



# **Terms of Reference: Safety Evaluation Services for Proposed Radiotherapy Facility**

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## **1. INTRODUCTION**

This document gives terms of reference for a Radiotherapy Specialist contracted by the Radiation Protection Authority of Zimbabwe (RPAZ) during the Review and Assessment Phases of an application for authorisation for a new-built radiotherapy facility.

The primary work of the Specialist shall be to review and assess information submitted by the applicant related to safety, technical matters and other information in order to verify the adequacy of the proposed safety measures

## **2. PART 1: REVIEW AND ASSESSMENT WORK**

### **2.1 Inputs to the Review and Assessment Process**

The specialist will during his/her tenure of work contracted by RPAZ make use of the following inputs to the work:

- National Legal and Regulatory requirements, guidance and regulatory procedures specific to review and assessment
- The application for authorisation and documents submitted in support of the application
- Technical and other documents required to assess compliance with the regulatory requirements and the authorization
- Operating experience
- Developments in international standards and research
- Outputs of other regulatory processes (e.g. inspection results, previous reviews and assessment results)

### **2.2 Implementation of the Review and Assessment process**

#### i) Overall responsibilities

To conduct review and assessment activities in support of the RPAZ authorization processes for a Radiotherapy facility.

#### ii) Tasks

The following tasks shall constitute the work of the specialist during the review and assessment period for an application for authorization by a facility:

- Extract relevant information from all inputs
- Request additional technical and other documents from the licensee through RPAZ, if necessary



- Establish a review and assessment plan (identify key issues/tasks, milestones, assigned resources – internal/external)
- Conduct review and assessment activities
- Collect and integrate assessment results and request additional information
- Document the conduct of review and assessment and results
- Propose authorization conditions
- Provide feedback into the authorization and other regulatory processes

### **2.3 Outputs of the Review and Assessment Process**

- The following shall be expected from the specialist following the assessment work:
  - Review and assessment results,
  - Reports giving recommendations and suggestions
  - Proposed conditions for authorization.

### **2.4 Interfaces during the Review and Assessment Process**

The specialist is expected to interface with the following regulatory system processes

- Authorization process
  - Inspection process
  - Enforcement process
  - Document control process
  - Communication process
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