**ANNEX A to ToR**

**LOT 1. ISO 9001:2015 Quality Management System implementation**

1. **Key Tasks and Activities**

To fulfil the General goal, the Contractor will seek to ensure the achievement of the following Objectives at the level of the mentioned companies by the end of the contract:

* Internal reorganization, efficient planning and efficient management of human resources, optimization of organizational and operational framework of the companies, to ensure the necessary resources for carrying out activities and improving performance.
* Quality improvement for provided services and facilitation of access to such services.
* The employees of the companies carry out their activities at a high level of quality, hence facilitating the achievement of the set strategic objectives in line with the mission of the company.
* Having a respectful attitude towards customers and ethical behaviour, improving the management system of the company, increasing the quality of products and services
* Involving companies in the application of Quality Management System principles and requirements, implementing and applying all documented procedures and quality control methods and applying for certification of the company's QMS according to ISO 9001:2015 requirements.

**The Contractor must fulfil the following tasks:**

1. **Process Initiation**

During this stage, the Contractor will launch the assistance activities in each company separately, including:

* to organize and to carry out the meetings for launching the assistance activity in every company separately;
* to submit to and to agree with each company the Initial GAP Analysis for the regulatory framework, organization and operation of service provision processes;
* to send the lists of documents, questionnaires / forms to request all necessary information in order to fulfil the set tasks;
* to receive documents, questionnaires / forms filled in with all necessary information for fulfilling the set tasks;
* based on these initial data and visit to the company, the consultants of the Company will vary out the preliminary evaluation, necessary upon the initiation of assistance activities;
* to organize discussions and preliminary interviews with the representatives of beneficiary companies, to agree upon the stages and activities to be carried out, and to present all these to the working teams;
* Working Groups will be stablished in each company to fulfil the set tasks;
* In each of those companies a person will be appointed to be responsible for the implementation of the Quality Management System as Project Coordinator.

1. **GAP Analysis**

During this stage, the Contractor will carry out the Gap Analysis of the internal organization, regulatory framework and service provision process in each beneficiary company. The objectives to be achieved during the Initial Audit are:

* Identification of the real working system and comparing it with the requirements of the reference standards ISO 9001:2015;
* Identification of technical-organizational elements and current practices which may be the bases for the future quality management system;
* Identification of situations of incompliance with the reference standards requirements;
* Identification of critical points in activity flow, which may provoke delays, deficiencies, etc. and implicitly additional costs.

The GAP Analysis shall cover, but will not limit itself to the following:

* Audit of organization and operation of companies, and identification of incompliances;
* Analysis on appropriateness of the structures in the organizational chart, personnel number, organizational and operation regulation of the company, provisions of the legal framework, institution’s objectives and mission;
* Analysis of all exiting documents (regulations, work instructions, operational manuals, correspondence registers, plans, strategic documents, quality manuals, inspection and control plans, performance evaluation instructions, etc.) and provision of recommendations for adapting them to the requirements of the standards of reference;
* Analysis of policy, mission, vision and specific objectives of existing systems;
* Human resources audit (internal regulations, organizational charts, job descriptions, etc.) and audit of existing materials.
* Analysis of the registration systems and existing record keeping, of the flow for managing/verifying documents and records;
* Analysis on interaction with customers, decision makers and external partners, and identification of meeting the relevant requirements for interaction with stakeholders;
* Analysis of risks’ management;
* Analysis of internal audit procedures, implementation of documented management system.

The result of this stage will be the GAP Analysis Report of the regulatory framework, organization and operation modality, service provision processes in each company. The reports will be developed for each company separately.

The initial audit reports will cover the detailed description of the results of analyzed processes, conclusions and practical recommendations for improving processes and organization, and concrete proposals for amending, adjusting, approving the necessary regulatory framework to meet the requirements of the ISO standards.

