

Standard license conditions for Y-90 microsphere 35.1000 medical use

(Additions to the standard license conditions for Y-90 microspheres are bolded below)

If the notification program was requested and approved:

12. Licensed material is only authorized for use by, or under the supervision of:

A. Individuals permitted to work as authorized users, authorized nuclear pharmacists, and/or authorized medical physicists in accordance with 10 CFR 35.13 and 35.14.

B. Physicians permitted to work as authorized users for 35.1000 TheraSphere[®] (and/or SIR-Spheres[®]) Y-90 microsphere use in accordance with the commitments for notification to the NRC in letter dated [date].

C. The following individuals are authorized users for the material and medical uses indicated:

Material and Use

[Name] [User Authorization(s)]

EXAMPLES:

Jane Jones, M.D. 35.100; 35.200; 35.300; 35.500; In vitro studies

Thomas Group, D.O. 35.100; 35.200; 35.300 except iodine-131

Gilbert Lawrence, M.D. 35.100; 35.200; 35.300 sodium iodide 1-131 in quantities less than or equal to 33 millicuries only for oral administration for imaging and localization

Yvonne M. Sphere, M.D. 35.400 and 35.1000 Y-90 TheraSphere[®] use

If program to make future changes in accordance with future guidance was requested and approved:

Tie Down condition

19. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below. This license condition applies only to those procedures that are required to be submitted in accordance with the regulations. Additionally, this license condition does not limit the licensee's ability to make changes to the Radiation Protection Program as provided for in 10 CFR 35.26 **and letter dated [date]**. The U.S. Nuclear Regulatory Commission's regulations shall govern unless the statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations.

A. Application dated [date].

B. Letter dated [date].

C. Letter dated [date].