Introduction:

This paper outlines the structure and implementation process for the quality system being put in place by the Biomedical Engineering program at the MRC Unit, the Gambia. The goal is to provide a unit-wide quality system implementation and achieve international standards such as Good Clinical Practices (GCP), Good Clinical Laboratory Practices (GCLP), and ISO 9001 accreditation. Documentations were developed on work processes and procedures that ensured higher quality services and meeting the accreditation requirements.

Background:

Medical Research Council, the Gambia Unit Biomedical engineering program was established 2004 when a Canadian biomedical engineer was hired to create a fully functional biomedical technology management program. The vision for was to provide a sustainable technology management programme, enabling clinical services and laboratory research at the Unit by providing a stable and reliable equipment platform to all our site facilities throughout the country.

Establishing a quality system:

Quality Manager was hired in 2008 to oversee the implementation of quality systems across all departments. For a biomedical engineering department, a good quality system starts with clearly defined policies, standard operating procedures, equipment support plans, and key performance indicators.

Process of developing documentation:

First to be developed was a departmental policy and health technology management program suitably modelled for in-house health technology management and for our distant locations from major equipment manufacturer’s and vendors service support. Next were Standard Operating Procedures for all work processes reflecting technologies life cycle through our organization; examples of those SOPs include, Procurement, commissioning, Inventory & Inspection, Preventive Maintenance, Corrective Maintenance, Decommissioning.

Lessons learned through the process:

The major lessons for all technologists were the understanding of the concept of quality standards, documentation and quality work processes, getting tuned into the practice of quality service delivery and above all understanding the importance and crucial role Biomedical engineering plays in MRC the Gambia Unit's overall objective of maintaining standards of GCP and GCLP.