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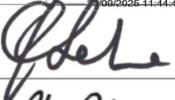|	NAME	SIGNED	DATE
Prepared	Shulam Mkwelo Senior Applications Developer	Signed by Shulam Mkwelo, Shulam.Mkwelo@ntp.co.za 16/09/2025 13:28:13(UTC+02:00)	
Prepared	Vusi Mohlatswa Systems Analyst	Signed by Vusi Mohlatswa, Vusi.Mohlatswa@necsa.co.za 16/09/2025 13:52:06(UTC+02:00)	
Reviewed	Kgomotso Gota Enterprise Applications Manager	Signed by Kgomotso Gota, Kgomotso.Gota@necsa.co.za 16/09/2025 09:51:49(UTC+02:00)	
Reviewed	Daphne Ledwaba Group IT: GM	Signed by Daphne Ledwaba, daphne.ledwaba@necsa.co.za 21/09/2025 07:35:05(UTC+02:00)	
Reviewed	Duduzile Tselidi AEC: Order Processor	Signed by Duduzile Tseleli, Dudu@aecam.co.za 23/09/2025 09:31:26(UTC+02:00)	
Reviewed	Beverly Miles Marketing & Sales: Supervisor	Signed by Beverley Miles, Beverley.Miles@ntp.co.za 23/09/2025 09:37:55(UTC+02:00)	
Reviewed	Sipho Dhlamini Radiochemical Production: Executive Manager	Signed by Sipho Dhlamini, sipho.dhlamini@ntp.co.za 23/09/2025 11:19:36(UTC+02:00)	
Reviewed	Ruan de Kock Marketing &Sales: Industrial Supervisor	Signed by Ruan de Kock, Ruan.deKock@ntp.co.za /09/2025 11:44:40(UTC+02:00)	
Reviewed	Jackson Selome Production: GM		2025/10/06
Recommended	Annette Lubbe Marketing &Sales: GM	pp	2025.10.09
Approved	Boyede QM Group Executive STRATEGY & BUSINESS ENABLEMENT	Signed by Qhamkile Boyede, Qhamkile.Boyede@necsa.co.za 15/10/2025 15:04:06(UTC+02:00)	

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1. INTRODUCTION AND PURPOSE

Necsa group is currently embarking on a project to implement an Orders Management System to manage all orders which includes radiochemical products, radiopharmaceuticals products and industrial services. The system must be customizable, regulatory-compliant, and scalable to accommodate evolving business and regulatory requirements.

The purpose of this request for information (RFI) is to outline the scope of work as well as define the high-level business and technical requirements for an Orders Management System designed to support the organization in managing the orders processes from inception to completion.

Note: This URS defines the high-level functional and regulatory requirements for the Order Management System. Specific business rules defined in SOPs are not included in this document.

1.1 Objectives

The Orders Management System will manage the entire orders lifecycles and in compliance with local and international regulatory requirements. Below are the main modules requirements:

- Customer contract management.
- Orders planning and management of approvals.
- Orders, products, services and customers data management.
- Orders dispatching workflows management (integration with Container Tracking System).
- Orders transportation for local and international shipment (integration with Airlines booking processes).
- Integration with Quality Management Systems for all non-compliance occurrences.
- Integration with Dispensing and Inventory Management Systems.
- Integration with Quality Control Systems.
- Finance and Invoices management (integration with Microsoft Dynamics).
- Reporting and analytics
- Increase data security with state-of-the-art data management

Centralize data management to prevent unnecessary errors Given that the nature of products and services handled is radioactive; the system must at least be in compliant with cGMP,

GDP, IAEA guidelines, FDA 21 CFR Part 11, ISO standards, and local nuclear regulatory requirements. The system must also be scalable, secure, and customizable.

1.2 Type of Contract Deliverables

It is expected that the selected service provider will be requested to enter into negotiations for an agreement with Necsa for the provision of post implementation support, and ongoing maintenance and support of a new Order Management System for an initial period of three years. The post implementation support will include, but is not limited to service disruptions, system failures, resolution of queries, and system enhancements and upgrades.

2. SCOPE OF WORK

2.1 Services Required

The service provider will be required to provide the following:

- An Orders Management System to manage the full orders lifecycle which must be customizable, regulatory-compliant and scalable to accommodate evolving business and regulatory requirements.
- The supplier will provide a consultation service to Necsa Group that will allow the software to be supplied to be best configured to suit the requirements of the Necsa Group (System Blueprint)
- The supplier will be responsible for implementing and configuring the chosen application software, and to work with Necsa Group staff to ensure successful implementation.
- Data transfer, conversion & mapping - the supplier will be responsible for extracting and migrating data from the existing system(s), converting and/or mapping the data as per the Necsa Group's requirements.
- Testing – the supplier will assist Necsa Group staff with acceptance testing of the system and correct any components that fail to meet the agreed specifications.
- Training – the supplier will provide training in the new system to Necsa Group staff.
- Commissioning – the supplier will be responsible for preparing and commissioning the system for live use.
- Maintain up-to-date documentation of system configurations, processes, and procedures, accessible to authorised personnel.
- Service providers providing service to Necsa are obligated to undergo a security vetting or screening. This measure is essential for safeguarding the integrity and security of the organisation operations, protecting sensitive information, and ensuring compliance with regulatory requirements.