The structure of the initial audit reports will be coordinated with the EU4Moldova: Focal Regions Programme. The conclusions of the initial audit reports and the audit recommendations shall be endorsed by each company separately.

The Contractor will organize and carry out the meetings for presenting the results of the initial audit in each company.

1. **Design of Quality Management System**

During this stage, the Contractor will develop and suggest to beneficiary companies the projects for implementing the Quality Management System.

The projects will be development based on the conclusions and recommendations of the Initial GAP Reports.

Project documentation will include:

* Quality policy;
* Goal and scope of Quality Management;
* Action directions and specific measures for quality assurance;
* Structure of management systems to be implemented in each company;
* Reference documentation (list of regulatory documents, instructions, etc.) to be amended, adjusted, completed and/or developed;
* Action Plan for carrying out the activities meant to implement the Quality Management;
* Necessary methods and means for meeting the management requirements defined in the standards of reference;
* Commitments of companies to implement the Quality Management.

The structure of project documentation shall be coordinated prior with the EU4Moldova: Focal Regions Programme.

The project documentation shall be approved according to the approval procedures in force by each company. In this respect, the Contractor will organize and carry out meetings to present the initial audit results in each company.

1. **Development of Documentation for Management Systems**

During this stage, the Contractor will develop and propose to the beneficiary companies the package of documents for implementing the Quality Management System.

The package of documents will cover, but will not limit itself to the following:

* Quality Management System Manual (Quality Manual and Quality Management System Procedures);
* Draft regulations, organizational chart, job descriptions, and other regulatory documents;
* Draft Working Instructions/process description;
* Human resources’ and existing materials’ management policy;
* Draft systems for registration and record keeping, flow and management/control of documents and records;
* Schemes, models and processes of interaction with customers, external partners and other stakeholders;
* Risk management policy;
* Internal audit procedures and documented management system;
* Other documents of management systems.

The structure of documentation for the Quality Management be coordinated with the EU4Moldova: Focal Regions Programme.

The package of documents regarding the implementation of the quality management system management system shall be approved according to the approval procedures in force, by each beneficiary. In this respect, the Contractor will organize and carry out meetings to present the package of documents regarding the implementation of the quality management system in each company.

1. **Implementation of Designed Quality Management Systems**

During this stage, the practical implementation of management systems shall be implemented under the guidance of the consultants of the Contractor. In a practical way, this stage will cover the following activities:

* Enforcement of the provisions of the regulatory framework developed and approved at the previous stages;
* Internal trainings with the entire personnel, from all the management and execution levels;
* Performing internal audits under the guidance of consultants so as to identify incompliances or emerged implementation problems;
* Workshops for analyzing the incompliances and establishing corrective and preventive measures.

The implementation of the requirements of the designed management systems will be structured to cover the categories of basic processes:

1. decision-taking and leadership process;
2. planning process;
3. activity support processes, including human and material resources’ management;
4. operational processes (communication, interdepartmental interaction, institutional hierarchy, interaction with customers and external environment, hierarchy;
5. measuring, monitoring, analysis and evaluation processes;
6. improvement processes.

To establish the way in which the applicable and specified requirements of the Quality Management System will be carried out, the companies will establish, implement, and use during this period of time the approved documented procedures of the management systems. This will be done gradually and afterwards continuously, in order to ensure, identify, define, control, verify measure, monitor and analyze different processes of the management system so as, on one hand - to ensure efficient implementation of standards’ requirements; and on the other hand – to ensure the compliance of performed activities and fulfilled tasks with ISO 9001:2015 – Quality Management System.

6. **Final Auditing – Internal audit and management review and initiating the certification procedure of the** Quality Management System according to ISO 9001:2015

This stage implies for the Contractor to perform an Internal Audit of management systems for the purpose of obtaining information on compliance with documented systems.

