TENDER SPECIFICATIONS

Public service contract for “**Provision of ISO 9001:2015 Lead Implementer and Lead Auditor Training Services for Rwanda Medical Supply Ltd (RMS Ltd)**”

Reference №: **RWA23002-10002**

Country: **Rwanda**

Negotiated Procedure without Prior Publication

Deadline for requesting clarifications:	Until the **tenth day** before the deadline for submission of tenders
Deadline for submission of tenders:	**13 October 2026** at **16:00 (Kigali time)**

Belgian development agency

enabel.be

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1 GENERAL REMARKS

1. THE CONTRACTING AUTHORITY

1.1. The contracting authority of this public contract is Enabel, public-law company with social purposes, with its registered office at Rue Haute 147, 1000 Brussels in Belgium (enterprise number 0264.814.354, RPM/RPR Brussels), called ' Enabel ' pursuant to the entry into force of Law of 23 November 2017 changing the name of the Belgian Technical Cooperation and defining the missions and functioning of Enabel, the Belgian agency for development cooperation.

1.2. Enabel has the exclusive competence for the execution, in Belgium and abroad, of public service tasks of direct bilateral cooperation with partner countries. Moreover, it may also perform other development cooperation tasks at the request of public interest organisations, and it can develop its own activities to contribute towards realisation of its objectives.

1.3. For this public contract Enabel, in Rwanda, is represented by:

Name	**Position**
Ms. Virginie HALLET	Country Director Rwanda & Tanzania
Mr. Réal NIMPAGARITSE	Expert in Contracting in Administration

1.4. Attention : even if Enabel as contracting authority is based in Belgium, Enabel has different “permanent establishments” in partner countries, who are 'customer' in the sense of tax legislation[1]. As a result, services of this contract are deemed to be located in Rwanda and applicable tax legislation is legislation of Rwanda. For more information on this tax regime, you can contact Mr. Evariste SIBOMANA, Contract Officer **(clause 3 of chapter 3 Award Procedure).**

2. RULES GOVERNING THE PUBLIC CONTRACT

2.1. The following, among others, apply to this public contract:

(a) The Law of 17 June 2016 on public procurement;
(b) The Royal Decree of 18 April 2017 on the award of public contracts in the classical sectors;
(c) The Royal Decree of 14 January 2013 establishing the general rules for the execution of public contracts;
(d) The Law of 17 June 2013 on motivation, information, and remedies in public procurement, certain works, supply, and service contracts, and concessions;
(e) Circulars of the Prime Minister with regards to public procurement;
(f) Enabels policy regarding sexual exploitation and abuse – June 2019;
(g) Enabels policy regarding fraud and corruption risk management – June 2019.

2.2. All Belgian regulations on public contracts can be consulted on https://bosa.belgium.be/en/themes/public-procurement;

Enabel's Code of Conduct and the policies mentioned above can be consulted on Enabel's website via https://www.enabel.be/who-we-are/integrity/.

[1] Article 13a of Council Implementing Regulation (EU) No 1042/2013: The place where a non-taxable legal person is established, as referred to in the first subparagraph of Article 56(2) and Articles 58 and 59 of Directive 2006/112/EC, shall be: the place where the functions of its central administration are carried out, or the place of any other establishment characterised by a sufficient degree of permanence and a suitable structure in terms of human and technical resources to enable it to receive and use the services supplied to it for its own needs (= permanent establishment).

3. APPLICABLE LAW AND COMPETENT COURTS

3.1. Belgian legislation applies for this public contract and no other. In the event of a conflict regarding the interpretation, application or performance of these tender specifications, the parties will first try all conciliation possibilities. Except for an emergency, the parties avoid litigation in court without preliminary notification.

3.2. In case of court action, correspondence must (also) be sent to the following address:

Enabel S.A.
Global Procurement Services
To the attention of Ms Laura Jacobs
Rue Haute 147
1000 Brussels
Belgium

3.3. Any litigation regarding this public contract is the exclusive competence of the Brussels legal district courts and tribunals. French or Dutch are the languages of proceedings.

2 SUBJECT-MATTER AND SCOPE OF THE PUBLIC CONTRACT

1. TYPE OF CONTRACT

1.1. This public contract is a service contract for provision of: *Specialized short-term training for RMS staff on ISO 9001:2015 Lead Implementer and ISO 9001:2015 Lead Auditor*.

1.2. Services required in this public contract fall under the CPV code(s): 80500000-9.

2. LOTS

2.1. This public contract is not divided into lots.

3. ITEMS

3.1. This public contract consists of the items listed **under Clause 3 of chapter 7 Forms - Tender form - Prices.**

3.2. These items are grouped together to form one single contract. It is not possible to tender for one or several items and the tenderer must submit price quotations for all items of the contract.

4. DURATION OF THE PUBLIC CONTRACT

4.1. This public contract starts **upon award notification** and ends **upon completion of performance (Clause 16 of chapter 4 Special Contractual Provisions).**

4.2. This public contract **MAY NOT** be renewed.

5. VARIANTS

5.1. Variants are **NOT** allowed. Each tenderer may submit only one tender; no variants will be accepted.

6. OPTIONS

6.1. The tenderer may **NOT** submit options. Free options are forbidden. Any proposed option will be discarded.

3 AWARD PROCEDURE

SECTION (A) - GENERAL PROCEDURE INSTRUCTIONS

1. AWARD PROCEDURE

This public contract will be awarded through a Negotiated Procedure without Prior Publication pursuant to Article 42, § 1, °1, a) of the Law of 17 June 2016 on public procurement.

2. PUBLICATION

2.1. This contract is advertised on the website of Enabel (www.enabel.be).

2.2. This publication constitutes an invitation to submit a tender.

3. FURTHER INFORMATION

3.1. Public procurement administrator

The awarding of this public contract is coordinated by:

Mr. Evariste SIBOMANA

Contract Officer

evariste.sibomana@enabel.be

All communication between the contracting authority and (prospective) tenderers regarding this public contract must go through this contact. Any other form of contact with the contracting authority about this public contract is prohibited unless otherwise stated in these tender specifications.

3.2. Requesting clarifications

Prospective tenderers have until the **tenth day**, inclusive, before the deadline for submission of tenders to submit any questions regarding these tender specifications and the contract. All inquiries must be sent in writing to the procedure coordinator mentioned under clause 3.1 (evariste.sibomana@enabel.be), and will be answered in the order received.

Until the notification of the award decision no information will be given about the evolution of the procedure.

3.3. Publication of clarifications and/or amendments to the tender specifications

The complete overview of questions and answers, as well as any amendments to these tender specifications, will be available at the sixth day before the deadline for submission of tenders, at the latest.

These updates will be published on the same platform as mentioned under clause 2.

The tenderer is to submit its tender after reading and taking into account any corrections made to these tender specifications that are published or that are sent to him by e-mail. To do so, when the tenderer has downloaded the tender specifications, it is strongly advised that he gives his coordinates to the public procurement administrator mentioned under clause 3.1 and requests information on any modifications or additional information.

4. VALIDITY PERIOD OF TENDERS

The tenderers remain bound by their tender for a period of **120 (one hundred and twenty) calendar days** from the tender reception deadline date.

5. DATA TO BE INCLUDED IN THE TENDER

5.1. Tenderers are advised to consult the general principles set out under Heading 1 of the Law of 17 June 2016 on public procurement, which are applicable to this award procedure.

5.2. The tender and all annexes to the tender form must be drawn up in English.

5.3. By submitting a tender, the tenderer automatically waives any of their own general or specific sales conditions, even if these are mentioned in any annexes to their tender.

5.4. The tenderers must clearly indicate within their tender any information that is confidential and/or relates to technical or business secrets, which may not be divulged by the contracting authority.

5.5. The tenderer must use the tender forms provided in the annex – **See below Chapter 7 – Forms.**

Should the tenderer fail to use these forms, they shall bear full responsibility for ensuring that the documents submitted are in perfect concordance with the forms.

5.6. The tenderer also attaches the following to his tender:

(a) All documents demanded for the application of selection and award criteria (**see below clause 13 and clause 15 and Chapter 6 Detailed Selection and Award Criteria**);

(b) A detail of the prices quoted, listing for each item the various elements that are included in the price and the applicable taxes;

(c) The statutes and/or any other document required to establish the power of attorney of the signer(s).

5.7. Where the tender is submitted by a group of economic operators, each of the participants in the group must also request the requirements mentioned in Chapter 7 – Forms.

