

B. DOCUMENTATION FOR GRANTING APPROVALS

The following information in appropriate detail, shall be given by the manufacturer to the competent authority for issuing prior approval.

- a) A description of the product, its intended use, its expected useful life and the function served by the radionuclide(s).

- b) The identification, concentration and total activity of the radionuclide(s) used in the product. (The applicant should justify the choice of radionuclide, particularly in relation to other radionuclides of lower radiotoxicity or more appropriate half-life that could be used.)

- c) The justification for the use of the radioactive substance in the product making comparisons with any non-radioactive alternatives.

- d) The chemical and physical form of the radionuclides to be applied to or incorporated in the product.

- e) Details of the design and construction of the product, particularly as related to the containment and shielding of the radionuclide under normal and adverse conditions of use and disposal, and the accessibility of the radioactive substance to unauthorised persons (detailed drawings should be provided).

- f) Details of manufacturing process. Give flow chart.

- g) The organisation of quality control and the quality control tests to be applied to radiation source and other components and to the finished products.

- h) The external radiation level from the product and the method of measurement.

- i) The activity of the total amount of radioactive material(s) expected to be distributed in the products annually and an indication of the importance of the market including a description of the future avenues of distribution or resale in second-hand market.

- j) Instructions for use, installation and maintenance as appropriate.

- k) Information on the possible consequences of misuse, damage or failure.

- l) A description and the results of tests for demonstrating the radiological integrity of the product in normal use, misuse and accidental damage.

- m) Details of information (in advertising material, technical brochures, maintenance instructions, guarantee certificates, etc...) on the radionuclide(s) incorporated and the total amount of activity in the product.

- n) Information on how it is intended to label the product, e.g. name of product, date of manufacture identification and activity of radionuclide(s).

I certify that the information furnished by me is correct to the best of my knowledge and belief.

Place:
Date :

Signature :.....
 Name :.....
 Designation :.....
 (Seal of the institution)