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Document No.	NTP-SPE-7045	Rev No.	2	
Title	User Requirement Specification for Quality Management System			Page 1 of 7





## 1. PURPOSE


The purpose of this document is to outline the system and functional requirements for the Quality Management System at NTP Radioisotopes.

## 2. SCOPE

The scope of this document will cover the system requirements and functional requirements of the Quality Management System on:

- Control of Documents
- Change Management
- Training Management
- Deviation Management
- CAPA Management
- Audit Management
- Complaints Management

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Document No.	NTP-SPE-7045	Rev No.	2	Page 2 of 7	
Title	User Specification Requirements for Quality Management System				

### 3. REFERENCES

This document complies with the requirements of

ISO 9001:2015: Quality Management systems - Requirements, Fifth edition, 2015.  
 PI011-3 Pic/S Good Practices For Computerised Systems in Regulated “GXP” Environments.  
 SAHPRA Guide to Good Manufacturing Practice for medicines in South Africa July 2019 v7.  
 US Food & Drug Administration – Code of Federal Regulations, Title 21, Part 11, and “Current Good.  
 NTP-PRG-0300 : Control of Documented Information and Forms  
 NTP-SOP-7079 : Validation of Computerized Systems Procedure

The following documents are referenced in this document:  
 N/A


### 4. ABBREVIATIONS AND DEFINITIONS

#### 4.1. The following abbreviations are used in this document:

cGMP	:	Current Good Manufacturing Practices
DQ	:	Design Qualification
FDA	:	Food and Drug Administration
IQ	:	Installation Qualification
GDP	:	Good Document Practice
N/A	:	Not Applicable
NTP	:	NTP Radioisotope SOC Ltd
OQ	:	Operational Qualification
URS	:	User Specification Requirements

#### 4.2. The following definitions are provided to ensure a uniform understanding of this document:

Design Qualification	:	The documented verification that the proposed design of the facilities, systems and equipment is suitable for the intended purpose.
Installation Qualification	:	The documented verification that the facilities, systems and equipment, as installed or modified, comply with the approved design and the manufacturer’s recommendations.
Operational Qualification	:	The documented verification that the facilities, systems and equipment, as installed or modified, perform as intended throughout the anticipated operating ranges.
21 CFR part 11	:	CFR Code of Federal Regulations on electronic records and electric signatures, defines the criteria under which electronic records and electronic signatures are considered trustworthy, reliable and equivalent to paper records

Document No.	NTP-SPE-7045	Rev No.	2	Page 3 of 7	
Title	User Requirement Specification for Quality Management System				

## 5. GENERAL

Quality Management System will help NTP to coordinate and direct activities to meet customer and regulatory requirements and improve its effectiveness and efficiency on a continuous basis.

## 6. RESPONSIBILITIES

### 6.1. QA Department

It is the responsibility of the QA Department:

6.1.1. To generate User Requirement document.

### 6.2. QA Manager

It is the responsibility of the QA Manager:

6.2.1. To approve the User Requirement Specification.

### 6.3. Service Provider (IT department)

It is the responsibility of service provider (IT department):

6.3.1. To source the required system(s).

6.3.2. To ensure system is available and functional at all times.

6.3.3. To implement the system according to NTP's requirements.

6.3.4. To backup data from the system(s).

## 7. PROCESS

### 7.1. System Requirements

#### 7.1.1 Security Control

The system must include mechanisms to ensure that consistent and accurate records are created:

- The system must allow only authorized personnel to create, capture, update or purge records, metadata associated with records, files of records, classes in classification schemes, and retention schedules.
- The system must control access to the records according to well-defined criteria.


#### 7.1.2 Meta Data

The system must allow creators of records to enter manually pertinent record metadata that cannot be captured automatically:

- The system must support the validation of metadata that is entered by users, or metadata that is imported from other systems.
- Metadata must be logically linked to the records, files, and classes it documents, so that users can review metadata information when they retrieve records.
- The system must allow for the modification or reconfiguration of metadata sets, but the authorization to make changes must be restricted.

#### 7.1.3 Access and Use

- The system must ensure that ALL records can be easily accessed and retrieved in a timely manner.
- The system must allow all record content and all record and file metadata to be searchable.

Document No.	NTP-SPE-7045	Rev No.	2	Page 4 of 7	
Title	User Requirement Specification for Quality Management System				

- The system must allow searching within an electronic file, across files, at any level in the classification scheme hierarchy.
- The system must ensure that all components of a record or file, including contents, relevant metadata, notes, attachments, etc., can be accessed, retrieved and rendered as a discrete unit or group and in a single retrieval process.

#### **7.1.4 Preservation, backup and recovery**

The system must incorporate a plan for backing up and preserving records:

- The system must ensure that records, components of records, audit trails, metadata, links to metadata or to files, and classification schemes can be converted or migrated to new system hardware, software and storage media without loss of vital information.
- The system must produce a report detailing any failure during a conversion or transfer and identifying records that were not successfully exported.
- The system must retain all records that have been exported until confirmation of a successful transfer process.
- The system must provide automated process that allow for the regular backup and recovery of all records, files, metadata, and classification schemes.

#### **7.1.5 Electronic Signatures**

The system must have electronic signatures:

- The signature should be uniquely linked to the person. The person's identity should have been verified adequately to prevent spoofing. It is important that the person's identity is cryptographically bound with their signature (requires the use of unique signing keys for each user) such that the identity can be verified as part signature verification process.
- There must be a mark to indicate the person's electronic signature. It can take any form and normally is the digitized version of the handwritten.

#### **7.1.6 Audit Trails**


The system must maintain audit trails for all processes that create, update or modify, delete, access and use records, categories or files of records, metadata associated with records, and the classification schemes that manage the records.

