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DE	VICE	TYPE:	Brachytherapy	Source and	Storage	e Devices	
<u>M01</u>	<u>DEL</u> :	Best/1,	Best/2, Best/3,	, and 81-01	(Seeds)	

MANUFACTURER/DISTRIBUTOR: Best Industries, Inc. 2244 S. Shirlington Road Arlington, VA 22206

MANUFACTURER/DISTRIBUTOR:

SEALED SOURCE MODEL DESIGNATION: Best Model 81-01 (Seeds)

ISOTOPE: Iridium-192

MAXIMUM ACTIVITY: 33 millicuries/seed

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LEAK TEST FREQUENCY:

PRINCIPAL USE: General Medical Use,

CUSTOM DEVICE: YES X NO

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DEVICE TYPE: Brachytherapy Source and Storage Devices

DESCRIPTION:

Best Industries, Inc. Storage Devices Model Number Best/1, 2, and 3 are identical to Rad/Irid. Inc. Storage Devices Model Number R1/P1, R1/P3, and R1/P4. These storage containers consist of channels to receive ribbong iridium-192 seeds and lead shielding measuring from seven to eight inches long x three inches in diameter.

The Best/1 container has 30 small, stainless steel channels (tubes) 1c ted around a 5/8 inch diameter circle in the center of the shield body. A 3/8 inch diameter hole extends from end to end and is plugged with a stainless steel friction fitted stopper at one end and a friction fitted lead stopper at the other. The lead plug prevents the nylon ribbon bearing seeds from being inadvertently removed from the 'evice. The device has a stainless steel jacket. See Figure 1.

Model Best/2 devices are not jacketed. A tight bundle of 14 to 18 channels enter one end of bare lead shield near the corner and exists on a diagonal from the other while taking a lazy "S" configuration through the shield. This "S" opening in the shield is cased by a copper tube. Again, the nylon ribbons are held in place by means of friction and tension. See Figure 2.

Model Best/3 devices have 18 stainless steel tubes coiled surrounding the central hole of 3/4 inch diameter, at the bottom of the central hole is lead with a thickness of 1-1/2 inches. It uses a lead plug of 3/4 inch diameter and 1-1/2 inch long, again, the nylon ribbons are held in place by means of friction in the coiling. See Figure 3.

Lead containers are designated as follows:

- Best/1 maximum capacity 30 ribbons maximum total activity 250 mCi.
- Best/2 maximum capacity 18 ribbons maximum total activity 250 mCi.
- Best/3 maximum capacity 18 ribbons maximum total activity 250 mCi.

Each of these containers is packaged in a 10 inch diameter x 10 inch high drum for shipping.

dest Industries, Inc. Model 81-01 iridium-192 seed source is identical to Rad/Irid, Inc., Model 1 source in design, construction and manufacturing. These iridium-192 seeds, following batch irradiation in a reactor, are assembled in nylon ribbons (tubes) and are used for interstitial treatment of cancer.

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DEVICE TYPE: Brachytherapy Source and Storage Devices

DESCRIPTION (CONT'D):

Each iridium-192 seed consists of an iridium - platinum 70 percent alloy in the form of a wire encapsulated doubly in Type 304 stainless steel. Capsules are cold welded by a shearing force (machine crimping). The outside dimension of the encapsulated seed is 3 mm long and 0.5 mm diameter. These capsules are forced into nylon tubing (ribbons) which have an inner diameter slightly smaller than the outside diameter of the capsule. Each seed may contain up to a maximum of 33 mCi of iridium-192, which is equivalent to 18.5 mg Raeq. The most commonly used activity is about DmCi per seed. Standard spacing of these seeds are 1 cm center to center. Each standard set consists of 14 ribbons with 12 seeds each assembled 1 cm center to center spacing. Each ribbon has about 100 cm of inactive leader on one end to facilitate handling and about 3 cm on the other end. However, custom assembly of sources if available and each centimeter can accommodate a maximum of three seeds and a maximum active length of about 20 cm is possible. See Figure 4 and Figure 5. The customer/user may also use up to 11 millicuries per seeds.

LABELING:

Seeds and ribbons are not labeled. However, ribbons may be color coded to designate the activity on date of shipment (mg Raeq). Each container bears a label stating the following markings:

"CAUTION - RADIOACTIVE MATERIAL" Best Industries, Inc. 2244 S. Shirlington Road Arlington, VA 22206 Radiation Symbol, Isotope, Amount, Date

Best Industries, Inc. 2244 S. Shirlington Road Arlington, VA 22206

Ship to:

Date of Shipment

P.O. Number

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DEVICE TYPE:	Brachytherapy Source	and Storage Devices		
LABELING (CONT'D)	:			
No. of Ribbons	No. of Seeds	Activity on Date of Shipment (mg Raeq)	Code*	Color**
		An and a second state of the second state of t		No. of Concession, Name of Concession, or

Internal code to identify reactor irradiated batch of seeds.

** Ribbons may be color coded to designate the activity on date of shipment (mg Raeq). Typical colors used are white, red and blue.

DIAGRAM:

See attached Figures 1 through 5.

CONDITIONS OF NORMAL USE

These sources and containers are designed for use in hospital or clinical environments for the treatment of cancer under the normal conditions encountered in clinical practice.

PROTOTYPE TESTING:

Best Industries, Inc. states that the listed storage containers are identical in design, construction and in manufacturing to the previously approved Rad/Irid devices. Therefore, additional prototype tests were not performed. The containers and sources have been approved for use by Rad/Irid devices dated December 24, 1975.

