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Checked	N Kalume *E&P: Project Co-ordinator*		2021/10/06
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Approved	SST Ramathe *Head: Group Programme Execution*		2021/10/07
		Implementation Date:	

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1. PURPOSE

This document defines the project Scope of Work for the Radiopharmaceutical synthesis units to be installed in the existing AGATHA-shielded cell with laminar flow at the NTP Cyclotron Facility (P-2000) at Pelindaba, South Africa.

The Scope of Work describes the Work that the Supplier shall perform for the design, procurement and manufacturing, installation, and support to NTP for commissioning, start-up and performance testing.

The Scope of Work contains the design requirements for the synthesis unit and other requirements for the execution of the Work to be performed by the Supplier for the realisation of the system.

The prime aims of this Scope of Work are:

a. To provide comprehensive information, basis of design, specifications and instructions to the Supplier for carrying out the Work.
b. To serve as a firm and agreed basis for the implementation of the project by the Supplier enabling NTP to monitor the progress and performance of the Supplier during all phases of the works execution.

In the event of an item being omitted from the Scope of Work, it does not relieve the Supplier of its responsibilities under the Service agreement to provide all facilities necessary to ensure the systems safety, operability, maintainability and to meet the required regulatory and environmental standards.

2. SCOPE

The Scope of Work will be executed in 6 phases, namely:

a. Phase 1 - Project Initiation Documents
b. Phase 2 – Procurement and Manufacturing (Including FAT & Site Delivery)
c. Phase 3 – Pre-Installation Requirements
d. Phase 4 – Unit 1: Installation, Cold and Hot Commissioning Including Training (IQ, OQ and PQ)
e. Phase 5 – Unit 2: Installation, Cold and Hot Commissioning Including Training (IQ, OQ and PQ)
f. Phase 6: Project Closure

3. REFERENCES

This document complies with the requirements of:

NTP-PRG-0300	:	Control of documented information and forms
NTP-SOP-6004	:	Access and Egress Control for Radiological Areas
NTP-SOP-6031	:	NTP ALARA Instruction
SHEQ-INS-0825	:	Necsa Requirements for Construction

The following documents are referenced in this document:

RPH-SPE-7507	:	User Requirement Specification: New Automated Dispensing Unit
SHEQ-INS-5450	:	Safety, health and Environmental Requirements for Contractors

4. ABBREVIATIONS AND DEFINITIONS

4.1 The following abbreviations are used in this document:

COC	:	Certificate of Conformance
FAT	:	Factory Acceptance Test
IQ	:	Inspection Qualification
MOM	:	Minutes Of Meeting
NLA	:	Necsa Learning Academy
NTP	:	Nuclear Technology Products
OQ	:	Operational Qualification
P&ID	:	Piping and Instrumentation Diagram
PPE	:	Personnel Protective Equipment
PQ	:	Performance Qualification
QA	:	Quality Assurance
QC	:	Quality Control
RPO	:	Radiation Protection Officer
RPWP	:	Radiation Protection Work Permit
SAT	:	Site Acceptance Test
SHEQ	:	Safety, Health, Environment and Quality
SSC	:	Structures, systems and Components
TBA	:	To be Advised

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

COID	:	The "Compensation for Occupational Injuries and Diseases Act" or "COID Act" states that all South African persons (individuals / companies) who employ one or more employees, in connection with their business / farming activities, organisation / association / trust are under the scrutiny of the COID Act. Employees will be covered for injuries whilst on duty.
Design Qualification (DQ)	:	The documented verification that the proposed design of the facilities, systems and equipment is suitable for the intended purpose.
Installation Qualification (IQ)	:	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 (OQ)	:	The documented verification that the facilities, systems and equipment, as installed or modified, perform as intended throughout the anticipated operating ranges
Performance Qualification (PQ)	:	The documented verification that the facilities, systems and equipment, as connected together, can perform effectively and reproducibly, based on the approved process method and product specification
Qualification	:	This is the planning, carrying out and recording of tests on facilities, systems and equipment, which form part of the validation process, in order to demonstrate that it will perform as intended.
Validation	:	Documented series of actions that prove that any procedure, process, equipment, material, activity or system performs its intended functions adequately and consistently, and lead to the expected results of uniform batches that meet the required specifications and quality attributes.

5. GENERAL

A task hazard assessment shall be completed prior to the installation, cold commissioning and hot commissioning activities. External service provider or contractor performing physical tasks shall undergo the Contractor Orientation at NLA prior to accessing the plant. External contract or service provider shall present a safety file to the RPO prior to commencing with the installation, cold commissioning and hot commissioning activities in the plant. All personnel shall keep to the ALARA principle as they perform various tasks and activities in the Radiochemistry Room and Cyclotron Room of the Cyclotron Facility.

