August 7, 1985

Our Lady of Mercy Hospital
ATTN: S. Lee, M.D.
Chairperson, Radiation Safety Committee
U.S. Highway 30
Dyer, IN 46311

Gentlemen:

This is in reference to your letter, dated June 13, 1985, to amend Byproduct Material License No. 13-12914-01. In order to continue our review, we need the following additional information:

1. List the physician users who will use or supervise the use of the bone mineral analyzer devices. Refer to the enclosed Policy and Guidance Directive 85-1 for specific training and experience criteria.

2. Specify the title and training of the individuals who will perform the installation, replacement , and removal of the sealed sources in the devices. Each individual who performs these functions should receive training from the manufacturer's representative when the devices are installed. Records of the individuals who have received this training should be maintained.

3. Submit procedures for each device that will be followed when installing, exchanging, or removing the sealed sources from the devices. You may submit or reference the manufacturer's instructions.

4. State the method that you will use for disposing of the sealed sources after they have decayed beyond their useful life or are otherwise no longer needed.

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5. Describe your procedures for assuring that the bone mineral analyzers and the sealed sources are secured at all times against unauthorized use or removal both when the devices contain the sealed sources and when the sealed sources are not within the devices.

We will continue our review of your application upon receipt of this information. Please reply in duplicate within 30 days and refer to Control No. 79312.

Sincerely,

Evelyn R. Matson

EVELYN R. MATSON
Material Licensing Section

Enclosures: Policy and Guidance Directive 85-1

OFFICE ▶	EVM					
SURNAME ▶	MATSON					
DATE ▶	8/7/85					