5.8. Participants in a group of economic operators must designate one member of the group who will represent the group vis-à-vis the contracting authority.

5.9. In accordance with Article 73 of the Royal Decree of 18 April 2017 on the award of public contracts in the classical sectors, where an economic operator wants to rely on the capacities of other entities (particularly subcontractors or independent subsidiaries) for replying to criteria of economic and financial capacity or technical and professional aptitude (see clause 13 and 6 detailed Selection and Award criteria Selection file), it shall prove to the contracting authority that it will have at its disposal the resources necessary, for example, by producing a commitment by those entities to that effect.

6. TENDER CURRENCY

All prices given in the tender form must obligatorily be quoted in **euro**.

7. DETERMINATION OF PRICES

7.1. In accordance with Article 37 of the Royal Decree of 18 April 2017 on the award of public contracts in the classical sectors, the contracting authority may for the purpose of verifying the prices carry out an audit of any and all accounting documents and perform on-the-spot checks with a view of verifying the correctness of the indications supplied.

8. ELEMENTS INCLUDED IN THE PRICE

8.1. The tenderer is to include in his unit and global prices any charges and taxes generally applied to services according to the applicable tax legislation of Rwanda, with the exception of the value-added tax. The VAT percentage is quoted separately, if applicable. As mentioned in clause 1 of chapter 1 General Remarks, **local tax regime is applicable**. For the provision of services in Rwanda, the attention of tenderers who are non-tax residents of Rwanda is drawn to the tax on the profits of non-residents (15%) applicable to this category of service provider. It is also the tenderer's responsibility to obtain information on all other tax provisions applicable in Rwanda.

The 15% non-resident income tax will be withheld at source at the time of payment of the invoice. Make sure to verify whether any bilateral or regional non-double taxation treaties apply to your situation.

8.2. The unit and global prices for this public contract must encompass any costs, measures, and charges related to the performance of the contract, including but not limited to:

(a) Administrative management and secretariat services;
(b) Documentation related to the services;
(c) Delivery of documents or records associated with the performance of the contract;
(d) Training required for operation;
(e) Where applicable, the measures imposed by occupational safety and worker health legislation.
(f) Acceptance costs.

8.3. All relevant costs must be factored into the prices for this public contract.

SECTION (C) - SUBMISSION OF TENDERS

9. SUBMISSION OF TENDERS

9.1. The tenderer may only submit one tender per contract.

9.2. *Considering article 14, § 2, °1 of the Law of 17 June 2016 on public procurement, it would not be appropriate to impose the obligation to use electronic means of communication referred to in article 14, § 7, of the Law of 17 June 2016 on public procurement.*

The nature of this public contract is such that national or regional economic operators do not have equal access to the requirements linked to the use of the Belgian federal "e-Procurement" platform. The technical characteristics can therefore be discriminatory and can restrict the access of economic operators to the procurement procedure, in particular, in terms of speed and quality of the internet connection, as well as the quality of the electricity transport network.

In addition, the particular forms provided by this platform from the point of view of electronic signature are not yet compatible with the ICT generally used.

9.3. The tenderer submits its tender as follows:

One original copy of the completed tender shall be submitted on paper.

The tenderer shall attach copies of the documents requested in these tender specifications. These copies may be submitted as one or more PDF files on a USB stick.

The submission is to be made in a properly sealed envelope, bearing the following information:

Tender: **RWA23002-10002 - Provision of ISO 9001:2015 Lead Implementer and Lead Auditor Training Services for Rwanda Medical Supply Ltd (RMS Ltd)**

To the attention of: **Mr. Evariste SIBOMANA, Contract Officer**.

9.4. **The tender must be submitted before 13 October 2026, at 16:00 (Kigali time)**, in one of the following ways:

(a) By mail (standard or registered mail): In this case, the sealed envelope should be placed in a second closed envelope addressed to:

Evariste SIBOMANA
Enabel Rwanda
KN 67 ST, n°10
SANLAM TOWERS,
Wing A, 6th Floor
Kigali, Rwanda.

(b) Delivered by hand with an acknowledgment of receipt: The tender may be delivered in person on working days during office hours, from 9 am to 12 pm and from 1 pm to 5 pm - see the address provided under this clause 9.4 (a).

9.5. **The contracting authority draws the attention of the tenderer to the fact that submitting a tender by email does not satisfy the requirements of this clause 9. A tender submitted by email will be discarded.**

10. TENDER SIGNATURE

10.1. **The tender and all accompanying documents must be numbered and signed by the tenderer or his/her representative.** The same applies to any alteration, deletion or note made to this document. The representative must clearly state that he/she is authorised to commit the tenderer.

10.2. Signatures are placed by the person(s) empowered or mandated to commit the tenderer. This obligation applies to each participant when the tender is submitted by a group of economic operators (consortium). These participants are jointly liable.

10.3. When the submission report is signed by a mandatary, he or she must clearly indicate whom he or she represents. The mandatary attaches the original electronic deed or private document that transfers these powers to him or her or a scanned copy of that proxy.

11. OPENING OF TENDERS

11.1. The tender opening session will take place behind closed doors at the address given under clause 9 for the submission of tenders.

SECTION (D) - SELECTION, AWARDING & CONCLUSION

12. EXCLUSION GROUNDS

12.1. The obligatory and facultative grounds for exclusion are provided in the declaration on honour attached to these tender specifications **(see clause 4 of chapter 7 Forms).**

12.2. By submitting the declaration enclosed in the annex to these tender specifications, the tenderer certifies that they are not in any of the exclusion cases listed in Articles 67 to 70 of the Law of 17 June 2016 on public procurement, nor Articles 61 to 64 of the Royal Decree of 18 April 2017 on the award of public contracts in the classical sectors.

12.3. The grounds for exclusion apply to all participants submitting a joint bid as a consortium of economic operators and third parties (in particular subcontractors or independent subsidiaries) whose capacity is invoked with regard to the criteria of economic and financial capacity or technical and professional aptitude (see clause 13 and Chapter 6 Detailed Selection and Award criteria, in accordance with Article 73 § 1 of the Royal Decree of 18 April 2017 on the award of public contracts in the classical sectors.

12.4. The contracting authority will verify the accuracy of this declaration on honour for the tenderer with the highest ranked tender. To this end, the contracting authority will request the tenderer concerned to provide the necessary information or documents to verify their personal situation. The tenderer must submit this information by the fastest means and within the deadline set by the contracting authority.

12.5. The tenderer may attach these documents directly to his tender. If the tenderer fails to deliver the requested document(s) on time, the contracting authority reserves the right to exclude the tenderer.

12.6. Tenderers are strongly advised not to wait for the request of the contracting authority and to request the documents they have not attached to their tender as soon as possible from the competent authorities of the country where they are based. After all, in some cases, it may take a long time to obtain particular documents.

12.7. The contracting authority will directly obtain any information or documents that can be accessed free of charge by digital means from the instances that manage the information or documents. This is the case for Belgian tenderers (via the Telemarc platform), with the exception of the extract from the criminal record, which must be requested by the tenderer himself.

12.8. **Conflicts of Interest – Revolving Doors (Article 51 of the Royal Decree of 18 April 2017 on the award of public contracts in the classical sectors)**

Without prejudice to Articles 6 and 69, paragraph 1, 5° of the Law of 17 June 2016 on public procurement, a conflict of interest also includes any “revolving doors” situation. This occurs when a natural person who previously worked for a contracting authority — whether as internal staff, in a hierarchical position, as a civil servant, public officer, or in any other capacity linked to the contracting authority — subsequently intervenes under a public contract awarded by that same contracting authority. A conflict of interest arises when there is a connection between the activities previously performed by the individual for the contracting authority and the activities carried out under the awarded contract.

13. QUALITATIVE SELECTION

13.1. By means of the documents requested in the **Chapter 6 detailed Selection and Award criteria Selection file**, the tenderer must demonstrate sufficient capacity to successfully perform this public contract.

13.2. Only tenders from tenderers who meet the selection criteria will be taken into consideration to participate in the comparison of tenders based on the award criteria outlined in clause 15 subject to the regularity of these tenders.

13.3. To meet the criteria of economic and financial capacity and the criteria on technical and professional aptitude, the tenderer may rely on the capacity of:

(a) all participants submitting a joint bid as a consortium of economic operators;

(b) other entities (in particular subcontractors or independent subsidiaries) regardless of the legal nature of the relationship with these entities, in accordance with Article 73 § 1 of the Royal Decree of 18 April 2017 on the award of public contracts in the classical sectors.

