



THOMAS J. VILSACK
GOVERNOR
SALLY J. PEDERSON
LT. GOVERNOR

DEPARTMENT OF PUBLIC HEALTH
STEPHEN C. GLEASON, DIRECTOR

November 16, 2000

Peter Chiefari, Assistant Division Director
Radiological Health Unit
Division of Safety and Health
New York State Labor Department
NYS Office Campus, Bldg. 12, Room 169
Albany, New York 12240

Dear Mr. Chiefari:

It has come to my attention that the New York Labor Department has not updated the Sealed Source and Device (SS&D) registration maintained by the US Nuclear Regulatory Commission on the VEECO Instruments, Inc's, Microderm beta-backscatter thickness gauge with HH-3 probe. During an inspection of one of our registrants, it was noted that the HH-3 probe did not match the SS&D specifications. In fact, a search of the SS&D revealed that the only registration form for this device was NY-650-D-101-G dated October 27, 1976 with Unit Process Assemblies, Inc., as the manufacturer of the device and the sources.

On November 7, 2000, Joyce L. Spencer of my staff contacted Clayton Bradt of the New York Department of Labor by telephone. Mr. Bradt stated that VEECO Instruments, Inc, purchased Unit Process Assemblies in 1994 and that the source manufacturer and maximum activity levels had been modified twice since that purchase. Although he provided a copy of the New York general license to manufacture and distribute the devices, Mr. Bradt confirmed that the SS&D had not been updated for any of the changes in ownership, source manufacturer, or source activity. The copy of the license did not include documentation as to the safety requirements for the devices. However, Mr. Bradt believed that the sources were to be leak tested every three years.

The Iowa Department of Public Health (IDPH) bases its licensing and inspection decisions on information obtained from the SS&D. The lack of current SS&D registration results in devices being held to the more restrictive requirements as set forth in the Iowa Department of Public Health rules, which includes leak testing every six months. It could also result in IDPH requiring the devices to be specifically licensed. Either determination would result in significantly increased costs to the licensee. A specific license would cost the licensee \$1300 initially and \$1170 every five years thereafter, plus an inspection fee of \$1927 every five years. These costs can be annualized to 645.40 for the first five years and \$619.40 per year thereafter for a specific license. When you compare those costs to the \$150 annual fee to be generally licensed, you can understand why a business would want to remain generally licensed.

LUCAS STATE OFFICE BUILDING / 321 E. 12TH ST. / DES MOINES, IOWA 50319-0075
DEAF RELAY (HEARING OR SPEECH IMPAIRED) 1-800-735-2942 / INTERNET: [HTTP://IDPH.STATE.IA.US/](http://idph.state.ia.us/)

DIRECTOR'S OFFICE 515-281-5605 FAX/515-281-4958	EXECUTIVE STAFF 515-281-5604 FAX/515-281-4958	DIV. OF ADMINISTRATION & REGULATORY AFFAIRS 515-281-5784 FAX/515-281-4958	DIV. OF ENVIRONMENTAL HEALTH 515-281-5784 FAX/515-281-4958
DIV. OF FAMILY & COMMUNITY HEALTH 515-281-3931 FAX/515-242-6384	DIV. OF HEALTH PROMOTION, PREVENTION & ADDICTIVE BEHAVIORS 515-281-3641 FAX/515-281-4535	DIV. OF TOBACCO USE PREVENTION & CONTROL 515-281-6225 FAX/515-281-4535	

This issue was recently discussed in a meeting with staff from the US Nuclear Regulatory Commission. IDPH is contemplating formal action to resolve this issue. Before any action is initiated, it would only be appropriate to provide the State of New York an opportunity to rectify this situation. Please advise me of any actions or pending actions by December 15, 2000. If you have any questions, do not hesitate to contact Joyce L. Spencer at 515-725-0310 or me.

Sincerely,

A handwritten signature in cursive script that reads "Donald A. Flater".

Donald A. Flater, Chief
Bureau of Radiological Health
515-281-3478

cc: Heather Adams, Assistant Attorney General
Clayton Bradt, New York Department of Labor
Frank Ferrandino, RSO, VEECO Instruments, Inc.
James Lynch, Nuclear Regulatory Commission, Region III
Duncan White, Nuclear Regulatory Commission, Region I