**Medical research — Administration of ionizing radiation to human subjects — Requirements**

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Kenya Industrial Research and Development Institute- Energy Division

Kenya National Accreditation Service

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**Foreword**

The Radiation Protection Act governs the use of ionizing radiation in Kenya. International consensus requires that in all cases of exposure to ionizing radiation, doses to persons and critical organs be kept as low as reasonably achievable, economic and social considerations taken into account.

During the preparation of this Standard reference was made to the following publications:

IAEA Safety Series No. 115 ‘International Basic Safety Standards for Protection against Ionizing radiation and the Safety of Radiation Sources

ICRP Publication 62 Radiological Protection in Biomedical Research, [Annals of the ICRP](https://uk.sagepub.com/en-gb/eur/series/Series2503)

RPS 14, Code of Practice for Radiation Protection in the Medical Applications of Ionizing Radiation (2008), Radiation Protection Series

The Radiation Protection Act, CAP 243 Laws of Kenya, 1985 (Revised)

The Science and Technology Act, Cap 250, Laws of Kenya

WHO, International Ethical Guidelines for Biomedical Research Involving Human Subjects 1993, World Health Organization

Acknowledgement is hereby made for the assistance derived from the above sources.

**KENYA STANDARD KS 1954: 2007**

**Medical research — Administration of ionizing radiation to human subjects — Requirements**

**1 Scope**

This standard specifies the requirements to be met when administering ionizing radiation to human subjects for purposes of medical research. This standard applies to the clinical trials stage of research only.

**2 Approvals**

Any administration of ionizing radiation to human subjects for the purposes of diagnostic or therapeutic research involving external irradiation, brachytherapy or the administration of radionuclides, shall be undertaken only after approval by the National Commission for Science, Technology & Innovation Ethics Committee. The ethics committee shall obtain advice from a person experienced in radiation protection and safety before granting approval. The research proposal shall comply with regulatory requirements relating to the use of ionizing radiation.

**3 Requirements**

The ethics committee shall have regard to:

**3.1** The guidelines of the National Commission for Science, Technology & Innovation Ethics in Medical Research.

**3.2** The guidelines of the World Health Organization on Ethics and Research on Human subjects 1993.

**3.3** A detailed protocol for the research project that shall include estimates of the radiation doses expected to be delivered and the individual and collective risks associated with these doses. A competent person not associated with the project, such as the institution’s radiation safety officer or an experienced medical physicist and radiation oncologist, shall verify these estimates.

**3.4** The manner in which the project is to be explained to the subjects and the informed consent obtained.

**3.5** The measures to be taken during the project to assess the radiation doses delivered, and to keep them to a minimum; As Low As Reasonably Achievable (ALARA).

**3.6** The review of the radiation doses actually delivered to the subjects as soon as reliable data are available, to validate predictions.

**4 Patients**

Where the person irradiated is a patient who may benefit from the procedure, the justification for the irradiation shall be the same as for other medical exposures. Nevertheless because of the experimental nature of the procedure, it shall still be subject to thorough review by the ethics committee.

**5 Non-patients**

No ionizing radiation (IR) shall be administered to non-patients for research purposes.

Where the irradiation is not designed to benefit the person irradiated, subjects shall be selected according to the following criteria:

**5.1 Age**

Because of the possibility of hereditary effects and also because of the long latent periods associated with certain somatic effects of radiation, subjects shall, where practicable, be aged over 40 years, and preferably over 50.

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**5.2 Number of individuals**

The number of subjects irradiated shall be restricted to the minimum necessary to acquire the information needed with sufficient accuracy.

**5.3 Exclusions**

Children and pregnant women shall be excluded as subjects except when problems specific to those groups are being investigated. Research involving administration of ionizing radiation to those groups shall only be performed when the information sought cannot be obtained by other means, and the risks are minimal.

**5.4 Radiation doses**

The radiation doses to subjects shall be kept to the minimum level practicable, and the accumulated effective dose equivalent to any individual subject in any year shall not exceed 5 millisievert\*, except with the approval of the regulatory authority responsible for radiation control. In the case of irradiation of children or of other persons incapable of giving informed consent, approval of the regulatory authority shall be obtained where

estimates of effective dose equivalent exceed 0.5 millisievert\*. For babies, infants or fetuses, approval of the regulatory authority shall be obtained where estimates of effective dose equivalent exceed 0.1 millisievert\*.

\* Excluding normal natural background radiation and exposure from diagnostic or therapeutic procedures.

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