13.4. For all such participants or entities, the contracting authority must verify that there are no grounds for exclusion.

13.5. In accordance with Article 73 of the Royal Decree of 18 April 2017 on the award of public contracts in the classical sectors, where an economic operator wants to rely on the capacities of other entities (particularly subcontractors or independent subsidiaries) for replying to criteria of economic and financial capacity or technical and professional aptitude, it shall prove to the contracting authority that it will have at its disposal the resources necessary, for example, by producing a commitment by those entities to that effect.

14. OVERVIEW OF THE PROCEDURE

14.1. In a first phase, the tenders submitted by the selected tenderers will be evaluated as to their formal and material regularity.

14.2. The contracting authority reserves the right to have the irregularities in a tender regularised.

14.3. In a second phase, the formally and materially regular tenders will be evaluated as to their content by an evaluation commission. The contracting authority will restrict the number of tenders to be negotiated by applying the award criteria stated in these tender specifications (clause 15). This evaluation will be conducted on the basis of the award criteria and aims to set a shortlist of tenderers with whom negotiations will be conducted.

14.4. Then, the negotiation phase follows. In view of improving the contents of the tenders, the contracting authority may negotiate with tenderers the initial tenders and all subsequent tenders that they have submitted, except final tenders. The award criteria are not negotiable. However, the contracting authority may also decide not to negotiate. In this case, the initial tender is the final tender.

14.5. When the contracting authority intends to conclude the negotiations, it will so advise the remaining tenderers and will set a common deadline for the submission of any BAFO's (*Best and Final Offer*). Once negotiations have closed, the BAFO's will be evaluated as to its regularity and compared on the basis of the award criteria. The tenderer whose BAFO shows the best value for money (obtaining the best score based on the award criteria given under clause 15) will be designated the succesful service provider for this public contract, after having been verified for absence of exclusion grounds and respect for the criteria of qualitative selection.

15. AWARD CRITERIA

15.1. The contracting authority will select the regular tender that it considers to be the most economically advantageous, based on the following criteria:

Award Criterion	Criterion Weight (%)
Technical proposal	70
Price	30

NB: Only tenders obtaining a minimum technical score of forty-nine (49) points out of seventy (70) shall proceed to financial evaluation, subject to confirmation of the applicable procurement procedure by Enabel Procurement.

15.2. The scores for the award criteria will added up. This public contract will be awarded to the tenderer that submitted the tender with the highest final score, after the contracting authority has verified the accuracy of the declaration on honour of this tenderer and provided the control shows that the declaration on honour corresponds with reality.

16. AWARDING THE PUBLIC CONTRACT

16.1. This public contract will be awarded to the tenderer who has submitted the most economically advantageous tender.

16.2. In accordance with Article 85 of the Law of 17 June 2016 on public procurement, the contracting authority is under no obligation to award the contract. The contracting authority may choose either not to award the public contract or to restart the procedure, if necessary, through another award procedure.

17. CONCLUDING THE CONTRACT

17.1. The contract is formed upon notification to the successful tenderer of the approval of their tender.

17.2. Notification is made via digital platforms or email.

17.3. The full public contract consists of the following documents:

(a) These tender specifications and their annexes;

(b) The approved BAFO and all of its annexes;

(c) The official letter notifying the award decision;

(d) Any later documents accepted and signed by both parties, as appropriate.

17.4. In the interest of transparency, Enabel commits to publishing an annual list of recipients of its contracts. By submitting their tender, the successful tenderer agrees to the publication of the contract title, nature and object of the contract, their name and location, and the contract amount.

4 SPECIAL CONTRACTUAL PROVISIONS

1. This chapter of these tender specifications holds the specific administrative and contractual provisions that apply to this public contract by way of derogation from the 'General Implementing Rules for public procurement' of the Royal Decree of 14 January 2013 (Royal Decree of 14 January 2013 establishing the general rules for the execution of public contracts), hereinafter referred to as "GIR", or as a complement or an elaboration thereof. The numbering of the articles below (between brackets) follows the numbering of the "GIR" articles. Unless indicated, the relevant provisions of the "GIR" apply in full.

2. These tender specifications do not derogate from the "GIR".

SECTION (A) - GENERAL

3. USE OF ELECTRONIC MEANS (ART. 10)

The use of electronic means for exchanges during the performance of the contract is permitted unless stated otherwise in these tender specifications. In such cases, notifications from the contracting authority will be sent to the address or registered office mentioned in the tender.

4. MANAGING OFFICIAL (ART. 11)

4.1. The managing official for this public contract is **Mr. Antoine GATERA**, **Strategy Expert/Project Manager – Health Care & Pharmaceutical Regulation**, email: antoine.gatera@enabel.be. The managing official is responsible for overseeing the performance of the contract.

4.2. Once this public contract is concluded, the managing official serves as the primary point of contact for the service provider. All correspondence or questions regarding the performance of the contract should be directed to him, unless otherwise explicitly stated in these tender specifications.

4.3. The managing official has full authority to monitor the satisfactory performance of the contract, which includes issuing service orders, preparing reports and statements, approving services, progress reports, and reviews. They may order changes to the contract with regards to its subject-matter or performance, provided that such changes remain within its original scope.

4.4. However, the signing of amendments or any other decision or agreement implying derogation from the initial terms and conditions of the contract are not part of the competence of the managing official. For such decisions the contracting authority is represented as stipulated under clause 1 of chapter 1 General Remarks.

4.5. Under no circumstances is the managing official allowed to modify the terms and conditions (e.g. performance deadline) of the contract, even if the financial impact is nil or negative. Any commitment, change or agreement that deviates from the conditions in these tender specifications and that has not been notified by the contracting authority, will be considered null and void.

5. CONFIDENTIALITY (ART. 18)

5.1. Service providers who, during the performance of the contract, receive information or documents or data of any kind that are classified as confidential and relate, in particular, to the subject matter of the contract, the resources required for its performance and the operation of the contracting authority's services, shall take the necessary measures to prevent such information, documents or data from being disclosed to third parties who have no right to know them.

5.2. Service providers who, in the performance of the contract, have knowledge of a drawing or model, know-how, method or invention belonging to the contracting authority or jointly to the contracting authority and the service provider, shall refrain from any communication concerning the drawing or model, know-how, method or invention to third parties, unless those elements are the subject of the contract.

6. PROTECTION OF PERSONAL DATA

6.1. Processing of personal data by the contracting authority

The contracting authority undertakes to process the personal data that are communicated to it in response to the call for the tenders with the greatest care, in accordance with legislation on the protection of personal data (General Data Protection Regulation, GDPR). Where the Belgian law of 30 July 2018 on the protection of natural persons with regard to the processing of personal data contains stricter provisions, the contracting authority will act in accordance with said law.

6.2. Processing of personal data by the service provider

During contract performance, the service provider may process personal data of the contracting authority exclusively in the name and on behalf of the contracting authority, for the sole purpose of performing the services in accordance with the provisions of the tender specifications or in execution of a legal obligation.

For any processing of personal data carried out in connection with this public contract, the service provider is required to comply with Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data (GDPR) and the Belgian law of 30 July 2018 on the protection of natural persons with regard to the processing of personal data.

By simply participating in the contracting process, the tenderer certifies that he will strictly comply with the obligations of the GDPR for any processing of personal data conducted in connection with that public contract.

The personal data that will be processed are confidential. The service provider will therefore limit access to data to the strictly necessary personnel for the performance, management and monitoring of the public contract.

For the performance of the public contract, the contracting authority will determine the purposes and means of processing personal data. In this case, the contracting authority will be responsible for the processing and the service provider will be its processor, within the meaning of Article 28 of the GDPR.

Processing carried out on behalf of a controller must be governed by a contract or other legal act that is binding on the processor with regard to the personal data controller and that sets out that the subcontractor acts only on the instruction of the person in charge of the processing and that the confidentiality and security obligations regarding the processing of personal data are also the responsibility of the subcontractor (Article 28, § 3 of the GDPR).

7. INTELLECTUAL PROPERTY (ART. 19 TO 23)

7.1. The contracting authority does not acquire the intellectual property rights created, developed, or used during performance of the public contract.

7.2. As the contracting authority does not acquire the intellectual property rights, it shall obtain a patent licence for the results protected by intellectual property law. This license must cover the modes of exploitation necessary for performance of this public contract.

