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HOWARD HOSPITAL SUPPLY CORP. (RAD/IRID INC.)
2212 GEORGIA AVE., N.W.
WASHINGTON, D.C.
INSPECTION REPORT 75-01
TRACK ITEM NO. F18098HO

Howard Hospital Supply Corporation, recently renamed Rad/Irid Incorporated, has a NRC license for the fabrication, testing and distribution of iridium-192 medical sealed sources. An application for amendment, dated October 10, 1974 is pending with Licensing. The last correspondence was from Licensing requesting more information and was dated May 19, 1975. To date the licensee has not responded to that letter.

The present license, dated May 26, 1971, allows wide latitude and interpretation on the part of the licensee on matters of the conduct of his radiation safety program and in the fabrication, testing, and distribution of the sealed sources. An inspection on September 30 and October 1, 1975 revealed the licensee lacks a strong management control program and cannot be expected to handle this latitude properly. A very tight license is required to assure proper safety.

Specifically, the following is required:

- Distribution*
- a. The need to specify the methods to be used by the licensee for individually inspecting a representative number of the sources to insure uniformity. The need to specify the number out of each lot to be inspected and to specify an acceptance criteria.

The inspection revealed that the licensee was inspecting the seeds by dropping a handful under a magnifying glass and removing those that "did not look good". No records were kept of these inspections.

- Distribution*
- b. The need to specify the methods used for leak testing the sealed sources. The need to specify the size of the lot of representative samples tested and the allowable percent defective before action is taken, and to specify if they are to be tested before or after they are placed in the nylon tubing.

The inspector revealed the leak test method currently employed is to smear many sources simultaneously after they have been loaded into the nylon tubing which make up the intercavity implants.

Consideration should be given to leak testing the seeds as other doubly encapsulated sources are tested, by immersion in a solution. Batches could be done at a time, thus providing 100% leak testing of all of the sources.

- c. The need to specify the equipment and the method to be used for manipulating the irradiated seeds into the nylon ribbon to insure control of exposures (including hand exposures).

Use
The inspection revealed that the handling of sources is done behind lead shielding (several lead bricks on a bench top) using remote handling equipment (bent wires, long handled magnet). Better control of exposures, including extremity exposures, is required. The inspectors measured levels of up to 20 mr/hr at the worker's body and up to 100 mr/hr at his hands. The worker estimated he spends approximately 25% of his time working with the radioactive materials.

- d. The need to specify the radiation surveys required following the processing of material and prior to leaving the restricted area.

Use
The inspection revealed that upon leaving the laboratory, employees do not perform area or personnel surveys to assure that sources have not been lost or misplaced. No method is maintained, such as a signout log book, to encourage these surveys. Internal rules indicated that area surveys will be performed weekly. Considering the use frequency and the seriousness of a lost source, weekly area surveys are inadequate, but should be done after each operation.

- e. The need to specify the training required of employees working in the restricted areas and the degree of supervision required.

Use
The inspection revealed that, on the day of the inspection, the employee preparing intercavity implants using iridium-192 seeds had been working with the company only a short time and was not familiar with internal rules and procedures. On the day of the inspection, he was working with the radioactive material and was without supervision. The licensee did not define the training or degree of supervision required. Having "talked to the RSO" was considered adequate to allow a worker to work unsupervised with the iridium seeds.

Use
The need to specify the method of inventory to insure control of the iridium-192 seeds.

The inspection revealed that the licensee has not provided for any method to maintain a material inventory balance except by the invoice received from the supplier. This is inadequate considering the number of operations performed in handling the sources and the ease by which a source may be lost or misplaced. During the inspection, the inspector located one misplaced source on a work bench and a second misplaced source on a desk in the unrestricted area.

- g. The need to clarify that the license authorizes the current method of manufacturing irradiated seeds. The need to further evaluate the health and safety aspects of the irradiated seeds.

Distribution

The inspection revealed that the licensee "encapsulates" the sources by threading a thin iridium wire into a stainless steel tube, then both into a second stainless tube. The final step is cutting the wires into the small sources. The licensee requires only that the capsules are cold welded by shearing forces. There have not been any tests made to assure that the licensee's manufacturing method produces a sealed source.

- h. The need to clarify that the license authorizes the radioactive impurities present in the seeds.

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The inspection revealed that the sources are prepared by encapsulating iridium wire in stainless steel and then irradiating the sealed capsule in a thermal neutron flux at the Union Carbide reactor in Tuxedo, New York. The stainless steel assay is 18% chromium by weight. The licensee indicated that no activation products other than iridium 192 are present, that radioactive iron and chromium, along with other radioactive impurities, have not been considered.

Although strong enforcement action has been taken by Region I as a result of the inspection, action by licensing is needed, particularly in the area of manufacturing procedures and quality assurance of the product, to ensure the safety of this licensed program.

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cc: F. Dreher