6. RESPONSIBILITIES

6.1 Project Management

6.1.1 Management Meetings

Regular meetings of a general nature, convened and chaired by the Supplier, are as follows:

a. Project Kick-off ,
b. Alignment meeting, and
c. Progress meetings.

Meeting schedules will be determined during the Project Kick-off Meeting. Meetings of a specialist nature may be convened as specified by persons and at times and locations to suit the Parties, the nature and the progress of the services. Minutes of these meetings (MOM) are submitted to NTP by the person convening the meeting within five working days of the meeting.

Meetings are recorded using minutes of meeting and an attendance register prepared and circulated by the convenor of the meeting, unless otherwise agreed. Issues arising from meetings are acted on by the Parties in accordance with the minutes of meeting and the service agreement (offer).
Items recorded in the MOM are not considered an instruction by NTP to the Supplier. Should a change to the services or its execution methodology be required that may be interpreted as a change instruction, the change management process should be followed prior to implementation.

6.1.2 Site visits

The Supplier complies with the relevant statutory regulations and NTP's procedures required to enter the site. The Supplier ensures that all the Supplier's personnel obtain the necessary permits to enter or work on site. The Supplier ensures that personnel visiting the site apply adequately in advance for the necessary permits.
The Supplier ensures:

a. Compliance with the SHEQ requirements as stipulated in the relevant site specific SHEQ procedures during site visits (SHEQ-INS-5450);
b. All its personnel entering the site wear the appropriate Personal Protective Equipment (PPE) required for the specific site.

6.1.3 Time management

The Installation planning and schedule reporting shall be based on the following:

a. The Suppliers Schedule shall be based on NTP's requirement and shall describe the Works phases overall duration and timescales, and identify Milestones and key dates.
b. The Suppliers Schedule shall be of sufficient detail to illustrate how the Supplier shall achieve completion of the Work within the target dates. Additional activities,

key dates and interfaces shall be shown where this helps to demonstrate critical or high-risk elements of the Work.

c. As a minimum, the Milestones shall be shown; these may be supplemented with additional Milestones to highlight key events and interfaces. The critical path shall also be shown.

d. NTP will approve the Supplier Schedule with the placement of the order. It shall not be changed without the written consent of NTP.

e. The Supplier Schedule shall be updated and reissued monthly using a "time now" line to emphasise progress achieved. A forecast bar line shall show the remaining duration to illustrate the time to completion of the Project. Where this impacts on the planned dates of achievement of Project Milestones, a forecast date shall be shown.

6.2 Quality Assurance

The Supplier implements and maintains a Quality Management System (QMS) that, as a minimum, meets the requirements of the standard for quality systems, ISO 9001:2015 or latest.

6.3 Communication Management

6.3.1 Progress Meetings

Weekly project progress meetings are held to report progress, plan events and resolve issues. These meetings are conducted face to face, via teleconference or video link, as appropriate.

6.3.2 Retention of documentation

The Supplier ensures all material, deliverables and supporting data and information generated in providing the services, are securely stored in such a manner that they are readily retrievable for the period/s specified herein (6.3.3).

The Supplier implements appropriate administrative controls to limit unauthorised access and to prevent inadvertent loss of or damage to material and deliverables.

6.3.3 Discarding of documents, material and deliverables

The Supplier ensures project related documentation is available in electronic format for the total of the defects period. Thereafter the Supplier retains its records in accordance with its own governance procedures in order to satisfy regulatory requirements.

6.3.4 Document Control Procedure

Project documents generated by the Supplier shall be numbered uniquely using the following format. AAA-PRJ-XX/XXX-BBB-X1X2X3X4 Rev Z, where:

AAA*	:	is a unique organisational identification code e.g. NTP for the Employer, the Supplier to utilise 3 letter from its organisations name e.g CMC
BBB*	:	3 letters (code) which denote the type of document, a list for codes to be used as well as document description is given in Table 2 below
$X_1X_2X_3X_4$	:	Four digits sequence number for documents generated starting at 0001 for first document in the document type and then 0002, 0003… etc.
Z	:	Is the revision number starting at 1 for all first editions issued to NTP and then 2, 3, 4…etc. The revision may be entered separately from the document number

Table 3: Document type codes (BBB*)

CODE	DESCRIPTION
CER	Certificate
COC	Certificate of Conformance
DIQ	Design Information Questionnaire
DSC	Description
ECP	Engineering Change Proposal
GDL	Guideline
HRA	Hazard Identification and Risk Assessment
INS	Instructions
LST	List
NDA	Non-Disclosure Agreement
ORG	Organisational structure
OTS	Operating Technical Specification
PLN	Plan
PRG	Programme
PRO	Protocol
SAR	Safety Assessment Report
SDS	Safety Datasheet
SOP	Standard Operating Procedure
SPE	Specification

7. PROCESS

Table 1 below provides a high-level definition of the work split of responsibilities between the Supplier and NTP as well as the initial milestones identified for the execution of the services. The Supplier schedule must support the milestone dates in the Table 1 below.

