

The probable source of bones would be:

1. Orthopaedic Hospitals - Bones from amputated part of Limb (due to trauma), bone from femoral head and bone slices following replacement surgeries.
2. Brain-Dead - Following organ harvesting, bones would be harvested from them;

The bones will need terminal sterilisation by gamma rays (25 kilo Grey)

Bone processed by two different types would need to be irradiated with above mentioned dose as a part of terminal sterilisation:

1. Lyophilised (Free-Dried bones);
 2. Deep- Frozen bones;
- 1) Lyophilised or Freeze-Dried Bone: This processed bone will be in packets of 20 grams to 100 grams each. It would be stored at room temperature. Terminal sterilisation of the product would require 25 kilo Grey of gamma radiation. The bone would be structurally weak. The bone will be in pieces. The processing would entail chemical treatment (70% ethanol, 0.5% Sodium Hypochlorite), pasteurization and freeze-drying. The estimated water content of the product would be less than 7%. The bone will be vacuum-sealed and triple packed (polythene), along with an indicator for radiation sterilization.
2. Deep-Frozen: Terminal sterilisation of the product would require 25 kilo Grey of gamma radiation. To maintain cooler temperatures during radiation, 1 kg of bones would be packed approximately with 1 kg of dry ice. The bone would be structurally strong. The bone would be in its entire length or divided into 2 halves in length. The bone will be triple layer packed (with appropriate packing material) and stored at minus 80° celcius. The maximum length of the bone would be 50 cms.

It is decided, for the present, that the radiation of bones sent from the INSTITUTE will be done by IGCAR without charges. The bones would be delivered to IGCAR, KALPAKKAM, in a sealed form by the INSTITUTE. The transportation of bones for radiation and bringing back to the INSTITUTE will be done by the INSTITUTE at its own cost. The following will be the box sizes in which packed bones will be kept to be irradiated:

1. Maximum Length 64.5 cms
2. Maximum Width: 40.5 cms
3. Maximum Height: 42 cms

Size of the pack may vary, but within the above limits. Multiple boxes also will be packed in a single box not exceeding the above dimensions.

IGCAR, KALPAKKAM would also provide a certificate/report on irradiation conditions including dose rate, time of exposure, distance, calibration of the facility. IGCAR would also ensure that the required dose has been delivered using radiation monitors/LTDs and chemical dosimetry techniques.

IGCAR hereby agrees to make available the gamma irradiator/calibration facility for irradiation of bones for the INSTITUTE as a service. The dose details for irradiation would be provided by the INSTITUTE and IGCAR's role is limited to irradiation of the bones following all prescribed safety norms of AERB. IGCAR is not liable for any of the consequences arising from irradiation and IGCAR takes no third party liability for its service. Transportation of the bones from the INSTITUTE and back following all prescribed safety norms is the responsibility of the INSTITUTE. All the permissions required for this purpose including medical/ethical/administrative/statutory/regulatory clearances would be the responsibility of the INSTITUTE. The same (relevant ones) shall also be shared with IGCAR, KALPAKKAM.


BOTH Parties shall adhere to the ethical norms required for such radiation as per the laws laid in India.


AGREEMENT signed this 18th day of November 2021

For **CANCER INSTITUTE (WIA)**

For **INDIRA GANDHI CENTRE FOR ATOMIC RESEARCH**




DR. E. HEMANTH RAJ
EXECUTIVE VICE CHAIRMAN
EXECUTIVE VICE CHAIRMAN
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WITNESS

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