Safety considerations

Radiopharmaceuticals are radioactive and can pose a risk to the personnel involved in handling them during inter alia manufacture, storage, transport, compounding, testing, dispensing and administration, to the patients to whom they are administered and to the environment.

All personnel involved in any part of the above operations are required to have appropriate specific additional training. All personnel with access to the areas where these operations are carried out, for example, maintenance and support staff such as cleaners should receive specific instruction and appropriate supervision whilst in the operational areas. Risk to patients should be minimized. It is essential to ensure that reproducible and clinically reliable results will be obtained. All operations should be carried out or supervised by personnel who have received expert training in handling radioactive materials.

Specialized techniques are required to minimize the risks to personnel. All procedures in which radiopharmaceuticals are handled must be designed and carried out in compliance with the ***ALARA principle***, that is to ensure that exposure to radiation is ***as low as reasonably applicable***. Three key components of the ALARA principle are ***time*** (reduce time of exposure), ***distance*** (the greater the distance, the lower the risk) and ***shielding*** (appropriate shielding is essential at all stages of handling).

Radiation shielding. Adequate shielding must be used to protect all personnel from ionizing radiation. Additionally, when testing radiopharmaceuticals instruments must be suitably shielded from background radiation.

Alpha and beta radiations are readily shielded because of their limited range of penetration, although the production of Bremsstrahlung by the latter must be taken into account. The range of alpha and beta particles varies inherently with their kinetic energy. The alpha particles are mono-energetic and have a range of a few centimetres in air. The absorption of beta particles, owing to their continuous energy spectrum and scattering, follows an approximately exponential function. The range of beta particles in air varies from centimetres to metres.

The secondary radiation produced by beta radiation upon absorption by shielding materials is known as Bremsstrahlung and resembles soft X-rays in its property of penetration. The higher the atomic number or density of the absorbing material, the greater the energy and probability of the Bremsstrahlung produced. Elements of low atomic number produce low-energy Bremsstrahlung, which is readily absorbed; therefore, materials of low atomic number or of low density, such as aluminium, glass, or transparent plastic materials, are used to shield sources of beta radiation.

Attenuation of gamma radiation in matter is exponential and is expressed in terms of half-value layers. The half-value layer is the thickness of shielding material necessary to decrease the intensity of radiation to half its initial value. A shield of 7 half-value layers is of a thickness that will reduce the intensity of radiation to less than 1% of its unshielded intensity of activity. Gamma radiation is commonly shielded with material of high atomic number such as lead and tungsten.

The intensity of gamma radiation is reduced according to the inverse square of the operational distance between the source and the point of reference. Radioactive materials of several gigaBecquerel (GBq) strength can be handled safely in the laboratory by using proper shielding and/or by arranging for the maximum practicable distance between the source and the operator by means of remote-handling devices.