SECTION (B) - FINANCIAL GUARANTEES

8. PERFORMANCE BOND (ART. 25 TO 33)

No performance bond is required for this public contract.

SECTION (C) - THE PUBLIC CONTRACT DOCUMENTS

9. CONFORMITY OF PERFORMANCE (ART. 34)

The services must comply in all respects with the procurement documents. In the absence of specific technical specifications in the procurement documents, the performance of the contract must meet the highest standards of good practice in the relevant field.

SECTION (D) - CHANGES TO THE PUBLIC CONTRACT

10. REPLACEMENT OF THE SERVICE PROVIDER (ART. 38/3, °1)

10.1. Scope

The clause may be applied in case the service provider is unable to continue the performance of the contract due to termination of the contract (art. 61, 62 or 62/1, °2 of the “GIR”) or after taking an ex officio measure (art. 47 of the “GIR”).

10.2. Nature of the amendment

In derogation of art. 47, § 2, °3 of the “GIR”, the contracting authority may, in all the above cases, immediately award a new contract to the subcontractor(s) of the service provider already involved in the performance of the contract or to the second-ranked tenderer, for all or part of the contract still to be performed, and this without initiating a new award procedure. This agreement will take the form of an amendment to the original contract to be concluded between the contracting authority and the new service provider.

10.3. Conditions under which this revision clause may be used

Provided that they meet the selection criteria and the exclusion grounds set out in this document, and if they can meet the initial conditions of the contract, the contracting authority may conclude a contract for account with the service provider 's subcontractor(s) already involved in the performance of the contract.

To this end, the contracting authority shall contact the subcontractor(s) or his (their) representative(s), asking whether he (they) can meet the original terms of the contract. If the subcontractor(s) cannot meet the original conditions, a contract for account may be concluded under amended conditions. Before concluding such an amended contract, the contracting authority shall check whether the new conditions are still more advantageous than those of the tenderer ranked second during the evaluation of the tenders under the original award procedure. If this is not the case, the contracting authority will conclude a contract for account as referred to in the paragraph below.

If the contracting authority is unable or unwilling to avail itself of the option mentioned in the preceding paragraph, a contract for account may be concluded with the tenderer who was ranked second during the evaluation of the tenders under the original award procedure, provided that he meets the selection criteria and the exclusion grounds set out in this document. To this end, the contracting authority contacts the second-ranked tenderer or his representative to ask whether he agrees to maintain his bid. If that bidder agrees without reservation, the contracting authority proceeds to award and conclude the contract for account. If the tenderer in question does not agree to maintain the terms of his initial tender or if his modified tender does not remain the most economically advantageous on the basis of the evaluation of the tenders under the original award procedure (after exclusion of the initial service provider), the contracting authority shall address itself:

(a) either successively, according to the ranking, to the other regular the tenderers. In this case too, the contracting authority contacts the tenderer concerned or his representative to ask whether he agrees to maintain his tender. If that tenderer agrees without reservation, the contracting authority proceeds to award and conclude the contract for account ;

(b) or simultaneously to all the other regular tenderers, asking them to revise their tender, on the basis of the initial terms of the contract, in order to award and conclude the contract on the basis of the tender that has become the most economically advantageous.

In any case, the contracting authority shall ensure that verification of the absence of grounds for exclusion and compliance with the selection criteria has taken place in an impartial and transparent manner, either in the context of the initial award procedure or at the time of the conclusion of the contract for account, so that no contract is awarded to a tenderer (or subcontractor) who should have been excluded or who does not meet the selection criteria. The minimum requirements of qualitative selection may, where appropriate, be adjusted in proportion to the remaining part of the contract if the contract for account is concluded only for part of the contract still to be performed.

The contract for account will be concluded by means of an amendment to the original contract, which will be signed by the contracting authority and the new service provider. If the contract has already been partially performed, this amendment will accurately mention all parts of the contract that still need to be performed. The amendment shall also mention all the changed conditions compared to the original tender of the initial service provider, and compared to the original tender of the new service provider. If necessary, the amendment shall state the method of application of the original conditions to the remaining part of the contract. All other conditions stated in the contract documents (the tender specifications and the original tender of the initial or new service provider), shall continue to apply unchanged.

If a contract for account is concluded, a copy of the amendment concerning the contract to be concluded shall be sent to the initial service provider by electronic transmission, in deviation from art. 47, § 3 (3) of the “GIR”.

If, following the application of an ex officio measure (art. 47 of the “GIR”), the price of the new contract for account concluded is higher than that of the initial contract, the initial service provider shall bear the additional costs.

11. REVISION OF PRICES (ART. 38/7)

Price revisions are not allowed under this contract.

12. INDEMNITIES FOR SUSPENSIONS ORDERED BY THE CONTRACTING AUTHORITY DURING CONTRACT PERFORMANCE (ART. 38/12)

12.1. The contracting authority reserves the right to suspend the performance of the contract for a given period, mainly because it considers that the procurement contract cannot be performed without inconvenience at that time.

12.2. The performance period is extended by the period of delay caused by this suspension, provided that the contractual performance period has not expired. If it has expired, the return of fines for late performance may be agreed.

12.3. When activities are suspended, based on this clause 12.3, the service provider is required to take all necessary precautions, at his expense, to protect the services already performed and the materials from potential damage caused by unfavourable weather conditions, theft or other malicious acts.

12.4. The service provider has a right to damages for suspensions ordered by the contracting authority when:

(a) The suspension lasts in total longer than one twentieth of the performance period and at least ten working days or fifteen calender days, depending on whether the performance period is expressed in working days or calendar days;

(b) The suspension is not due to unfavorable weather conditions or other circumstances beyond the contracting authority's control which, in the contracting authority's discretion, constitute an obstacle to the continued performance of the contract at that time;

(c) The suspension occurs during the contract's performance period.

13. UNFORESEEABLE CIRCUMSTANCES

13.1. As a general rule, the service provider is not entitled to request modifications to the contractual terms for circumstances unknown to the contracting authority.

13.2. A decision by the Belgian state to suspend cooperation with a partner country, or a decision of a government of a partner country to suspend cooperation with the Belgian state, constitutes an unforeseeable circumstance under this clause 13. In the event that the Belgian state or the partner country terminates or ceases activities, which implies therefore the financing of this public contract, Enabel will make reasonable efforts to negotiate a fair maximum compensation amount.

14. TAXATION HAVING AN EFFECT ON THE VALUE OF THE PUBLIC CONTRACT (ART. 38/8)

14.1. For this public contract, a price revision resulting from a change in taxation is possible if the case occurs in Belgium or in the country of performance concerned by this public contract and has an incidence on the value of the public contract.

14.2. Such price revision is only possible if both the following conditions apply:

(a) The change entered into force after the tenth day preceding the deadline for submission of tenders, and

(b) Either directly, or indirectly by means of an index, such taxation is not included in the revision formula provided for in procurement documents in application of Article 38/7 of the “GIR”.

14.3. In the event of an increase in charges, the service provider must prove that it has actually borne the additional charges it has claimed and that they are related to the performance of the contract.

In case of a reduction, there is no revision if the service provider proves that he paid the charges at the old rate.

15. TERMS OF INTRODUCTION (ART. 38/14 TO 38/17)

15.1. The contracting authority or the service provider who wishes to rely on one of the review clauses, as referred to in Articles 38/9 to 38/12 of the “GIR”, must give written notice of the facts or circumstances invoked on which it relies within 30 days, either after they occurred or after the date on which the contracting authority or the service provider should normally have known about them.

15.2. The service provider may only invoke the application of one of these review clauses if it succinctly discloses the influence of the facts or circumstances invoked on the course and cost of the contract to the contracting authority within the period mentioned under clause 15.1, regardless of whether the contracting authority is aware of the facts or circumstances.

SECTION (F) - PERFORMANCE MODALITIES

16. DEADLINES AND TERMS (ART. 147)

16.1. This public contract starts **upon award notification** and ends **upon completion of performance**.

16.2. The service provider shall complete the services within **3 (three) months**, starting from **the day to be set in an order form**.

17. PLACE OF PERFORMANCE (ART. 149)

17.1. The services must be performed at the following address:

Rwanda Medical Supply Ltd (RMS Ltd) HQ, KN 8 Ave, KG 509 St, Kacyiru sector of Gasabo District, Kigali, Rwanda*.*

18. INSPECTION OF THE SERVICES (ART. 150)

18.1. If irregularities are identified during the performance of this contract, the service provider will be promptly notified by registered post or e-mail (with proof of the exact dispatch date). The service provider is required to rectify the non-compliant services.