The Internal audit will identify, at least, without limiting itself to the following:

* Is the Quality Management System established, documented, implemented, maintained and continuously improved in line with the requirements of these standards;
* Are the processes and all applications requested by the Quality Management defined;
* Is the sequence of processes and the interaction between them well-determined;
* Are the necessary criteria and methods established for ensuring the efficiency of operation and control of processes;
* Are the regulatory resources and necessary information available to support the processes functioning and monitoring;
* Are the new activity processes measured and analyzed; Are the actions undertaken to obtain the planned results and to continuously improve the processes;
* Are these processes in line with the conditions specified in the standards;
* If certain processes need to be outsourced, is there any control over these processes, Will the necessary control be ensured over these outsourced processes within quality management;
* Does the documentation for the Quality Management include documented declarations on quality policy and quality objectives; Are the Quality Manuals, systems-required documentation procedures, the documents necessary to ensure the planning, execution, and efficient control of processes and registrations required by these standards;
* Is there a Quality Manuals established and maintained;
* Does these Manuals include the scope of the Quality Management System, details and reasoning for any exclusions, set documented procedures or those regarding the Quality Management System and a description of the interaction between the processes of the Quality Management System;
* Are the documents requested by the Quality Management System verified;
* Are records registered and maintained to demonstrate that the Quality Management are compliant with the requirements and are efficiently implemented;
* Has the senior management established evidence of fulfilling the commitments regarding the implementation, development, and continuous improvement of the efficiency of the Quality Management System?

**The Internal audit** will end with a Report on identified incompliances and a Report of final recommendations to eliminate the incompliances and to improve certain processes for them to comply with the requirements of ISO standards.

As a result of the Internal audit, meetings will be organized to present the results of the Audit Reports and workshops for:

* establishing the modalities for treating the identified incompliances;
* identifying the primary causes of incompliances;
* establishing corrective actions necessary to prevent the re-emergence of the same incompliances.

The management review of the quality management system according to the requirements of ISO 9001:2015 involves evaluating the effectiveness and efficiency of the system to ensure that it meets the stated objectives and requirements of the standard.

The management review of the quality management system (QMS) according to ISO 9001:2015 requirements will include input information and generate the following outputs:

Input information:

1. Quality management system (QMS) documentation: this includes policies, procedures, work instructions, audit reports, incident records, customer feedback, etc.
2. Internal audit reports: Results of previous QMS internal audits, which can identify weaknesses, non-conformities and opportunities for improvement.
3. Performance monitoring data: Information on the performance of quality management system, such as laboratory test results, non-compliance reports, quality incidents, customer feedback, etc.

Outputs generated:

1. QMS Management Review Report is a detailed report documenting the results of the QMS management review. It will include:
   * The findings and conclusions of the analysis, including identified weaknesses, non-conformances, performance trends and opportunities for improvement.
   * Recommendations for corrective and preventive actions to address non-conformances and improve the effectiveness and efficiency of the QMS.
   * Assessment of compliance with the requirements of ISO 9001:2015 and identification of potential gaps in the quality management system.
2. Action Plan: Action Plan: A detailed plan setting out specific actions to be taken to address identified weaknesses and improve the QMS. It will include responsibilities, deadlines and resources required to implement corrective and preventive actions.
3. Updates to QMS documentation: Updates to policies, procedures, work instructions, etc. to reflect necessary changes identified in the management review.

By the end of this Stage, the Contractor shall formulate practical recommendations regarding the participation in certification procedure fulfilled by certification bodies and shall establish the modalities for ensuring (if needed) necessary assistance over the entire duration of the certification process.

The structure of the Internal Audit Reports and Management Review Report shall be coordinated with the EU4Moldova: Focal Regions Programme.

The Reports on identified incompliances and Reports of final recommendations to eliminate the incompliances and improve certain processes for them to comply with the requirements of ISO standards shall be approved according to the approval procedures in force by each beneficiary.