At a minimum, it tracks:

- what data or information was accessed, added, deleted or modified;
- who performed these functions; and
- When they were performed.
- The system must automatically capture the audit trail.
- The audit trail data must be unalterable.
- The audit trail must be maintained for as long as required by QA
- The audit data must be available for inspection or export (without affecting vital audit trail data) by authorized users with little or no experience with the system.
- The system must maintain basic system documentation and audit trails of system modifications as long as they are required to facilitate continued access to records.
- The system must provide reports for actions taken on basis of audit trail data.

#### **7.1.7 Validation**

Validation of the system should address FDA 21 CFR part 11 requirements. It is preferable that the service provider perform the validation of the system and generate all the relevant protocols. The NTP Validation Team should provide the requirements and facilitate the validation activities.

Document No.	NTP-SPE-7045	Rev No.	2	Page 5 of 7	
Title	User Requirement Specification for Quality Management System				

### **7.1.8 Service Level Agreement**

A service level agreement should be in place between NTP and the service provider and this should include after sale support, maintenance requirements and service terms. Warranties and/or guarantees of software (where applicable) should be clearly stated in the agreement.

### **7.1.9 Compliance**

There should be relevant compliance or conformance certificates or management process that can provide assurance to the Quality department on the system design, controls and fitness of purpose.

## **7.2. Functional Requirement**

### **7.2.1. Control of Documents and Records**

- 7.2.1.1. Seamless collaboration for co-authoring, review and approval processes
- 7.2.1.2. Security and classification and customised access levels to various documents
- 7.2.1.3. Storage and Expiry dates and retention management
- 7.2.1.4. Compliant Electronic signature
- 7.2.1.5. Version control management
- 7.2.1.6. Distribution workflows
- 7.2.1.7. Ease of accessibility
- 7.2.1.8. Audit and track record
- 7.2.1.9. Archiving and backups management
- 7.2.1.10. Workflows notifications for expiring documents, or pending actions

### **7.2.2. Change Management**


- 7.2.2.1. Provision for change control to manage the following phases of change management:
- 7.2.2.2. Identify, propose and justify change;
- 7.2.2.3. Review and categorisation of proposed change;
- 7.2.2.4. Evaluation of the change;
- 7.2.2.5. Evaluation of regulatory approval;
- 7.2.2.6. Approval for implementation;
- 7.2.2.7. Post-implementation follow-up.
- 7.2.2.8. Full Trace and audit reports for all change requests
- 7.2.2.9. Seamless notifications and workflows for routing the change through various approval and implementing phases.

### **7.2.3. Training Management**

- 7.2.3.1. Track and manage training records
- 7.2.3.2. Reminders and notification for new training and renewals
- 7.2.3.3. Training reports
- 7.2.3.4. Secure Storage and easy accessibility of training records
- 7.2.3.5. Link to the document centre for automatic update the training matrix

### **7.2.4. Deviations Management**

- 7.2.4.1. Registration of deviations
- 7.2.4.2. Investigation of deviations
- 7.2.4.3. Reviewing of the investigation information and acceptance of it
- 7.2.4.4. Closure of the deviations upon approval
- 7.2.4.5. Reports on deviations (trends, reoccurrence, history track etc.)
- 7.2.4.6. Deviations workflows from one stage to another
- 7.2.4.7. Notifications and reminders for actions to be performed
- 7.2.4.8. Escalations workflow
- 7.2.4.8. Customised access control

Document No.	NTP-SPE-7045	Rev No.	2	Page 6 of 7	
Title	User Requirement Specification for Quality Management System				

#### **7.2.5. CAPA Management**

- 7.2.5.1. Registration of CAPA
- 7.2.5.2. Risk assessment
- 7.2.5.3. Identify root cause
- 7.2.5.4. Determine corrective actions
- 7.2.5.5. Verify proposed actions
- 7.2.5.6. Approval of proposed actions
- 7.2.5.7. Implementation of the propose actions
- 7.2.5.8. Approval of the implemented actions
- 7.2.5.9. Review of the implemented actions and close out
- 7.2.5.10. Reports
- 7.2.5.11. Notifications and reminders of due actions
- 7.2.5.12. Escalations workflow
- 7.2.5.13. Seamless routes of the CAPA for various stages and personnel

#### **7.2.6. Audit Management**

- 7.2.6.1. Manage internal and external audits findings
- 7.2.6.2. Track audits communications and their workflows
- 7.2.6.3. Manage audits reminders and escalations
- 7.2.6.4. Generate customised audit reports for different stakeholders

#### **7.2.7. Complaint management**

- 7.2.7.1. Registration of complaint
- 7.2.7.2. Investigation of complaint
- 7.2.7.3. Reviewing of the investigation information and acceptance of it
- 7.2.7.4. Closure of the complaints upon approval
- 7.2.7.5. Reports on complaints (trends, reoccurrence, history track etc.)
- 7.2.7.6. Complaint workflows from one stage to another
- 7.2.7.7. Notifications and reminders for actions to be performed
- 7.2.7.8. Customised access control

## **8 RECORDS**


Record	Retention Period	By Whom
N/A	N/A	N/A

## **9 TASK HAZARD ASSESSMENT**

Not applicable to this document

## **10 LIST OF FORMS**

Form Title	Form Number	Exhibit Number
N/A	N/A	N/A

Document No.	NTP-SPE-7045	Rev No.	2	Page 7 of 7	
Title	User Requirement Specification for Quality Management System				

## 11 REVISION HISTORY

Rev.	Date Approved	Nature of Revision	Originated by
1	2021/01/25	First issue.	E Motsoene
2	See title page	Updated to include validation, service level agreement and compliance requirements	E Motsoene