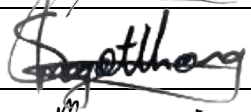
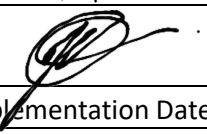
ACTION	NAME & EXPERTISE	SIGNATURE	DATE
Originated By:	MM van Vuuren *Engineering*		2026/08/18
Checked By:	T More *HVAC Engineering Review*		2026/08/18
Checked By:	L Mogotlhong *Project Management Review*		2026/08/18
Checked By:	M Sekgodi *Operations Review*		2026/08/18
QA Approved By:	L Moremi *Quality Assurance Review*		2026/08/19
Approved By:	V Legoabe *Engineering Review*		2026/08/19
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Title	Radioiodine API Manufacturing Facility Scope of Services				
CMS Unique ID	N/A				
Project Number	NTP-PRJ-22/001				

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Project Number	NTP-PRJ-22/001				

1 PURPOSE

The purpose of this document is to outline the scope of services for the modification of an existing structure for the establishment of a Radioiodine Active Pharmaceutical Ingredient (API) facility.

2 SCOPE

This document outlines the the scope of services for the modification of an existing structure for the establishment of a Radioiodine Active Pharmaceutical Ingredient (API) facility.

The Radioiodine Active Pharmaceutical Ingredient (API) facility will be located in Building P1900 on the South African Nuclear Energy Corporation (NECSA) Complex [Elias Motsoaledi Street Extension (Church Street West), R104 Pelindaba, Brits Magisterial District, Madibeng Municipality, North-West Province, 0240] and will be used to produce non-sterile I-131 API in liquid form.

3 REFERENCES

This document complies with the requirements of:
NTP-PRG-0300: Control of Documented Information and Forms
NTP-PRG-0730: Design and Development
NTP-PRG-0740: Procurement of Safety and Quality Classified Products and Services
SHEQ-INS-0234: Necsa QMS Requirements for External Design Organizations
Engineering Council of South Africa (ECSA), Guideline Scope of Services and Professional Fees — Scope of Services and Professional Fees for Persons Registered in terms of the Engineering Profession Act, 46 of 2000, Government Gazette No. 52691, 16 May 2025.

The following documents are referenced in this document:
NTP-SPE-4162: Requirements Specification for the Activation I-131 Manufacturing Facility
NTP-SPE-4168: Activation Iodine-131 API Manufacturing Facility Building Management System User Requirements Specification
SHEQ-INS-0234: Necsa QMS Requirements for External Design Organizations
ISO 14644: Cleanrooms and Associated Control Environments

4 ABBREVIATIONS AND DEFINITIONS

4.1 The following abbreviations are used in this document:

API	:	Active Pharmaceutical Ingredients
CAD	:	Computer-Aided Design
cGMP	:	Current Good Manufacturing Practices
HVAC	:	Heating Ventilation and Air Conditioning
I-131	:	Iodine-131

IFC	:	Issued for Construction
IFD	:	Issued for Design
ISO	:	International Organization for Standardization
PDF	:	Portable Document Format
QMS	:	Quality Management System
SAHPRA	:	South African Health Product Regulatory Authority
SPE	:	Specification
SOW	:	Scope of Work
PIC/S	:	Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme
URS	:	User Requirements Specification