18.2. The service provider must notify the managing official in writing, either by registered post or e-mail (with proof of the exact dispatch date), specifying the date on which the services will be available for inspection.

19. LIABILITY OF THE SERVICE PROVIDER (ART. 152-153)

19.1. The service provider assumes full responsibility for any mistakes or deficiencies in the services delivered.

19.2. The service provider shall indemnify the contracting authority against any damages it may incur as a result of liability towards third parties arising from delays in the performance of the services or any failure by the service provider to fulfil its obligations.

SECTION (G) - MEANS OF ACTION

20. FAILURE OF PERFORMANCE (ART. 44)

20.1. The service provider shall be considered in breach of this public contract under the following circumstances:

(a) When contract performance is not carried out in accordance with the conditions specified in the procurement documents;

(b) When, at any time, contract performance has not progressed in such a way that it can be fully completed on the due dates;

(c) When the service provider fails to comply with written orders issued in due form by the contracting authority.

Any failure to comply with the provisions of the public contract, including the non-compliance with orders from the contracting authority, will be documented in a report ('process verbal'). A copy of this report will be sent immediately to the service provider either by registered post or e-mail (with proof of the exact dispatch date).

20.2. The service provider must address the defects without delay. He may assert his right of defence, either by registered post or e-mail (with proof of the exact dispatch date), addressed to the contracting authority within fifteen days from the date of dispatch of the report (process verbal). Silence on his part after this period shall be deemed as acknowledgement of the reported facts.

20.3. Any defects that can be attributed to the service provider may result in the application of one or more measures as provided in Articles 45 to 49, 154 and 155 of the “GIR”.

21. FINES FOR DELAY (ART. 46 AND 154)

21.1. Fines for delay differ from penalties referred to in Article 45 of the “GIR”. They are due, without the need for notice, by the mere lapse of the performance period without the issuing of a report and they are automatically applied for the total number of days of delay.

21.2. Fines for delay are calculated, according to Article 154 of the “GIR”, at a rate of **0.1%** per day of delay, with a **maximum of 7.5%**, of the value of all or part of the services that were performed with the same delay.

21.3. If the execution deadline is an award criterion, the penalty rate may increase to a **maximum of 10%**, depending on the weight assigned to this criterion in the tender specifications.

21.4. Without prejudice to the application of these fines, the service provider shall indemnify the contracting authority where appropriate against any damages owed to third parties on account of its delay in performing the contract.

22. MEASURES AS OF RIGHT (ART. 47 AND 155)

22.1. When, upon the expiration of the deadline specified in Article 44, § 2 of the “GIR”, to present justifications, the service provider has remained inactive or has submitted justifications deemed insufficient by the contracting authority, the latter may invoke the measures as of right outlined in clause 22.2 However, the contracting authority may apply these measures before the expiration of the aforementioned term when the service provider has explicitly acknowledged the identified shortcomings.

22.2. The measures as of right are:

(a) Unilateral termination of the contract. In this case the entire performance bond, or if no bond has been posted an equivalent amount, is acquired as of right by the contracting authority as lump sum damages. This measure excludes the application of any fine for delay in performance in respect of the terminated part;

(b) Completion of all or part of the unfulfilled contract by the contracting authority itself;

(c) Conclusion of one or more replacement contracts with one or more third parties for all or part of the contract remaining to be performed.

The measures outlined in points (a), (b), and (c) will be executed at the expense, risk, and peril of the defaulting service provider. However, any fines or penalties imposed during the performance of a replacement contract will be borne by the new service provider.

SECTION (H) - END OF THE PUBLIC CONTRACT

23. ACCEPTANCE OF THE SERVICES PERFORMED (ART. 64 AND 156)

23.1. The managing official will closely follow up the services during their performance. The services will not be accepted until after having satisfied the inspections, technical acceptance operations and prescribed tests.

23.2. Final Acceptance will occur upon service delivery completion, marking full contract completion.

23.3. When the contracting authority is in possession of the list of services provided or the invoice and the total or partial completion of the services is established in accordance with the procedures laid down in the contract documents, the contracting authority shall carry out the verification, proceed with the acceptance formalities and notify the service provider of the result. In any event, the verification shall be carried out within the processing period referred to in Article 160(1) of the "GIR" (clause 24).

23.4. If the services are completed before or after the expected date, the service provider must notify the managing official by registered letter or electronic mail that provides equivalent assurance of the exact date of dispatch, and shall request that the acceptance procedure be carried out.

23.5. The acceptance process is final and concludes the services under the contract.

24. INVOICING AND PAYMENT (ART. 66-72 AND 160)

24.1. The contracting authority shall verify and pay the amount due to the service provider within a processing period of thirty days from the date on which it is established that all or part of the services have been completed, the terms of which shall be laid down in the contract documents. However, payment can only be made if the contracting authority is in possession of the duly established invoice.

24.2. Only services that have been performed correctly may be invoiced. The invoice must be issued in EURO.

24.3. The service provider sends (one copy only of) the invoices and the contract acceptance report (original copy) to the following address: **rwa.invoices@enabel.be, with a copy to the Enabel Managing Official antoine.gatera@enabel.be – Enabel in Rwanda.**

24.4. Payments will be made according to the following milestones **(see also below Chapter 5 Terms of references):**

- *20% upon acceptance of D1 – Inception Report and D2 – Training Materials and Assessment Tools;*
- *25% upon acceptance of D3 – Completion of ISO 9001:2015 Lead Implementer Training, including the required supporting documentation;*
- *25% upon acceptance of D4 – Completion of ISO 9001:2015 Lead Auditor Training, including the required supporting documentation;*
- *30% upon acceptance of D5 – Assessment and Certification Package and D6 – Final Training Report.*

Payments shall only be due following satisfactory performance, formal acceptance of the corresponding deliverables, and receipt of a valid invoice and all required supporting documentation, in accordance with the contractual provisions and applicable Enabel procedures.

25. ADVANCE PAYMENTS

25.1. Notwithstanding clause 24 and in accordance with Articles 12/1 to 5 of the Law of 17 June 2016 on public procurement, inserted by the Law of 22 December 2023 amending the regulations on public procurement in order to promote SMEs' access to these contracts, an advance may be granted to the service provider.

25.2. The amount of the advance is calculated by applying the following percentages to the reference value of the public contract:

(a) 20% if the winning tenderer is a micro-enterprise, i.e. a company that employs fewer than ten people and whose annual turnover or annual balance sheet total does not exceed two million euros;

(b) 10% if the winning tenderer is a small enterprise, i.e. a company that employs fewer than fifty people and whose annual turnover or annual balance sheet total does not exceed ten million euros;

(c) 5% where the winning tenderer is a medium-sized enterprise, i.e. a company that employs fewer than two hundred and fifty people and with an annual turnover not exceeding fifty million euros or an annual balance sheet total not exceeding forty-three million euros.

25.3. The advance is calculated on the basis of the reference value of the public contract, i.e.:

(a) If the duration of the public contract is equal to or less than 12 months, the reference value is equal to the initial value of the public contract, all taxes included;

(b) If the duration of the public contract is greater than 12 months, the reference value is an amount equal to 12 times the initial value of the public contract, including taxes, divided by the duration of the contract expressed in months;

(c) In the case of an open-ended public contract, the reference value is the value per month of the public contract multiplied by 12.

a For the calculation of the initial value of the contract, neither conditional blocks nor renewals shall be taken into account.

25.4. No advance is granted before:

(a) Notification of the conclusion of the public contract;

(b) A written dated demand submitted to the contracting authority;

(c) A bank guarantee for the full amount of the advance deemed acceptable by the Contracting Authority, is provided.

25.5. The guarantee will only be released when the amount of the advance has been fully covered by the performance of the public contract and has been the subject of invoices approved by the contracting authority. This financial guarantee must enable the contracting authority to obtain reimbursement of the advance it has paid in the event of total or partial non-performance of the public contract.

25.6. Payment of the advance may be suspended if it is found that the service provider does not comply with his contractual obligations or if they contravene the provisions of Article 7 of the Law of 17 June 2016 on public procurement.

