

HANSELL & POST

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March 7, 1986

VIA HAND DELIVERY

Mr. Thomas E. Hill
Chief, Radioactive Materials Unit
Radiological Health Section
Georgia Dept. of Human Resources
878 Peachtree Street, N.E.
Atlanta, Georgia 30309

Re: Application for Device Registration---Leksell
Gamma System

Dear Tom:

7, Enclosed please find several pages revising and amending the Application, to broaden the scope of procedures contemplated for loading the Leksell Gamma System ("LGS"). As revised, the Application now indicates that the LGS will be loaded in a hot cell or in an equivalent environment (including where appropriate the treatment site itself), but in any case under procedures approved and licensed by the appropriate nuclear regulatory agency. *or agreement with*

This change permits Elekta to have some flexibility to schedule loading of the LGS in the manner most suitable for each unit, which may be to build a hot-cell environment in the intended treatment room.

If you have any questions, please do not hesitate to call.

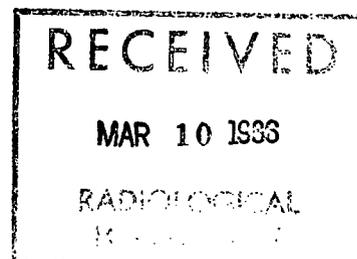
Sincerely,



John D. Maiers

JDM/sd

Enclosures: Revised Pages 7,8,
17, and 26



There is an access port or sump at the rear of the radiation unit which is closed off by means of a stepped plug bolted into place. This port is not routinely used for any purpose but does provide access to the base of the unit to remove any foreign object which might drop into the treatment cavity. Removing the plug does not allow any primary radiation to leak from the unit, but the plug should be removed only under the health physics supervision of a licensee's radiation safety officer, due to scattered radiation that might be present.

The radiation unit weighs 16.8 metric tons, or about 37,000 pounds. It rests on a trolley equipped with roller tracks by means of which it can be rolled into position for installation.

Loading of the Cobalt-60 sources into the radiation unit must be done in a hot cell with a door large enough to accommodate the 5'5" diameter of the shield and with remote manipulation of the unit and the sources. This will be done in a hot cell licensed by an Agreement State or the NRC, as appropriate, to perform the loading operation. The Leksell Gamma System may be loaded at the hot cell of the source supplier or by an independent hot cell operator who would receive the sources directly from the source supplier.

Inside the hot cell, the massive hemispherical shield is lifted open on its hinge to expose the source cavities of the central body. (Enclosure 4) Each of the registered sealed sources is placed in an aluminum bushing assembly for accurate centering into the beam channel. The cap of the aluminum bushing is designed for convenient handling by the remote manipulators of the hot cell. This bushing assembly is not relied on for radiation and source containment. Radiation shielding is provided by the large hemispherical shield above the sources, by the central body in which the source bushing assemblies fit, by the collimators below the bushing assemblies, and by the base and shielding door of the unit. The inside diameter of the tungsten collimator bushing immediately adjacent to and directly below each source bushing assembly, is only 4.4 mm., as compared to the sealed source's outside diameter of 8 mm.

Once all the sources are inserted, the hemispherical shield is lowered into place. The tight fit between the hemispherical shield and the central body holds the sources in their channels. The hemispherical shield is bolted to the base of the unit with twelve 20 mm.-diameter steel bolts. The lifting ring and the external parts of the hemispherical shield's hinge are removed after loading, and the remaining holes in the hemispherical shield are filled with threaded steel plugs.

of the source assembly, the assembly shall be checked by the manufacturer for contamination...."

The manufacturer will leak test and certify the sources as recommended by NCRP Report No. 33 and as required by his license and source registration.

"4.1.3. Replacement of Gamma-Beam Sealed Sources: Contamination tests of the source assembly housing shall be conducted whenever a gamma-beam source is replaced. Any removable contamination shall be removed prior to insertion of the new source. Should the radiation survey of the source assembly housing reveal contamination, the used source shall not be reused until it has been definitely determined that the source is not leaking. Such a determination may require that the source be inspected in an appropriate hot cell."

The Leksell Gamma System is not designed or intended for source removal or replacement except by moving the entire unit to a hot cell for opening and remote handling as is done for the initial loading.

"4.2.1(a) Protective Source Housing: Beam "OFF" Position. The housing shall be so constructed that at 1 meter from the source, the maximum and the average exposure rates do not exceed 10 mR/h and 2 mR/h, respectively, when the beam control mechanism is in the "OFF" position...."

Measurements by the hospital physicist of exposure rates for the unit in Stockholm, as prescribed in NCRP Report No. 33, are provided in Enclosure 7. The radiation shielding for the new Leksell Gamma System Model 23016, which is the subject of this

any defects that would be detectable by weight difference. All machined surfaces, including the interfaces between the hemispherical shield, the base section, and the central body, and the beam channels drilled through the central body are visually inspected and measured for casting integrity, as well as for fit and finish of the machining.

The final and most conclusive test of the shielding will be done by surveying the unit at the hot cell after the Cobalt-60 sources are loaded. This survey will be done in accordance with the procedures recommended in Section 4.2.2(a) of NCRP Report No. 33. Any unit which does not meet the leakage radiation limits recommended by NCRP 33, i.e. 2 mrh average at 1 meter and 10 mrh maximum at 1 meter, will not be shipped from the hot cell until the leakage radiation is reduced to specification limits by repair or reloading or until such discrepancies are determined to be acceptable by the licensing agency of the ultimate user based on consideration of the totality of facts and circumstances of the particular intended use.

All machined and assembled parts of the beam-defining, focus, and target-localizing and locating systems will be 100% inspected for dimensions and tolerance to assure that the design specifications for accuracy are met.

There is an access port or sump at the rear of the radiation unit which is closed off by means of a stepped plug bolted into place. This port is not routinely used for any purpose but does provide access to the base of the unit to remove any foreign object which might drop into the treatment cavity. Removing the plug does not allow any primary radiation to leak from the unit, but the plug should be removed only under the health physics supervision of a licensee's radiation safety officer, due to scattered radiation that might be present.

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Loading of the Cobalt-60 sources into the radiation unit must be done in a hot cell or equivalent environment, with remote manipulation of the unit and the sources. This will be done according to procedures approved and licensed by an Agreement State or the NRC, as appropriate. The Leksell Gamma System may be loaded at the hot cell of the source supplier, or in a hot cell or equivalent environment by a licensed independent source-loading operator who would receive the sources directly from the source supplier.

At the loading site, the massive hemispherical shield is lifted open on its hinge to expose the source cavities of the central body. (Enclosure 4) Each of the registered sealed sources is placed in an aluminum bushing assembly for accurate centering into the beam channel. The cap of the aluminum bushing is designed for convenient handling by the remote manipulators of the hot cell. This bushing assembly is not relied on for radiation and source containment. Radiation shielding is provided by the large hemispherical shield above the sources, by the central body in which the source bushing assemblies fit, by the collimators below the bushing assemblies, and by the base and shielding door of the unit. The inside diameter of the tungsten collimator bushing immediately adjacent to and directly below each source bushing assembly, is only 4.4 mm., as compared to the sealed source's outside diameter of 8 mm.

Once all the sources are inserted, the hemispherical shield is lowered into place. The tight fit between the hemispherical shield and the central body holds the sources in their channels. The hemispherical shield is bolted to the base of the unit with twenty-four 20 mm.-diameter steel bolts. The lifting ring and the external parts of the hemispherical shield's hinge are removed after loading, and the remaining holes in the hemispherical shield are filled with threaded steel plugs.

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