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

Change Control	:	A formal system by which qualified representatives of appropriate disciplines review proposed or actual changes that might affect the validated status of facilities, systems, equipment or processes. The intent is to determine the need for action that would ensure and document that the system is maintained in a validated state.
Client	:	Any juristic person, entity, or organ of the State who enters into an agreement with a consulting engineer for services on a project.
Contractor	:	The person or entity appointed by the client under a construction contract to execute and complete the works in accordance with the contract, including the approved drawings, specifications, programme, quality requirements, applicable legislation, standards and other contractual requirements.
Radioactive Iodine	:	An unstable radioactive isotope of iodine that undergoes nuclear decay and emits ionising radiation, such as beta particles and/or gamma radiation. Radioactive iodine may be used for diagnostic or therapeutic purposes and can present an external and, particularly when inhaled or ingested, an internal radiation hazard.
Scope of Services	:	The documented description of the professional, technical, management, advisory and other services to be performed by the service provider in delivering the project. it defines the required activities, responsibilities, deliverables, performance requirements, project stages and applicable standards and establishes the extent and limits of the service provider's appointment.
Service Provider	:	A Service Provider is an individual, company, organisation, or other entity appointed or contracted by a client or organisation to provide specified professional, technical, consulting, operational, or other services in accordance with an agreed scope of work, terms and conditions, and applicable legislation
Service	:	The professional, technical, advisory, consulting, management, operational, or other activities performed by the Service Provider for the Client, as defined

		in the agreed scope of services and subject to the applicable terms and conditions of the appointment.
Specifications	:	Specifications are detailed written requirements that define the technical, functional, performance, quality, materials, workmanship, testing, and acceptance criteria that a product, service, system, or construction work must satisfy.
Works	:	Works refers to the physical construction, installation, alteration, refurbishment, repair, maintenance, demolition, or other activities required to deliver a completed facility, infrastructure asset, or project in accordance with the contract requirements

5 GENERAL

5.1 The Radioiodine Active Pharmaceutical Ingredient (API) facility to be located in Building P1900 on the South African Nuclear Energy Corporation (NECSA) Complex [Elias Motsoaledi Street Extension (Church Street West), R104 Pelindaba, Brits Magisterial District, Madibeng Municipality, North-West Province, 0240] will be used to produce non-sterile I-131 API in liquid form. Due to the nature of the product being manufactured, the premises, services, systems, equipment, and processes must be designed to comply to the principles and guidelines of current Good Manufacturing Practice (cGMP), as prescribed by SAHPRA, PIC/S, ISO 14644 and other national and international guidelines and standards.

5.2 The Radioiodine Active Pharmaceutical Ingredient (API) facility will house the I-131 production process together with its support functions and infrastructure to enable safe, compliant and sustainable manufacturing of the I-131 API product.

6 RESPONSIBILITIES

6.1. The Client (NTP) shall

- Provide the project brief, requirements, funding and necessary information.
- Appoint and manage the relevant professional service providers.
- Provide approvals and decisions within the required timeframes.
- Ensure compliance with applicable legislation, policies and procurement requirements.

6.2. Project Manager (NTP and Service Provider) shall:

- Manage and coordinate the project within the approved scope, budget and programme.
- Coordinate the Client, Service Provider, Contractor and other stakeholders.
- Monitor cost, programme, quality, risks and progress.
- Manage project reporting, meetings, actions and project documentation.

6.3 The Service Provider shall:

- Provide the required professional and technical services in accordance with the Scope of Services.
- Prepare designs, specifications, reports and other required deliverables.
- Ensure compliance with applicable legislation, standards and professional requirements.
- Provide technical advice, monitor quality and support procurement, construction, commissioning, qualification and close-out as applicable.

6.4 The Contractor shall:

- Execute and complete the works in accordance with the contract, drawings and specifications.
- Manage construction activities, labour, materials, plant and subcontractors.
- Comply with applicable health, safety, environmental and statutory requirements.
- Maintain the required quality standards and conduct necessary testing and inspections.
- Manage the construction programme and report progress and delays.
- Rectify defects and non-conforming work.
- Maintain required construction records and documentation.
- Complete commissioning, handover and close-out requirements.

7 PROCESS

7.1 Project Stages

7.1.1 The service provider shall render engineering design and project management services of NTP-SPE-4162 Rev 2 and NTP-SPE-4168 Rev 1 according to the scope of services defined below.

7.1.2 <u>Stage 1: Inception/Initiation</u>

7.1.2.1 Requirements:

The professional service provider shall assess and establish NTP's requirements, preferences, user needs and options. The service provider shall evaluate the User Requirement Specification (NTP-SPE-4162 and NTP-SPE-4168) against NTP's established and regulatory (incl. cGMP) requirements and where necessary, recommend on amendments to be made to the URS for alignment with such requirements.