Table 1: Milestones and work split for the execution of the services

Milestone	Estimated Completion Date	Supplier	NTP
PHASE 1: PROJECT INITIATION DOCUMENTS			
User Requirement Specification	2021/09/30		In Scope
Project Charter	2021/09/30		In Scope
Project Scope	2021/10/05		In Scope
Quality Risk Assessment	2021/10/07		In Scope
Change Control Committee	2021/10/11		In Scope
PHASE 2: PROCUREMENT AND MANUFACTURING			
Request For Proposal	2021/10/13	Participate	In Scope
Order placement	2021/12/02		In Scope
Supplier contract finalisation	2021/12/09	Participate	In Scope
FAT for Unit 1 and Unit 2	2022/01/24	TBA by supplier	Participate
Manufacturing & Delivery	2022/02/28	TBA by supplier	
PHASE 3: PRE-INSTALLATION REQUIREMENTS			
Removal of Unit 1	2022/02/21	TBA by supplier	Participate
NECSA Induction & SHEQ Requirements	2022/03/03	Participate	In Scope
Installation Procedural Hazop	2022/03/08		In Scope
PHASE 4 – UNITS 1: INSTALLATION, COLD AND HOT COMMISSIONING INCLUDING TRAINING (IQ, OQ AND PQ)			
Installation Unit 1 (IQ included)	2022/03/23	TBA by supplier	Participate
SAT/Cold Commissioning of Unit 1 (OQ included)	2022/03/28	TBA by supplier	Participate
Hot Commissioning of Unit 1 (PQ included)	2022/04/05	TBA by supplier	Participate
Operator Training of Unit 1	2022/04/06	TBA by supplier	Participate
Handover Unit 1 (Production resumes)	2022/04/12	TBA by supplier	Participate
PHASE 6 – UNIT 2: INSTALLATION, COLD AND HOT COMMISSIONING INCLUDING TRAINING (IQ, OQ AND PQ)			
Installation Unit 2 (IQ included)	2022/04/29	TBA by supplier	Participate
SAT/Cold commissioning of Unit 2 (OQ included)	2022/05/03	TBA by supplier	Participate

Hot commissioning of Unit 2 (PQ included)	2022/05/13	TBA by supplier	Participate
Operator Training of Unit 2	2022/05/16	TBA by supplier	Participate
Handover Unit 2 (Operation Starts)	2022/05/27	TBA by supplier	Participate
PHASE 8: PROJECT CLOSURE			
Project Complete	2022/06/06		In Scope

The Suppliers schedule shall be such that all activities in Phase 1 are completed to ensure that the installation activities are done during the upcoming cyclotron facilities shutdown period.

7.1 Deliverables

The Suppliers deliverables shall include but not be limited to the preparation, updating or compilation of all necessary documents including standards, procedures, plans, flow diagrams, data sheets, specifications, requisitions, hook up drawings, loop diagrams, reports, calculations, Spare Parts and Interchangeability Record (SPIR) etc., within the scope of its Work as is required:

a. To fulfil the requirements of the Scope of Work;
b. To comply with internationally accepted standards and Good Manufacturing Practice (cGMP);
c. To complete the Engineering Record; and
d. To provide NTP with sufficiently detailed instructions, operating manuals, maintenance manuals and records of the system to allow safe and efficient commissioning, start-up, operation, maintenance and safe shutdown.

7.1.1 Documentation and deliverables

The documentation and deliverables are as a minimum as per Table 2 below:

Table 2: Documentation and deliverables

Deliverables	
1	Technical description
2	Design Specification (Equipment and Software)
3	Design Qualification Results
4	Process design data shall contain (e.g.) the following: PFDs, P&IDs, interface between synthesis unit and existing system data, Details of Hazardous Materials (Safety Data Sheets), Materials of Selection Diagrams, Alarm and trip list containing all defined alarms and trips as well as their associated actions, Reliability data of all components
5	Operation manuals shall contain (as a minimum) the following: Start-up procedure, Shutdown procedure, Utility loop diagram, Power distribution circuits, Operations manuals, Calibration certificates and Calibration requirements and tools, Safety procedures, Alarm and trip list (if any)