25.7. The advance granted is charged to the amounts owed to the service provider, as follows: The first half of the advance payment shall be offset against the sums due to the service provider when the value of the services performed reaches 30 per cent of the original order amount and the second half of the advance shall be offset against the sums due to the service provider when the value of the services performed reaches 60 per cent of the original order amount.

5 TERMS OF REFERENCE

1. SUBJECT MATTER OF THE ASSIGNMENT

This assignment consists of the delivery of an internationally recognized certified training course for RMS staff with subject: **ISO 9001:2015 Lead Implementer and Lead Auditor training services.**

The assignment includes course **preparation** and contextualisation, **training delivery**, practical **exercises**, participant **assessments**, **certification** of successful participants and **final reporting**.

2. BACKGROUND

Rwanda Medical Supply Limited (RMS Ltd) is a government-owned corporation established and owned by the Government of Rwanda with a mandate to manage end to end health supply chain of Rwanda. The vision of RMS Ltd is to be the leading pharmaceutical supply chain company in terms of Corporate Governance, Delivering Quality Products and Services to the People of Rwanda.

Recently, the Headquarters of RMS successfully obtained ISO 9001:2015 certification, demonstrating the institution's commitment to quality management systems, customer satisfaction, continuous improvement, and operational excellence. To ensure sustainability of the certification and facilitate the extension of ISO 9001:2015 implementation to RMS Branches and HUB warehouses, there is a need to strengthen internal capacity in Quality Management Systems (QMS), auditing, implementation, monitoring, and continuous compliance.

RMS therefore seeks to engage a qualified service provider to deliver specialized short-term training courses for RMS staff on ISO 9001:2015 Lead Implementer and ISO 9001:2015 Lead Auditor.

The trainings will equip participants with practical competencies required to effectively implement, maintain, audit, and improve the ISO 9001:2015 Quality Management System across RMS operations.

3. REGULATORY AND QUALITY MANAGEMENT CONTEXT

RMS is committed to maintaining compliance with ISO 9001:2015 requirements and strengthening quality management practices across its Headquarters, Branches and HUB warehouses. This assignment shall contribute to sustaining certification achievements and supporting future certification readiness activities.

4. TRAINING OBJECTIVES

4.1. General Objective

To strengthen institutional capacity in implementation, auditing, and maintenance of ISO 9001:2015 Quality Management Systems within RMS.

4.2. Specific Objectives

The training will enable participants to:

- Understand ISO 9001:2015 principles and requirements;
- Implement and maintain an effective QMS;
- Plan and conduct internal and external QMS audits in accordance with applicable auditing principles and understand third-party certification audit requirements;
- Identify non-conformities and corrective actions;

- Support RMS Branches and HUBs in ISO certification readiness;
- Promote continuous quality improvement initiatives.

5. EXPECTED OUTCOMES

Upon completion of the assignment:

- RMS will have qualified internal ISO 9001 Lead Implementers and Lead Auditors;
- Internal audit capacity will be strengthened;
- RMS Branches and HUBs will be better prepared for ISO certification activities; and
- Successful participants will receive an official internationally recognized certificates corresponding to the course(s) successfully completed.
- Quality compliance and operational efficiency across RMS facilities will be strengthened through enhanced internal QMS capacity

6. SCOPE OF THE SERVICES

The selected service provider shall deliver two comprehensive trainings covering the knowledge, skills and competencies required for effective implementation, maintenance, auditing and continual improvement of an ISO 9001:2015 Quality Management System within RMS**.**

The service provider shall also provide the required training materials, practical exercises and case studies relevant to the RMS operational context, conduct participant assessments, arrange the applicable certification examinations, and issue or arrange internationally recognized certificates for participants successfully meeting the applicable requirements.

6.1. ISO 9001:2015 LEAD IMPLEMENTER

Training shall include at minimum:

- Introduction to Quality Management Systems (QMS);
- ISO 9001:2015 clauses and requirements;
- Context of the organization;
- Interested parties and stakeholder’s requirements;
- Risk-based thinking;
- Leadership and planning;
- Process approach and documentation;
- Performance evaluation;
- Continuous improvement;
- QMS implementation methodologies;
- Change management and compliance monitoring;
- Practical exercises and case studies on QMS implementation; and
- Participant assessment/certification examination.

6.2. ISO 9001:2015 LEAD AUDITOR

Training shall include at minimum:

- Principles of auditing;
- Audit planning and preparation;
- Conducting internal and external audits
- Audit reporting techniques;
- Identification and classification of non-conformities;
- Root cause analysis;
- Corrective and preventive actions;
- Audit follow-up and closure;
- Practical audit simulations and case studies;
- ISO 19011 auditing guidelines;
- Participant assessment/certification examination.

7. TRAINING

7.1. Methodology

The training shall combine theoretical instruction, practical exercises, case studies, group discussions, and assessment activities designed to strengthen participants' practical competencies in implementing and auditing ISO 9001:2015 Quality Management Systems.

The methodology shall combine:

- Classroom instruction;
- Facilitated discussions;
- Practical exercises;
- Group work;
- Case studies;
- Simulated audits;
- Real-life quality management scenarios;
- Knowledge assessments;
- Individual and group presentations.

The provider shall ensure that training sessions encourage active participation and the practical application of ISO 9001:2015 requirements within the RMS operational context.

The methodology proposed by the bidder shall clearly explain:

- How learning objectives will be achieved;
- How participants' understanding will be assessed;
- How practical competencies will be developed;
- How participants will be prepared for certification examinations, where applicable.

7.2. Training materials

The service provider shall provide comprehensive training materials to all participants, including:

- Participant manuals;
- Presentations;
- Practical exercises;
- Case studies;
- Assessment tools;
- Reference materials;
- Relevant ISO guidance documents, where permitted.

7.3. Training language

The training sessions, training materials, assessments, reports and certificates shall be provided in English.

8. TARGET PARTICIPANTS

The trainings shall involve eight (8) RMS staff.

The participants will be designated by RMS and are expected to include staff involved in quality assurance, quality control, auditing, compliance, warehousing and/or supply-chain management.

9. PLACE OF PERFORMANCE AND LOGISTICAL ARRANGEMENTS

The assignment shall be implemented in Kigali, Rwanda, at the Rwanda Medical Supply Ltd (RMS Ltd) Headquarters located in Kacyiru.

Training activities shall be conducted on-site at RMS Headquarters unless otherwise agreed in writing by RMS.

The **Contracting Authority and/or the Partner** will provide the training venue, projector, internet connectivity and standard meeting facilities.

The Service Provider shall provide all trainers, course materials, assessments and certification arrangements required for delivery of the assignment.

All professional fees, travel, accommodation, subsistence, certification/examination fees and any other costs necessary for performance of the assignment shall be included in the financial offer.

10. DURATION OF THE ASSIGNMENT

10.1. Performance period

The Service Provider shall complete all services and submit all required deliverables within a **maximum performance period of 3 months** from the contract commencement date.

The contract shall remain in force until completion and final acceptance of all contractual obligations.

Within the above performance period, the training shall be conducted over **ten (10) working days**, as follows:

- **Five (5) days – ISO 9001:2015 Lead Implementer Training**
- **Five (5) days – ISO 9001:2015 Lead Auditor Training**

The remaining activities within the performance period shall include, as applicable, **course preparation and contextualisation, preparation of training materials, participant assessments and certification, reporting, and administrative closure.**

10.2. Estimated level of effort

For planning and budgeting purposes, the assignment is estimated at approximately **seventeen (17) person-days** including preparation, course delivery, assessment and reporting.

- Inception, preparation of training materials and course customization: 4 person-days;
- Delivery of ISO 9001:2015 Lead Implementer Training: 5 person-days;
- Delivery of ISO 9001:2015 Lead Auditor Training: 5 person-days;
- Participant assessment, preparation of the final training report, issuance of certificates, and administrative closure: 3 person-days.

The ten (10) working days allocated to the delivery of the two training courses are mandatory. The remaining estimated person-days are indicative and cover the activities necessary to complete the required deliverables within the contractual performance period.

The detailed implementation schedule shall be agreed with the Contracting authority together with the Partner Institution RMS, and the selected Service Provider during the inception phase of the assignment.