Best Industries further states that the sources have been in use for 26 years and no problems have been encountered in clinical practice.

Tests to which the sources have been subjected are:

Sources have been exposed to water and cold and warm isotonic saline solutions (0.25 percent sodium chloride by weight) for periods up to six months without signs of corrosion or deterioration.

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DEVICE TYPE: Brachytherapy Source and Storage Devices

PROTOTYPE TESTING (CONT'D):

- Prolonged exposure to concentrated "aepherin" (antiseptic solution) up to six months shows no signs of corrosion or deterioration.
- Sources are autoclaved at pressure up to 350 psi and temperatures up to 250°F for 30 minute periods without any adverse affects notices.

EXTERNAL RADIATION LEVELS:

Source radiation dose rate for the most commonly used activity of 1 mCi per seed:

5 cm = 184 mr/hr 30 cm = 5.1 mr/hr

Source container's radiation profile:

Maximum Reading with Maximum Activity (250 mCi)	Best/1	Model Number Best/2	Best/3
Top	90 mr/hr	50 mr/hr	60 mr/hr
Bottom	90 mr/hr	60 mr/hr	60 mr/hr
Side	90 mr/hr	50 mr/hr	60 mr/hr

Shipping Container's radiation profile:

Maximum Reading with Maximum Activity	Best/1 Model Number Best/2		Best/3	
Top	20 mr/hr	20 mr/hr	30 mr/hr	
Bottom	20 mr/hr	25 mr/hr	30 mr/hr	
Side	20 mr/hr	20 mr/hr	30 mr/hr	

QUALITY ASSURANCE AND CONTROL:

Best Industries, Inc. states that quality assurance and control are provided routinely throughout the manufacture and use of the sources. The stainless steel tubing from which the capsules are made is certified by the manufacturer (Superior Tube Company) to be type 304 stainless steel hyperdermic needle tubing with chemical composition and mechanical properties tested and notorized. The

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DEVICE TYPE: Brachytherapy Source and Storage Devices

QUALITY ASSURANCE AND CONTROL (CONT'D):

manufacturer (Engelhard Industries) of the wire used certifies it to be an alloy of 30 percent iridium and 70 percent platinum. During seed fabrication representative numbers are individually inspected with a magnifying glass to ensure the cold weld when fabrication is complete, all seeds are individually inspected for uniformity, bent or damaged seeds are discarded. After seeds are irradiated they are comparatively measured with a standard of known activity. Representative seeds are then smear tested for the possible contamination.

A Capintec CRC-5R Isotope Calibrator is used for calibration of all Best Industries, Inc. Model 81-01 iridium-192 sources and ribbons. The activity of seeds and ribbons are measured in mCi. The calibrator is standardized against an iridium-192 seed calibrated by the National Bureau of Standards, Washington, D.C. A specific Gamma Ray Constant of 4.6 R.cm²hr⁻¹ mCi⁻¹ is used for converting mCi values into milligram radium equivalent.

Best Industries further states that their rigid quality control program ensures that iridium seeds are produced with close tolerances and that they are uniform in their activity. All assembled ribbons are calibrated before shipping and no ribbon is sent to customers if it varies more than = 5 percent from the state average activity.

The factor used for the conversion of millicuries of iridium-192 to milligram radium equivalent is 0.56, assuming a specific Gamma Ray Constant of 8.25 R.cm²hr⁻¹ mCi⁻¹ for radium-226. Each batch of seeds is given a code number for traceability and ribbons are smear tested for contamination to an acceptance limit of 10⁻⁰ microcurie.

LIMITATIONS AND/OR OTHER CONSIDERATIONS OF USE:

- A. Sources and containers may be distributed to persons specifically licensed pursuant to §§ 35.13, 35.14, and 33.100 Group VI, 10 CFR 35, or under equivalent regulations of Agreement States.
- B. Sources should not be subjected to autoclave pressures in excess of 350 psi and temperatures in excess of 250°F, nor to these temperatures and pressures for periods in excess of 30 minutes.

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LIMITATIONS AND/OR OTHER CONSIDERATIONS OF USE (CONT'D):

- C. These sources shall be leak tested at intervals not to exceed six months using techniques approved by the licensing authority and capable of detecting 0.005 microcurie of removable contamination.
- D. Handling, Storage, Use, Transfer and Disposal: To be determined by the licensing authority.

SAFETY ANALYSIS SUMMARY:

The Best Industries, Inc. Model sources consists of iridium-192 metal wire doubly encapsulated in stainless steel. It is further contained in nylon ribbon (tubing) and is for use by trained radiotherapist for the interstitial treatment of cancer. Sources identical in design, construction and in manufacturing have been in use in this country and around the world for more than 26 years.

From the information and test data in the references cited below, we conclude that these sources in nylon ribbon will be manufactured pursuant to the requirements specified in § 32.74 of 10 CFR 32, and that the sources and device will maintain integrity under stresses likely to be encountered in normal use and accidents and, therefore, are acceptable for licensing purposes.

REFERENCES:

- Clicense application dated July 24, 1981 and document entitled, "Device and Source" signed by Krishnan Suthanthiran, President, Best Industries, Inc., dated September 3, 1981.
- Catalog Sheet issued by NRC to Rad/Irid, Inc. 2212 Georgia Avenue, Washington, D.C., dated December 24, 1975.
- Supersedes registry document No. NR-187-D-101-S dated September 11, 1981.

ISSUING AGENCY: U.S. Nuclear Regulatory Commission

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