

7 July 1995

Mr. Ben Kapel
Radiologic Health Branch
Department of Health Services
P.O. Box 942732
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Subject: Request to Revise Sealed Source and Device Registry Sheets
(CA501D101G and CA501D102G)

Dear Ben:

From discussions with Duane Hall and Michael Cobian of 3M Health Physics Services, we understand that regulatory agencies have begun to interpret Sealed Source and Device Registry Sheets in a way that Measurex had not anticipated. In both registrations for Measurex-manufactured sensors (CA501D101G and CA501D102G), *Limitations and/or Other Considerations of Use* (Item 1) presently mentions only General Licenses. Regardless of the original intent, some agencies now interpret the absence of references to Specific Licenses as equivalent to a ban on possession of the device under a Specific License. This interpretation has caused difficulties for some recipients of our devices.

Measurex wishes to eliminate further misunderstanding and customer inconvenience by having the wording changed in the registry sheets. Please modify CA501D101G and CA501D102G to explicitly state that each of the listed sensor models may be distributed by Measurex to **either General or Specific Licensees**.

Using the gauge model numbers applicable to each registration in place of "XXXX" below, the wording we suggest for Item 1 of *Limitations and/or Other Considerations of Use* is:

Measurex Model XXXX gauges shall be distributed to persons Specifically or Generally Licensed by the NRC or an Agreement State.

Please also modify first paragraph of the section titled *Labeling* (Page 4) of both CA501D101G and CA501D102G to state:

Series XXXX gauges are labeled in accordance with California Radiation Control Regulations, Title 17, Sections 30192.1 and 30278 (equivalent to 10CFR32.51 and 10CFR20.1904 respectively).

Please change CA501D101G to quote the same sensor head label text as presently appears in CA501D102G:

In the U.S., the receipt, possession, use, and transfer of this device are subject to the requirements described on this label, the requirements of the General or Specific License, and the regulations of the U.S. NRC or applicable Agreement State.

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It is required that the sealed source in this device be tested for leakage at installation and every six months thereafter, except that Kr-85 sources need not be tested. It is also required that this device be tested for proper operation of the on-off mechanisms and indicators at six-month intervals. The tests described in this paragraph must be performed by an individual authorized by a Specific License.

Except for those service operations that are specifically described in the Measurex Customer Radiation Safety Manual, installation, replacement, disposal, testing, repair, and maintenance operations that involve the source or detector sensor head, on-off mechanisms or indicators, safety interlocks, and the radioactive source and its holder must be performed by an individual authorized by a Specific License.

For both registry sheets, please retain the current wording: "... this label has the following text (or equivalent)".

Please contact me with any questions; I can be reached at (408) 725-3127.

Sincerely,
MEASUREX CORPORATION



Elsa Nimmo
Radiation Safety Officer

CC: Brendan Brady
Doug McFarlin
Duke Nelson
John Preston
Mark Van Buskirk
Glenn Wienkoop
Radiation Safety Committee

Michael Cobian
Duane Hall
Robert Wissink