disposition Project.

Problems with BREI design work performance were first noticed in November 2004, when Isotek engineers expressed concern that BREI had not implemented a formal design review process or document control system. Further audits and assessments conducted by Isotek and the DOE Office of Environmental Management revealed continuing uncorrected problems in the QA aspects of the design work being performed by BREI. On September 19, 2008, BREI was issued a Stop Work Order by Isotek.

Title 10 C.F.R. Part 820, *Procedural Rules for DOE Nuclear Activities*, appendix A, section IX(1)(d) states that "contractors are normally held responsible for the acts of their employees and subcontractor employees in the conduct of activities at DOE



facilities.” Additionally, section X(c) of this appendix states that “Notices of Violations and civil penalties will be issued, as appropriate, for DOE contractor failures to ensure that their subcontractors and suppliers provide products and services that meet applicable DOE requirements.” Consistent with this policy, DOE holds Isotek, as the prime contractor, responsible for BREI engineering design activities associated with the U233 Material Downblending and Disposition Project.

Isotek was not sufficiently effective in its oversight of BREI (member company and subcontractor) design activities. Problems with BREI design work performance were well known and documented over an extended period of time, as evidenced by several Isotek and DOE Office of Environmental Management audits and assessments. However, Isotek failed to: (1) effectively control and correct known quality problems with BREI work activities; (2) ensure that adequate resources were assigned to perform its QA oversight responsibilities; (3) ensure independence in its management oversight of BREI; and (4) adequately evaluate BREI as a supplier of engineering design work before selecting them to perform the work.

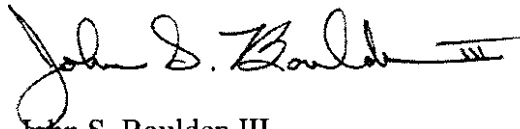
Based on the inadequacy of BREI’s corrective actions taken in response to its June 2008 audit of the BREI QA program, Isotek issued a Stop Work Order to BREI in September 2008. Immediate compensatory measures included a review of two other subcontractors providing design services to Isotek; transfer of the BREI work to Mesa Associates, Inc.; and the initiation of efforts to reconstitute the facility design. Isotek completed its 60 percent design review in September 2009, with no evidence of the previous problems experienced with BREI. The Office of Enforcement has been continuously monitoring activities and notes several corrective actions aimed at improving Isotek oversight of its subcontractors have been identified and implemented.

The U233 Material Downblending and Disposition Project is a major modification to an existing DOE hazard category 2 nuclear facility. Consequently, the Office of Enforcement views the longstanding, uncorrected problems in the design of the project to be an important nuclear safety issue. However, the Office of Enforcement has decided to use its enforcement discretion in this case and issue this letter in lieu of a more formal investigation. This decision is based on the fact that the deficiencies occurred early in the design phase of the project and as such are more readily recoverable, and the fact that Isotek, in close cooperation with ORO, has taken aggressive and comprehensive action to correct the design deficiencies.

In partnership with the DOE Office of Environmental Management and ORO, we will continue to monitor the design and construction of the U233 Material Downblending and Disposition Project and the effectiveness of Isotek corrective actions taken to improve the project design deliverables.

No response to this letter is required. Should you have any questions, please contact me at (301) 903-2178, or have your staff contact Mr. Glenn Morris, Director, Office of Price-Anderson Enforcement, at (301) 903-7707.

Sincerely,

A handwritten signature in black ink, appearing to read "John S. Boulden III". The signature is written in a cursive style with a long horizontal flourish at the end.

John S. Boulden III
Acting Director
Office of Enforcement
Office of Health, Safety and Security

cc: Frank Casella, Isotek
Jay Larson, SC
Richard Azzaro, DNFSB