11. DELIVERABLES

The service provider shall be responsible for producing and submitting the following deliverables

Deliverables	Activities	Expected timeframe
D1 – Inception Report and training work plan	Kick-off meeting; confirmation of methodology, detailed work plan and agenda training schedule, trainer allocation, assessment approach and certification arrangement	**Within 1 week after the contract start date**
D2 – Training Materials and assessment tool	Preparation and finalization of course materials, presentations, practical exercises, case studies and pre- and post-training assessment tools for both training courses.	**Within 2 weeks after the contract start date**
D3 – ISO 9001:2015 Lead Implementer Training report	Delivery of the five-day ISO 9001:2015 Lead Implementer course, including attendance records, practical exercises and participant assessment results.	**Within 5 weeks after the contract start date**
D4 – ISO 9001:2015 Lead Auditor Training report	Delivery of the five-day ISO 9001:2015 Lead Auditor course, including practical audit studies, attendance records and participant assessment results.	**Within 8 weeks after the contract start date**
D5 – Assessment report and Certification Package	Finalization of participant assessment results and issuance of internationally recognized certificates to successful participants,, together with a summary of results.	**Within 10 weeks after the contract start date**
D6 – Final Training Report	Consolidated summary of training activities, attendance, assessment and certification results, training outcomes, observations, challenges together with recommendations for RMS QMS improvement and a certification- extension roadmap for RMS.	**Within 11 weeks after the contract start date**

All reports and deliverables shall be:

- in English
- in both editable Microsoft Word format and PDF format.
- submitted to the Enabel Contract manager, for review and validation.

The service provider shall address any relevant comments and resubmit revised deliverables as soon as possible. Deliverables shall be considered accepted upon formal validation by the Enabel Contract Manager.

12. REPORTING MODALITIES

The service provider shall work closely with the RMS Quality Assurance and Quality Control (QA/QC) Directorate and the Enabel Health Care & Pharmaceutical Regulation Expert/Project Manager, who shall serve as the Contract Manager for this assignment.

All deliverables shall be submitted to the Managing Official. He shall be responsible for:

- Overall contract oversight
- Ensuring alignment of the assignment with the Terms of Reference and expected results, in coordination with the RMS Technical Focal Point;
- Coordination with RMS during implementation;
- Contractual acceptance of deliverables following RMS technical validation, as applicable;
- Contract management and administrative oversight of the assignment;

- Facilitation of payment processing in accordance with the contractual provisions and applicable Enabel procedures.

The RMS Technical Focal Point shall be responsible for the technical review and validation of the training content and technical deliverables and for confirming their conformity with RMS requirements.

13. PAYMENT MODALITIES

Payment shall be made according to the following milestones:

- 20% upon acceptance of D1 – Inception Report and D2 – Training Materials and Assessment Tools;
- 25% upon acceptance of D3 – Completion of ISO 9001:2015 Lead Implementer Training, including the required supporting documentation;
- 25% upon acceptance of D4 – Completion of ISO 9001:2015 Lead Auditor Training, including the required supporting documentation;
- 30% upon acceptance of D5 – Assessment and Certification Package and D6 – Final Training Report.

Payments shall only be due following satisfactory performance, formal acceptance of the corresponding deliverables, and receipt of a valid invoice and all required supporting documentation, in accordance with the contractual provisions and applicable Enabel procedures.

6 DETAILED SELECTION AND AWARD CRITERIA

6.1 SELECTION CRITERIA

6.1.1. Service provider – Technical and professional capacity

The bidder may be either a legal person or a natural person and shall meet the following requirements:

- successful completion, **within the last 7 years of at least 2 similar assignments** involving **ISO 9001:2015 training**, QMS implementation, auditing or comparable Quality Management System services.
  Evidence may include certificates of satisfactory completion, client references, or other equivalent evidence considered valid by the Contracting authority;

- Capacity **to issue or facilitate, the issuance of relevant ISO certificates**[3], to participants who successfully completing the relevant training and assessment requirements.
  The bidder shall provide appropriate evidence of such capacity, which may include copy of accreditation, authorization, affiliation, recognition, partnership with a recognized certification/training body, or equivalent supporting documentation.

Experience with public institutions, healthcare or pharmaceutical organisations, supply-chain or warehousing organisations, or similar entities shall be considered an asset.

6.1.2. Key Expert(s)

The bidder shall propose **one or more qualified expert(s) to deliver the ISO 9001:2015 Lead Implementer and Lead Auditor training.**

The proposed expert(s) may include the bidder itself, provided that all required qualifications and experience are met.

The **proposed expert(s) shall (collectively) meet all the minimum requirements necessary to deliver both training courses.**

Where only one (1) expert is proposed that expert shall act as the Lead Trainer and shall meet all the requirements applicable to both the ISO 9001:2015 Lead Implementer and Lead Auditor training courses.

Where more than one expert is proposed:

- one expert shall be designated as the Lead Trainer and principal focal point for coordination;
- the qualifications and experience of the proposed team shall be assessed collectively in relation to the two required training courses; and
- each expert shall meet the specific qualification, certification and authorisation requirements applicable to the training course or activities assigned to him/her.

Minimum requirements applicable to the proposed expert(s)

The proposed expert(s) shall (collectively) demonstrate:

[3] Equivalent internationally recognised certification or training schemes shall be accepted, provided that the proposed training, cover ISO 9001:2015 Lead Implementer and ISO 9001:2015 Lead Auditor.

- **at least a Bachelor's degree** in Quality Management, Engineering, Pharmacy, Public Health, Business Administration, Supply Chain Management, or another field relevant to the assignment (**copy of the relevant degree/diploma to be provided for each proposed expert**);
- **at least five (5) years of relevant professional experience** in Quality Management Systems, including QMS implementation, auditing and/or training;
- experience in the delivery of **at least two (2) relevant ISO 9001 training assignments**.

For the **ISO 9001:2015 Lead Implementer Training**, the expert(s) assigned to deliver the course shall possess:

- a valid **ISO 9001:2015 Lead Implementer certification** issued by, or recognised under, an internationally recognized certification or training scheme and **where required by the proposed certification/training scheme, evidence that he/she is qualified, authorized or recognised to deliver the Lead Implementer training and related assessment.**

For the **ISO 9001:2015 Lead Auditor Training**, the expert(s) assigned to deliver the course shall possess:

- a valid **ISO 9001:2015 Lead Auditor certification** issued by, or recognised under, an internationally recognised certification or training scheme; and **where required by the proposed certification/training scheme, evidence that he/she is qualified, authorised or recognised to deliver the Lead Auditor training and related assessment.**

Means of Proof

The bidder shall provide, for each proposed expert(s) as applicable:

- CV;
- copies of relevant academic qualifications;
- copies of the professional certification(s) relevant to the course(s) assigned;
- evidence of the required relevant training experience; and
- evidence of trainer qualification, authorisation, approval or recognition under the proposed certification/training scheme, where applicable.

Expert(s) shall confirm availability during the assignment period.

6.2 AWARD CRITERIA

6.2.1. Technical Proposal – 70 points

Criterion	Maximum Score
1. Quality and relevance of the proposed training approach and methodology *Clarity, relevance, coherence and suitability of the proposed approach for delivering the ISO 9001:2015 Lead Implementer and Lead Auditor training, including the proposed training methods and contextualisation to RMS operations and QMS needs*.	**25 points**
2. Practical training and participant assessment approach *Quality and relevance of the proposed practical exercises, case studies, audit simulations, participant assessment/examination approach and certification arrangements.*	**20 points**
3. Work plan and organisation of the assignment *Clarity, feasibility and coherence of the proposed work plan, including preparation activities, training schedule, sequencing of the two courses, allocation of the proposed expert(s), and management of the required deliverables within the contractual performance period.*	**15 points**
4. Knowledge transfer and application at RMS – 10 points *Quality and practicality of the proposed approach to strengthening RMS internal capacity for QMS implementation and auditing and supporting the application of acquired competencies within RMS.*	**10 points**
Total Technical Score	**70**

Only tenders obtaining a minimum technical score of forty-nine (49) points out of seventy (70) shall proceed to financial evaluation, subject to confirmation of the applicable procurement procedure by Enabel Procurement.

6.2.2. Price – 30 points

The tender with the lowest evaluated price shall receive the maximum financial score of thirty (30) points. The financial scores of the other tenders shall be calculated proportionally using the following formula:

Financial Score = (Lowest Evaluated Price / Evaluated Price of the Tender) × 30

See also below Clause 3 - Chapter 7 Forms.

7 FORMS

1. LEGAL IDENTIFICATION FORM

Please complete the form in CAPITAL LETTERS and LATIN LETTERS.