	Deliverables
6	Maintenance manuals shall contain (as a minimum) the following: General information (process data), All technical datasheets/specifications, control system electronic loop diagrams, Pneumatic loop diagrams, maintenance manual, Installation Manual, Mechanical and electrical component data, manufacturer and vendor references, Any other information required to carry out maintenance of the system.
7	Drawings (e.g.): General arrangement, Erection and Installation Drawings (includes Hook up drawings), Utility loop diagram, Electrical layout, Cable schedule, Power distribution diagram, Electrical control circuit, Internal signals and control wiring diagrams, wiring diagrams for junction boxes, Loop diagrams for common trouble alarm, Lay out drawings, mechanical/Instruments Interface drawings
8	Equipment guarantees
9	Signal Input/output List
10	Factory Acceptance Test (FAT) Test Protocols & Results
11	Installation Qualification Protocols and Results
12	Site Acceptance Test (SAT) Test Protocols & Results
13	Certification file shall contain as (a minimum) the following: Certificate of compliance by a master electrician for electrical installation; Hazardous area certification for all equipment which is to be suitable for installation in a hazardous areas, Certificate stating that synthesis unit components are compatible to the FDG and Environment; material certificates; All documentation generated at inspection and factory acceptance testing, as well as site acceptance testing, including standard checklist used for inspection purposes at equipment vendor's premises
14	Complete Spare parts list for equipment parts that are subjected to: Wear, corrosion or erosion during normal operation; Failure that would cause shutdown of the equipment; Damage or breakage during routine maintenance or inspection.
15	Functional safety file
16	QA/QC plan
17	Operations and Performance Qualification Protocols & Results

7.2 Equipment Procurement and Manufacturing

The supplied equipment or system design shall comply with the technical specification supplied by NTP in Attachment 1: User Requirement Specification of the new synthesis unit for P2000 FDG Facility (RPH-SPE-7507 rev1).

The Supplier delivers the synthesis units and components (System) to site (Incoterms; Delivered at Place Unloaded (DPU)). Options for DAP Incoterms; Delivered at Place) can be discussed as part of the offer.

7.3 Installation and Pre-commissioning

7.3.1 Pre-Installation

The Supplier and sub-suppliers/vendors and their staff performing installation onsite shall comply with the following before they are allowed access to the construction site, the supplier to allow and plan for these activities in its schedule:

a) Attendance of sites SHEQ Orientation programme and facility specific orientation (The training lasts for 3hrs, allow time at least a day prior to anticipated installation day),

b) Signing of SHEQ Indemnity form by the contractor as acceptance of all safety requirements contained therein and communicating them to the personnel (SHEQ-INS-5450),

c) Presenting a safety file to the RPO with following minimum requirements:
- Letter of Good Standing,
- Proof of medical fitness,
- Proof of qualification/Training for the job being performed,
- Legal appointments (Section 16.1, supervisor, manager and so forth),
- Certificate for working on heights (where work on heights will be performed)
- Inspection of tools and equipment,
- Certified ID Copies,
- Proof of SHEQ Contractor Course (NSD),
- Copy of Necsa SHEQ Regulations (attached above),
- SHEQ Indemnity form (if NTP or Necsa tools will be borrowed by the contractor) - also in the attached.
- Visitor COVID-19 screening forms.

d) Security vetting to the level prescribed by the Chief Security Officer (could take up to 4 weeks),

e) Compliance with the prescribed medical fitness requirements

f) Compliance with the South African COID Act or equivalent for international Suppliers.

An Installation Oversight committee shall be established to ensure proper interface management. The committee will be responsible for status reporting and monitoring, SHEQ statistics, event and non-conformance reporting etc. the members of the committee shall include:

a) Supplier and Sub-Supplier representative(if applicable)

b) NTP representatives for:
- SHEQ,
- Maintenance,
- Engineering,
- Safety Officer: Radiation Protection officer

The Supplier shall prepare and submit to NTP for approval an Installation plan including at least the following:

a) Installation programme and schedule with an indication of installation verification hold points.
b) Suppliers installation organogram with names and responsibilities at least 4 weeks prior to installation (this information is needed for the security vetting process)
c) Testing programme for constructed Structures Systems and Components (SSC)
d) Maintenance and care process of stored and constructed parts before commissioning
e) Installation Change Management Process
f) Installation Health and Safety Plan
g) The Supplier shall prepare and submit for review by NTP all Installation procedures.
h) The Supplier shall carry out constructability studies to verify that Installation activities can be executed in a safe, efficient and logical manner that incorporates equipment and material deliveries, and access availability, these shall be shared with NTP for acceptance.

