

JUN 12 1985

Daybreak Nuclear and Medical Systems, Inc.
ATTN: Mr. V. J. Bortolot
50 Denison Drive
Guilford, CT 06437

Gentlemen:

This is in regard to your manufactured device designed to contain radioactive sources of Strontium-90 and/or Curium-244 to be used for thermoluminescence authentication of artifacts. As of this date, there are at least three American customers that have been authorized by HRC or an Agreement State to possess and use byproduct material with your device.

Reviewing devices intended to contain byproduct material on a one-of-a-kind basis is a time consuming, labor intensive, repetitive process which requires the handling of voluminous paperwork submitted by the applicant which must describe your device and its intended use. The current registration status of your device requires such a review each time an applicant proposes to use your device. (A fee, as required by Item 93 of Section 170.31, 10 CFR Part 170, must accompany each review.) It would be advantageous to you and certainly to your customers if your device was generically registered rather than being reviewed repetitively each time an applicant for a license wishes to use your device. Currently, most device manufacturers generically register their devices with a licensing authority. This not only promotes an accelerated licensing process, but also facilitates the uniform application of safety standards to protect the public health and safety. Once the device is registered, your customer, the applicant, then only needs to identify the specific device and the radioactive source in order to be licensed for possession of byproduct material for use with the device.

If you wish to have your device registered with the NRC for routine distribution, you should submit the application in accordance with the enclosed guide, "Guidelines for Applications for Registration of Devices." A fee, as required by Item 9A of Section 170.31, 10 CFR 170 (copy enclosed), must accompany each application.

9701310278 920612
PDR RC *
SSD PDR

JUN 12 1985

Daybreak Nuclear and Medical Systems, Inc.

-2-

If you should have any questions concerning this matter, please feel free to contact Mr. Steven Baggett of my staff. His phone number is (301) 427-9005.

Sincerely,

Original Signed By

VANDY L. MILLER

Vandy L. Miller, Chief
Material Licensing Branch
Division of Fuel Cycle and
Material Safety

Enclosure: As stated

DISTRIBUTION

SBaggett
VLMiller/JHickey
TDorian
FCML r/f
FC Central File
NMSS r/f

*See Previous Concurrence

OFFICE ▶	FCML*	ELD*	FCML	FCML			
SURNAME ▶	SBaggett/sc	TDorian	JHickey	VLMiller			
DATE ▶	6/4/85	6/7/85	6/12/85	6/17/85			