7.1.2.2 The service provider shall also:

- Attend project meetings, as required (virtual or in-person).
- Advise on the rights, constraint consents and approvals.
- Define the scope of services and scope of work required.
- Conclude the terms of the agreement with NTP.

- Inspect the site and advise on the necessary surveys, analyses, tests and site or other investigations where such information will be required for Stage 2 including the availability and location of infrastructure and services.
- Advise on criteria that could influence the project life cycle cost significantly.

7.1.2.3 Deliverables

Deliverables of the service provider shall include:

- Agreed scope of services and scope of work.
- Signed agreement.
- Report on project site and functional requirements.
- Schedule of required surveys, tests, analyses and site investigations.
- Schedule of consents and approvals and related timeframes.
- Inception/Initiation Report.

7.1.2.4 Stage 1 is complete when the Inception/Initiation Report is approved by NTP.

7.1.3 <u>Stage 2: Concept and Viability/ Preliminary Design</u>

7.1.3.1 Requirements:

The service provider utilize the User Requirement Specification (NTP-SPE-4162 and NTP-SPE-4168) and Stage 1 deliverables to develop the concept and preliminary design, including but not limited to systems such as HVAC, electrical reticulation, lighting, building finishes, etc.

7.1.3.2 The service provider shall also:

- Attend project meetings, as required (virtual or in-person).
- Agree documentation programme with NTP.
- Advise NTP on the necessary surveys, analyses, tests and investigations that may be required, including the availability and location of infrastructure and services.
- Establish the concept design criteria.
- Establish the regulatory authorities' requirements (including cGMP).
- Prepare initial concept design and related documentation, in accordance with the concept design criteria and the regulatory authorities' requirements (including cGMP).
- Refine and assess the concept design to ensure conformance with all regulatory requirements and consents (including cGMP).
- Establish access, utilities, services (including HVAC) and connections required for the design.
- Coordinate design interfaces.
- Prepare process designs, preliminary designs, and related documentation for approval by NTP.
- Provide cost estimates and life cycle costs as required.
- Liaise, co-operate, and provide necessary information to NTP.

7.1.3.3 Deliverables

Deliverables of the service provider shall include:

- Concept design criteria and regulatory authorities' requirements (including cGMP).
- Concept design (.pdf and drawing format).
- Quality assessment report (to provide assurance that the design complies with all the requirements).
- Schedule of required surveys, tests and other investigations and related reports.
- Process design.
- Preliminary design (including HVAC, pressure cascade, material and personnel diagrams) (.pdf and drawing format).
- Preliminary cost estimates of the establishment of the new facility.
- Concept report.

7.1.3.4 Stage 2 is complete when the Concept Report is approved by NTP.

7.1.4 Stage 3: Design Development/ Detail Design

7.1.4.1 Requirements:

The service provider shall develop the client accepted concept to finalise the design, outline specifications, cost plan, financial viability, and programme for the project.

7.1.4.2 The service provider shall also:

- Review documentation programme with NTP.
- Attend project meetings, as required (virtual or in-person).
- Incorporate NTP's and regulatory authorities' (including cGMP) detailed requirements into the design.
- Prepare design development drawings including draft technical details and specifications, including but not limited to:
  - Architectural plans
  - MEP (Mechanical, Electrical, Plumbing) systems
  - Laboratory casework and equipment layout
  - HVAC and ventilation systems
  - Fire safety and emergency systems
- Review and evaluate design and outline specification and exercise cost control.
- Prepare detailed estimates of construction cost in the form of a bill of quantities.
- Liaise, co-operate, and provide necessary information to NTP.
- Submit the necessary design documentation (i.e fire, electrical, security designs etc.) to local and other authorities for approval.

7.1.4.3 Deliverables

Deliverables of the service provider shall include:

- Design development drawings, in CAD and PDF formats.
- Outline specifications.
- Local and other authority submission drawings and reports.
- Detailed estimates of construction costs in the form of a Bill of Quantities (BOQ).
- Design Development Report.