7.3.2 Installation

Interface points for available utilities will be provided by NTP, Supplier will be responsible for connections into the provided interface points within the lab. Where additional scope is required to be executed by NTP for a full solution, these need to be highlighted in detail and interface points defined and aligned. Daily toolbox talk will be held throughout the installation.

Installation safety reviews (Procedural HAZOPS/Task hazard Assessment) shall be conducted prior to permits being granted to the supplier to commence work. The hazard Assessment session will be facilitated by NTP representative and shall be conducted remotely prior to any installation work done. Work permits facilitated by the Employer will be issued prior for any work being done, this will be done a day prior to installation.

7.3.3 Installation Completion and Qualification (IQ)

Procedures/protocols to be followed for installation completion:

a) A completion checklist, containing work necessary to arrive at the various completion stages is to be generated by the Supplier.
b) The Supplier shall make use of this checklist, where applicable, as a guideline to check that it has completed all work.
c) This shall not, however, relieve the Supplier of responsibility for the completion of all such Work as required for a complete functional system.
d) The Supplier shall provide a detailed procedure/protocol including forms, document flow, schedule, certification scheme and status monitoring method for attaining the various completion stages including Installation Qualification, Site Acceptance Test. This procedure shall be agreed upon with NTP

e) Procedures shall include for the provision of Notice to NTP of days in each instance of the Suppliers notifications of achievement of:-
   a. Mechanical Completion
   b. Electrical Completion
   c. Instrument Completion
   d. Ready for Commissioning for any System

f) When the supplier considers that the System or Unit is approaching Installation Completion, s/he shall give notice in writing to NTP two (2) days in advance of the expected date to allow NTP the opportunity to perform system installation verifications.

g) NTP in the presence of the Supplier will conduct installation verifications so as to identify any defects/deficiencies. The Supplier will capture all non-conformances items in a list.

h) Installation Qualification reports are to be compiled by Supplier.

7.3.4 Pre-Commissioning, Acceptance Test and Handover

The system shall be pre-commissioned and Site Acceptance Test (SAT) conducted after final installation in the field prior to hot commissioning. This work shall be conducted by the supplier and witnessed by the Employer, after which hand over or Transfer of Care, Custody and Control from supplier to NTP will occur. This is not final acceptance.

Pre-commissioning activities include all non-operating activities such as adjustments, cold alignment checks, hydrostatic/pneumatic testing, loop checking, motor rotational checks, flushing and blowing-out etc. Pre-commissioning and Site Acceptance reports are to be compiled by the supplier and accepted by NTP.

7.4 Training, Hot Commissioning and Operations

7.4.1 Training of NTP Production and Maintenance Personnel

To assure continual successful operation of the synthesis system after start-up has been completed, the Supplier shall transfer the accumulated experience and detailed knowledge to NTP personnel. This shall be done by having designated NTP personnel working together with the Supplier as well as holding formal lectures for designated NTP personnel.

Furthermore, in order to ensure that NTP is able to maintain the new installation, service training is to be provided to the maintenance personnel. This training should ensure that the maintenance personnel are suitable qualified to provide maintenance services including and not limited to basic trouble shooting, preventative maintenance (Level 1 training) etc. Training shall take place in the Republic of South Africa and shall preferably be done on site. The Supplier to schedule this activity in the offer plan including anticipated durations.

7.4.2 Hot Commissioning

The Supplier shall prepare and submit to NTP for approval a cold (if required) and hot commissioning manual. The hot commissioning manual shall be agreed with NTP and the following shall serve as a minimum:

a) NTP production/Operations will execute the cold commissioning jointly with the supplier as part of training (if required).
b) NTPs business owner of the production facility concerned shall certify that the process sample is within specified limits for synthesis before the sample is introduced into the synthesis system during hot commissioning of the system;
c) NTP shall now commission the synthesis system. The Supplier shall be available during this period in order to assist with possible challenges with the synthesis systems, signal handling, power distribution etc.;
d) The dispensed products will be checked for compliance.
e) After successful operation of the synthesis systems for an agreed upon period, the equipment can be accepted and signed off (as agreed upon between NTP and the suppliers of systems).
f) OQ reports are to be compiled by Supplier and accepted by NTP. Supplier to support NTP in performing PQ.

8. RECORDS

Record	Retention Period	By Whom
None	None	None

9. TASK HAZARD ASSESSMENT

None.

10. LIST OF FORMS

Form Title	Form Number	Exhibit Number
None	None	None

11. REVISION HISTORY

Rev.	Date Approved	Nature of Revision	Originated by
1	See title page	First Issue	MI Modukanele