

APPLIC. # 3170INSP. AGCY DN varian/611 hansen way/palo alto/california 94303/u.s.a./415/493-4000DATE 3-1-77

Contro	708081
CG: <u>DN</u>	Rvwr: <u>KF</u>

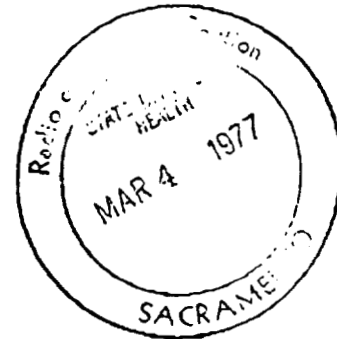


February 28, 1977

State of California  
Department of Health  
Radiologic Health Section  
744 "P" Street  
Sacramento, Calif. 95814

Attn: Dr. G. Wong, Licensing

Gentlemen:



Varian Associates requests a specific license for mass volume applications of depleted uranium in medical and industrial linear x-ray accelerators. The products to be covered under the license are the Clinac 4, Clinac 4S, Clinac 6X, Clinac 6S, medical accelerators used in radiotherapy and the Linatron 400, used for industrial radiography. The Clinac 4, 4S and the Linatron 400 produce x-rays with a maximum energy of 4 MeV, while the Clinac 6X and 6S produce x-rays with a maximum energy of 6 MeV. Photo-fission production in depleted uranium by the 6 MV x-ray beam has been thoroughly investigated and found to be negligible relative to the normal radioactivity of U-238. Supporting information is presented in Enclosure 1.

Varian's Radiation Division, located in Building 3, 611 Hansen Way, Palo Alto, California, has produced some 300 high energy x-ray accelerators containing depleted uranium as shielding material. The Clinac 4 and 6X use an isocentrically-mounted rotational gantry with an 80 cm source to axis distance. In order to insure minimum entrance dose to the skin during treatment, it is necessary to maintain a maximum distance between the bottom of the collimator to isocenter. This condition is best achieved by the use of uranium shielding.

All four Clinac's have a common head assembly, containing eight uranium shielding components with the following approximate dimensions and weights:

(a) One collimator: 6" diameter x 3.7" high	70 lbs.
(b) Two upper collimator jaws: 6" x 3" x 2.5"	62 "
(c) Two lower collimator jaws: 7.5" x 3" x 3.5"	106 "
(d) Two face plate shields: 7-3/4" x 2" x 5/8"	17 "
(e) One gun shield back disk: 6" x 4" x 1-5/16"	19 "
	<hr/> 274 lbs.

Enc 1 #32



State of California  
Department of Health  
February 28, 1977  
page 2

A photograph of these components is shown in Enclosure 2, Figure 2-1, together with brochures on the Clinac 4, 6X and the Clinac 4S. Location of the uranium components may be found in the tube head assembly drawing in the Clinac 6X brochure. Additionally, a small number of Clinac 4 accelerators have converted from the standard lead flattening filter (located directly above the monitor ionization chamber) to a depleted uranium flattening filter (see figure in Clinac 6X brochure locating the uranium components). This new filter, weighing two pounds, extends field flatness over the diagonals of the 32 cm x 32 cm field, which is not possible with the standard unit. These are optional filters found on about ten accelerators and are supplied only on special request.

The Linatron 400, an industrial x-ray linear accelerator, contains only two pieces of depleted uranium, namely, the primary collimator and the gun shield back disk. Their total weight is approximately 100 pounds.

All the described depleted uranium components are supplied in final form by the National Lead Company with material derived from production tailings from the gaseous diffusion process, which contains a maximum of 0.22 percent U-235. Nickel plus cadmium plating approximately 0.001" thick is used to minimize the possibility of uranium oxide forming on the surface. Each piece is drilled and tapped or indented in such a way that it can be permanently attached to the head assembly. Before plating, each piece is stamped with the following identifying symbols: CAUTION - RADIOACTIVE MATERIAL - DEPLETED MATERIAL. Prior to final assembly, the upper and lower collimator jaws are sprayed with a dull black finish.

NRC Requirements for the issuance of specific licenses for manufactured products containing depleted uranium are specified in Section 40.34 of Title 10, Code of Federal Regulations, Part 40, as published in Federal Register Vol. 41, No. 235, Monday, December 6, 1976. We feel that the general requirements in Sections 40.34 (a)(1)(i) for a license to manufacture, import or transfer industrial products containing depleted uranium have been met.



State of California  
Department of Health  
February 28, 1977  
page 3

Regarding Section 40.34(a)(1)(ii), a quality control program has been established whereby each piece of uranium received from the supplier is inspected for proper identification and plating integrity. The material is then inventoried and stored in an area designated for depleted uranium. Assembly workers are instructed on the radiological hazards of uranium and the proper handling of the material. Personal dosimetry consists of body film badges and finger rings as required. During some seven years of production, the average finger dose has been less than 20 mR/month, with the whole body dose less than 10 mR/month. The beta plus gamma dose rate has been measured as 200, 25 and 8 mrad/hr. at the surface and at distances of six and twelve inches. The corresponding gamma ray dose rate is typically 8, 0.9 and 0.6 mr/hr. at these locations. Labeling of the individual pieces has already been described. G.C.

Regarding Section 40.34(a)(1)(iii), the unique benefits accrued to the public from the use of depleted uranium is increased distance of the tube housing from the patient during cancer therapy, thereby providing minimum surface skin dose per treatment rad.

Following receipt of the specific license, each unit shall be labelled with the following information: (1) Manufacturer, (2) License number under which the product was manufactured, (3) The fact that the product contains a specified quantity of depleted uranium, (4) A statement that the receipt, use, and transfer of the product are subject to a general license or the equivalent and the regulations of the U. S. NRC or of an Agreement State. Please note that special safety precautions on the handling and subsequent disposition of the depleted uranium contained in these devices are described in the Operators Manual. A copy of instructions contained in the Clinac 4 Manual are given in Enclosure 2.

The individual responsible for the physical control and radiation safety associated with the use of depleted uranium is Mr. Eugene Tochilin, Radiation Safety Officer, Radiation Division, 611 Hansen Way, Palo Alto, Ca. Any further questions that may be required concerning the issuance of a specific license should be directed to Mr. Tochilin.



varian

State of California  
Department of Health  
February 28, 1977  
page 4

In summary, the products to be covered under this specific license are the Clinac 4, Clinac 4S, Clinac 6X, Clinac 6S and the Linatron 400. The Clinac's are used for medical therapy while the Linatron 400, which contains only the uranium collimator and back disk, used for industrial radiography.

The State of California Department of Health's Form RH 2065, used for describing devices containing radioactive material, is attached.

Very truly yours,

R. Lavine  
General Manager  
Radiation Division

RL/sm

Enc.