7.1.4.4 Stage 3 is complete when the Design Development Report is approved by NTP.

7.1.5 Stage 4: Design Documentation and Procurement

7.1.5.1 Requirements:

The service provider shall prepare procurement and construction documentation, advise on procurement strategies and procedures for effective and timeous procurement of necessary resources for execution of the project.

7.1.5.2 The service provider shall also:

- Attend project meetings, as required (virtual or in-person).
- Prepare specifications and preambles for the works.
- Accommodate services design.
- Check cost estimates and adjust designs and documents, if necessary, to remain within budget.
- Prepare and submit relevant documentation for contractor procurement by NTP.
- Review designs, drawings, and schedules for compliance with approved budget.
- Liaise, co-operate, and provide necessary information to NTP.
- Assist in the evaluation and recommendation of tenders.
- Perform due diligence inspections of recently completed installations by tenderers , provide document evidence to NTP and determine the veracity thereof.
- Assist NTP with assessing samples and products for compliance and design intent.

7.1.5.3 Deliverables

Deliverables of the service provider shall include:

- Specifications.
- Services co-ordination.
- Working/ construction-ready drawings, in CAD and PDF formats.
- Budget construction cost.
- Tender documentation.
- Tender evaluation and recommendation report, including a due diligence inspection report of recently completed installations by tenderers.
- Priced contract documentation.

- Design Documentation Report.

7.1.5.4 Stage 4 is complete when the Design Documentation Report is approved by NTP.

7.1.6 Stage 5: Works, Contract Administration and Inspection

7.1.6.1 Requirements:
The service provider shall manage, administer, and monitor the construction contracts and processes, including preparation and coordination of procedures and documentation to facilitate practical completion of the works.

7.1.6.2 The service provider shall also:

- Attend site handover.
- Coordinate construction activities with NTPs production, engineering and maintenance activities, ensuring minimal disruption of NTP's normal business activities during construction.
- Issue construction documentation in accordance with the documentation schedule, in the case of structural engineering, reinforcing bending schedules and detailing, and specifications of structural steel sections and connections.
- Assist NTP with contract administration procedures in terms of the contract.
- Assist NTP with preparing schedules of predicted cash flow.
- Attend regular site, technical and progress meetings.
- Inspect works for conformity to contract documentation.
- Review the outputs of quality assurance procedures and advise the contractor and NTP on adequacy and need for additional controls, inspections and testing.
- Adjudicate and resolve financial claims by contractor(s).
- Assist in the resolution of contractual claims by the contractor.
- Assist NTP with establishing and maintaining a financial control system.
- Clarify details and descriptions during construction as required.
- Prepare valuations for payment certificates.
- Witness and review of all tests and mock-ups carried out both on and off site.
- Check and approve contractor drawings for design intent and compliance with contract documents.
- Update and issue drawings register.
- Issue contract instructions as and when required.
- Review and comment on operation and maintenance manuals, guarantee certificates and warranties.
- Inspect the works and issue practical completion and defects list.
- Arranging for the delivery of all test certificates, including the Electrical Certificate of Compliance, statutory and other approvals, as built drawings, and operating manuals.

7.1.6.3 Deliverables:

Deliverables of the service provider shall include:

- Schedules of predicted cash flow.
- Construction documentation.
- Drawing register.
- Contract instructions.
- Valuations for payment certificates.
- Progressive and draft final account(s).
- Practical completion certification and defects list.
- All statutory certification and certificates of compliance (i.e. Electrical) as required by the local and other statutory authorities.
- Works Completion Report.

7.1.6.4 Stage 5 is complete when the Works Completion Report is approved by NTP.

7.1.7 Stage 6: Handover and Close-Out

7.1.7.1 Requirements:

The service provider shall fulfil and complete the project close-out, including necessary documentation to facilitate effective completion, handover, and operation of the project.