2.2 Solution Approach Options

The following proposed solution approaches will be considered:

1. **Configurable Off-the-Shelf Solution**

   o A solution that can be configured to meet requirements.

2. **Hybrid Solution**

- Off-the-shelf solution extended with custom-built modules.
- Suppliers may propose a hybrid solution where a configurable Orders Management System is enhanced with custom modules or extensions to meet unique business or regulatory requirements.
- Long-term support, maintenance, and upgrade strategy for custom-built features must be included
- Suppliers must commit to providing all validation documentation (IQ, DQ, OQ, PQ) for custom-built modules.

Suppliers must clearly state which approach they are proposing.

Note: The system must provide an on-premise deployment option to comply with internal security, data privacy, and regulatory requirements. Cloud-only solutions will not be considered.

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3. REQUIREMENTS TABLE

The requirement listed in the functionality requirements tables are Mandatory; also described as "Must Have" unless stated otherwise.

Please use the following matrix as a key for responding to the requirement tables.

Response Code	Description
Y - Existing	Feature is delivered as standard functionality in the proposed version of the software and can be demonstrated by the vendor.
C - Customer Customization	Not included. Tools are provided for customization at no additional cost.
V - Vendor Customization	Not included. Vendor provides customization at an additional cost.
N - Not Available	Requirements cannot be met.

	Requirements	Code	
Customer Contract & Management	System must support storage and approval of sales contracts for all customers. All customers must have an active, approved sales contract before ordering.		
	Sales contracts must specify permitted products, quantities, pricing, and validity. (Orders restricted to terms defined in the active sales contract.)		
	Contract approval workflow (multi-departmental).		
	Contract renewal and expiry management – system must be able to automatically flag contracts nearing expiry.		
	Link sales contracts to customer master data (e.g. licenses, permits, and approved products, etc.)		
	Orders must be validated against the approved sales contract.		
	System must support the ability to flag a customer as a priority customer		
	System must distinguish customer status between internal and external		
	System must provide ability to link customer to multiple addresses		
	System must not allow a customer that has been registered to be deleted from the system, they may only be terminated/archived		

	System must send timely customised escalation notifications to top management on all idle actions.		
Order Management	Customers must be able to place, modify, and track orders via multiple channels (web portal, manual entry).		
	Configurable order workflows (approvals, release checks, authorizations).		
	System must support for ad-hoc and routine orders.		
	System must be able to determine product order cut-off times		
	System must be able to link orders to specific production batches		
	System must support contract and pricing management.		
	System must allow for the order status to be updated/changed accordingly through the order management process		
	System must notify the relevant production facility and other relevant stakeholders of the placed order and allow production to accept or reject an order; and notify stakeholders		
	System must allow for the creation/capturing of a planning list and allow for capturing of orders on the planning list		
	System must allow for the selection of a container when placing an order		
Regulatory & Compliance	Full compliance with 21 CFR Part 11 (electronic records & signatures).		
	System must provide complete audit trails for all order transactions.		
	System must support automated regulatory reporting i.e. reports must me generated in the required formats		
	System must generate transport documentation (labels, permits, certificates).		
Logistics	Dangerous goods labelling and compliance documents must meet regulatory requirements.		
	System must support chain of custody tracking i.e. the system must log custody transfer points from production to delivery		
	The system must allow for capturing of flight details for international orders		
Finance	The system must be able to handle the invoicing of products to the customer		

	The system must allow for pro-forma invoices to be issued		
	System must support multiple currencies and tax rules		
	Integration with the finance/ERP system		
Reports	Business analytics (orders, trends, fulfilment)		
	Regulatory reporting dashboards.		
	The system must have detailed and summarized reports		
	The system must provide the ability to create ad-hoc reports		
Security	System must support role-based access		
	System must be able to integrate with AD and provide Single-Sign on		
	System must identify unauthorized access and alert relevant stakeholders		
	System must provide data encryption in transit and at rest.		
	Compliance with applicable data protection and privacy regulations		
Technology	System must be customizable (workflows, reporting).		
	System must use Microsoft SQL server as its database system		
	System must be a web-based application accessible through standard web browsers		
	API/standard interfaces for integration (Integration with ERP, Container Tracking, Production systems, Quality systems, etc.).		
Availability & Performance	Scalability to handle future growth.		
	System should provide redundancy/failover at critical points.		
Validation & Qualification	Service provider must provider system validation documentation (IQ/OQ/PQ).		
	Support for validation activities per GxP guidelines		
User Training	The service provider must provide comprehensive user training on the system to ensure effective adoption and usage		

4. SUPPORT

The bidder/service provider is required to provide comprehensive information addressing the following areas:

- An overview of the customer support and maintenance services offered.
- The cost of the annual maintenance plan.
- Provision of 3 years of post-implementation support to assist with system stabilization.
- A commitment to regularly train service and support staff, as necessary, to ensure up-to-date knowledge and skills.
- Delivery of service and support in accordance with the agreed Service Level Agreement (SLA).
- After-hours emergency contact details, including applicable service rates for support provided outside regular business hours.
- Detailed information on the frequency of new software version releases.
- A proposed plan for implementing new releases and upgrades (e.g., scheduling during weekends or non-business hours).
- The process followed for testing new versions, upgrades, and patches prior to deployment.
- A detailed migration process to be followed when upgrading to new software versions.