PRIVATE/PUBLIC-LAW ENTITY WITH A LEGAL FORM

OFFICIAL NAME *As indicated on the official document.*	
COMMERCIAL NAME *(if different from official name)*	
ABBREVIATION *(if applicable)*	
LEGAL FORM	
TYPE OF ORGANISATION *(Delete as appropriate)*	- FOR PROFIT - NOT FOR PROFIT - NGO
PRINCIPAL REGISTRATION NUMBER	
SECONDARY REGISTRATION NUMBER *(if applicable)*	
PLACE OF REGISTRATION *City* *Country*	
DATE OF REGISTRATION *DD MM YYYY*	
VAT NUMBER	
ADDRESS OF REGISTERED OFFICE *Street+ P.O. Box* *Postal code* *City, Region/Province* *Country*	
TELEPHONE NUMBER	
E-MAIL	
DATE *DD MM YYYY*	SIGNATURE OF AUTHORISED REPRESENTATIVE

2. FINANCIAL IDENTIFICATION FORM

ACCOUNT NAME (1)			
ADDRESS			
TOWN/CITY		POST CODE	
COUNTRY			
CONTACT			
TELEPHONE		TELEFAX	
E - MAIL			

<u>BANK</u> (2) - -

NAME OF BANK			
ADDRESS (OF BRANCH)			
TOWN/CITY		POST CODE	
COUNTRY			
ACCOUNT NUMBER			
IBAN (3)			
NAME OF SIGNATORIES	NAME & FORENAME	FUNCTION	

<u>STAMP of BANK + SIGNATURE of BANK'S REPRESENTATIVE</u> (both are obligatory)	<u>DATE + SIGNATURE OF ACCOUNT HOLDER</u>(Obligatory)

(1) The name or title under which the account was opened and not the name of the authorised representative.
(2) It is preferable to attach a copy of a recent bank statement. Please note that the bank statement must provide all the information indicated above under "ACCOUNT NAME" and "BANK". In this case, the bank's stamp and the signature of its representative are not required. The signature of the account holder is obligatory in all cases.
(3) If the IBAN code (international bank account number) is applicable in the country where your bank is situated.

3. TENDER FORM - PRICES

Item	Total incl. WHT, excl. VAT
Expert(s) Fees (lump sum)	€ __________
SUB-TOTAL: Expert(s) Fees (A)	**€ __________**
WHT to be retained at source: 15% of (A) for international bidders or applicable DTA rate **(B)**	€ __________
NET amount after WHT (C) = (A − B)	**€ __________**
VAT of 18% on (A), where applicable; for international bidders, refer to the relevant footnote **(D)**	€ __________
SUB-TOTAL incl. WHT and VAT (E) = (A + D)	**€ __________**

Reimbursable Costs, if applicable

Item	Total taxes incl.
International travel costs	€ __________
Visa costs	€ __________
SUB-TOTAL: Reimbursable Costs (F)	**€ __________**
GRAND TOTAL (G) = (E + F)	**€ __________**

Breakdown

For transparency and price analysis purposes, the bidder shall provide the following breakdown of the lump-sum amount quoted under Expert(s) Fees (A). This breakdown shall not alter the lump-sum nature of the financial offer.

Cost Component	Amount incl. WHT, excl. VAT
Preparation, course customisation, work plan and training materials	€ __________
ISO 9001:2015 Lead Implementer Training – preparation and delivery	€ __________
ISO 9001:2015 Lead Auditor Training – preparation and delivery	€ __________
Participant assessments/examinations and certification for both courses	€ __________
Final report, recommendations and administrative closure	€ __________
Other costs included in Expert(s) Fees, if any – specify: __________	€ __________
TOTAL – must equal Expert(s) Fees (A)	**€ __________**

Date:
By (Name of entity):
Represented by (Full name):

Signature of authorised representative:

4. DECLARATION ON HONOUR - EXCLUSION GROUNDS

Hereby, I / we, acting as legal representative(s) of above-mentioned tenderer/beneficiary/partner/co-contractor declare that the tenderer is not in any of the following cases of exclusion:

The counterparty or one of its directors has not been convicted by a final judicial decision of any of the following offenses:

a. Participation in a criminal organization;

b. Corruption;

c. Fraud;

d. Terrorist offenses, offenses linked to terrorist activities or incitement to commit such offenses, complicity, or attempt;

e. Money laundering or terrorism financing;

f. Child labor and other forms of trafficking in human beings;

g. Employment of third-country nationals in illegal residence;

h. Creation of offshore companies.

The counterparty fulfills its obligations related to the payment of taxes, duties, and social security contributions for an amount exceeding €3,000, unless it can demonstrate that it holds one or more certain, due, and unencumbered claims against a contracting authority for at least the amount corresponding to the overdue tax or social debt.

The counterparty is not in a state of bankruptcy, liquidation, cessation of activities, judicial reorganization, has not admitted bankruptcy, is not the subject of liquidation or judicial reorganization, or any analogous situation derived from similar procedures in other national regulations.

The counterparty has not committed any serious professional misconduct that questions its integrity. Serious professional misconduct particularly includes:

a. Breach of Enabel's policy on sexual exploitation and abuse;

b. Breach of Enabel's policy on fraud and corruption risk management;

c. Violation of local legislation concerning sexual harassment at work;

d. Serious false statements or use of false documents in providing information required for exclusion checks or selection criteria, or concealing information;

e. Evidence sufficient to conclude anti-competitive acts, agreements, or arrangements;

Regarding conflict of interest:

The counterparty or its directors have no actual or potential conflict of interest, no real or potential business or family relationship, nor appear to have such, with any member of Enabel's Board, personnel, or others involved in tender preparation, selection, or contract execution.
or

The counterparty informs Enabel of any actual, potential, or reasonably perceived conflict of interest that may affect or appear to affect impartiality in the procurement, granting, selection, or contract execution process.

➔ *A detailed description of any such conflicts, including nature and persons involved, will be annexed to this declaration.*

The counterparty has not committed any serious or persistent failures during the execution of a prior essential contractual obligation with another contracting authority resulting in measures, damages, or comparable sanctions.

The counterparty attests that no restrictive measures have been taken against it related to international peace and security violations such as terrorism, human rights violations, destabilization of sovereign states, or proliferation of WMD.

The counterparty does not appear on any sanction lists maintained by the United Nations, European Union and Belgium, as well as.

I/we commit to promptly inform Enabel of any change in the above points, including sanctions or embargo measure adopted by the United Nations, the European Union and/or Belgium occurring after our signature of this Declaration.

Certified true and sincere,

Done at:

Date:

By (Name of entity):

Represented by (Full name):

Signature of authorised representative:

8 OVERVIEW OF THE DOCUMENTS TO BE SUBMITTED

1. **LEGAL IDENTIFICATION FORMS[4] – see Clause. 1 of Chapter 7 Forms**

2. **FINANCIAL IDENTIFICATION FORM – see Clause. 2 of Chapter 7 Forms**

3. **PROFILE REQUIREMENTS AND SUPPORTING DOCUMENTS – see Chapter 6 Detailed Selection and Award Criteria**

4. **TENDER FORM -PRICES – see Clause. 3 of Chapter 7 Forms**

5. **DECLARATION ON HONOUR – EXCLUSION CRITERIA[5] – see Clause. 4 of Chapter 7 Forms**

6. **POWER OF ATTORNEY**

The Tenderer shall include in his tender the **power of attorney empowering the person signing the bid** on behalf of the company, joint venture or consortium.

In case of a **consortium** or a **temporary association**, the joint bid must specify the role of each member of the consortium. A group leader must be designated, and the power of attorney must be completed accordingly (association agreement signed by each participant, clearly showing who represents the association should be provided as well).

7. **CRIMINAL RECORD CERTIFICATE FOR THE PERSON MANDATED TO COMMIT FOR THE FIRM**

8. **CERTIFICATION OF CLEARANCE WITH REGARDS TO THE PAYMENTS OF SOCIAL SECURITY CONTRIBUTIONS[6]**

At the latest before award, the Tenderer must provide a certification from the competent authority stating that he is **in order with the obligations with regard to the payments of social security contributions** that apply by law in the country of establishment.

9. **TAX CLEARANCE CERTIFICATE[7]**

At the latest before award, the Tenderer must provide a valid **recent certification** (up to 6 months) from the competent authority stating that the Tenderer is **in order with the payment of applicable taxes** that apply by law in the country of establishment.

[4] Mandatory for each participant for tenders submitted by a group
[5] Idem
[6] Idem
[7] Idem