7.1.7.2 The service provider shall also:

- Inspect and verify the rectification of defects.
- Receive, comment-, and approve relevant payment valuations and completion certificates.
- Prepare and/or procure operations and maintenance manuals, guarantees and/or warranties.
- Prepare and/or procure as-built drawings and documentation.
- Conclude the final accounts where relevant.

7.1.7.3 Deliverables

Deliverables of the service provider shall include:

- Valuations for payment certificates.
- Works and completion lists.
- Operations and maintenance manuals, guarantees and/or warranties.
- As-built drawings and documentation.
- Final accounts.
- Close-out Report.

7.1.7.4 Stage 6 is complete when the Close-out Report is approved by NTP.

7.2 Quality Requirements

7.2.1 The service provider shall comply with the quality requirements stipulated in SHEQ-INS-0234.

7.2.2 The service provider shall prepare a Design and/or Project Quality Plan before the commencement of the design services. The Design and/or Project Quality Plan shall define, as a minimum:

- The purpose, goals, objectives and scope of the design and development programme, including a clear description of the facility, systems and deliverables to be developed.
- The applicable design phases and the activities, major tasks and deliverables required during each phase.
- The project organisation, including the roles, responsibilities, authorities, staffing and resources of the customer, Project Manager, designers, contractors, vendors and other participating organisations or stakeholder.
- The controls for managing interfaces between internal and external parties, including responsibility for the review, approval, release, distribution and revision of design information and documents.
- The method for communicating design information across interfaces, including identification of document status, outstanding or incomplete items, and the timely confirmation of information initially communicated verbally or informally through controlled documentation.
- The design inputs and constraints, including user and process requirements, engineering procedures, quality assurance requirements, regulatory requirements, applicable codes and standards, required design methodologies and other project-specific limitations.
- The design outputs and documents required for each design phase.
- The design review, verification and validation activities required at each phase, in accordance with NTP-SPE-4162 Section 7.11 and NTP-SPE-4168, where applicable.
- The safety, quality and technical assessments to be performed at the relevant design stages.
- The risk management approach, including how design and project risks will be identified, assessed, controlled, communicated and reviewed throughout the project lifecycle.
- The design programme and schedule, including key activities, milestones, submission dates, review periods and approval points.
- The document management arrangements, including document numbering, version control, checking, review, approval, issue status, distribution, retention and retrieval.
- The requirements for issuing design documents at predefined stages, such as Concept, Issued for Design (IFD) and Issued for Construction (IFC).
- The process for conducting and documenting design and project progress reviews.
- The change-control process for evaluating, approving, implementing, communicating and documenting design and project changes.
- The process for recording, assigning, tracking, closing and verifying issues, actions, deficiencies and punch-list items.

- The requirements for the review, approval and controlled use of vendor documentation and data supporting system design, procurement, construction, installation, commissioning, qualification and verification.
- The arrangements for monitoring compliance with the Design Control Plan and/or Project Quality Plan.
- The Design Control Plan and/or Project Quality Plan shall be maintained as a controlled document and shall be reviewed, updated and approved at appropriate stages as the design and development programme progresses.

7.2.3 The service provider shall comply with the life-cycle requirements stipulated in NTP-SPE-4162 Section 7.11 and NTP-SPE-4168.

8 RECORDS

Record	Retention Period	By Whom
None	N/A	N/A

9 TASK HAZARD ASSESSMENT

N/A

10 LIST OF FORMS

Form Title	Form Number	Exhibit Number
None	N/A	N/A

11 REVISION HISTORY

Rev.	Date Approved	Nature of Revision	Originated by
1	2026/08/14	First Issue	MM van Vuuren
2	See Title Page	Removed reference to Framework for Infrastructure Delivery and Procurement Management (FIDPM) from sections 3, 4 and 7. Added definition of “Client” to section 4.2. Removed responsibilities of Project Sponsor/Owner from section 6. Removed the following from section 7.1.5.2: • Participate in calling for tenders for NTP • Prepare contract documentation for signtaure.	MM van Vuuren