The implementation of the Quality Management is completed only after getting the certification from an independent certification body. During this stage, the Contractor will inform and recommend practical modalities and steps to be followed in the certification procedure by a certification body. At the same time, the Contractor will establish the modalities of assistance in negotiating and signing the certification contract and assistance at the certification audit stage (if agreed with the beneficiary companies).

The Contractor will submit a Report describing the contributions provided in guiding the companies regarding the certification procedure by a certification body and assistance in negotiating the certification conditions and provided support.

7. **Finalizing Activities**

The Contractor will summarize all implemented activities and obtained results and will submit a final Activity Report, describing, as well, the contribution provided in implementing activities, obtained results, lessons learned, good practices and recommendations for the Programme.

1. **Key deliverables and indicative timeframe**

The Company shall deliver to EU4Moldova: Focal Regions Programme the following Deliverables, in accordance with the schedule set forth in Section below.

| **Deliverables** | **Expected Period** |
| --- | --- |
| **Deliverable 1: Progress Report 1. Initiating the Process**  The Contractor shall submit the Progress Report including:   * The GAP Analysis Plan endorsed by each company separately; * List of received documentation necessary to carry out the Initial Audit. | **4 weeks since the contract signature** |
| **Deliverable 2: Progress Report 2.** GAP Analysis  The Contractor shall carry out the GAP Analysis , present the of the GAP Analysis , submit the Progress Report on these activities and attaches:   * Initial GAP Analysis of internal organization, regulatory framework and service provision processed in each company, separately; * Meetings Agenda for presenting the results of GAP Analysis and Lists of participants; * Information materials used during the meetings for presenting the results of GAP Analysis (word version and .ppts, photo, audio, video records); * Decisions for endorsing the GAP Analysis by each company, separately.   The Company shall submit the draft reports and presentations to the Programme for review and approval prior to the events. | **2 months since submission of Deliverable 1** |
| **Deliverable 3: Progress Report 3, Design of Quality Management System**  The Contractor shall submit the Progress Report including:   * Projects for implementing the Quality Management in each company, according to the requirements of Terms of Reference; * Meetings Agendas to present the projects for management systems implementation and Lists of participants; * Information materials used during the meetings to present the implementation projects for management systems (word versions and PPPs); * Decisions for endorsing the projects for implementing the management systems by each company separately; * Commitment of the company to implement the quality management.   The draft documents will be completed in Romanian, presented in electronic version and endorsed by the Programme prior to submission to companies. | **1 month since submission of Deliverable 2** |
| **Deliverable 4: Progress Report 4. Development of the Documentation of Quality Management System**  The Contractor shall develop the packages of documents for implementing the Quality Management System in each company, according to the Terms of Reference and present the Progress Report including the following that shall be attached:   * Packages of documents for implementing the Quality Management System, according to the list of documents and Terms of Reference requirements; * Agenda of meetings for presenting the projects to implement the management systems; * Information materials used during the meetings to present the packages of documents for implementing the management systems (word version and PPPs); * Decisions to approve the packages of documents to implement the management systems by each company separately. | **2 months since submission of Deliverable 3** |
| **Deliverable 5: Progress Report 5. Implementation of Designed Management System**  The Progress Report shall include the description of contributions provided in the process of Implementing the requirements of designed management systems. The following shall be annexed under the Report:   * Internal audit reports for identifying incompliances or emerged implementation problems; * Agendas of workshops/ trainings sessions and Lists of participants; * Confirmation photo, video and audio materials; * Results of workshops /training sessions; * Information materials (word versions and PPPs) used during the workshops / meetings; * Decisions to endorse the Reports on implemented requirements of designed management systems, separately by each company. | **3 months since submission of Deliverable 4** |
| **Deliverable 6: Progress Report 6. Internal audits and management review and initiating the certification procedure of the Quality Management System according to ISO 9001:2015** The Progress Report will include the description of performed pre-certification audits of the management systems for identifying the compliance of organization, regulatory framework and processes in the companies with documented systems, and the following annexes:   * Reports of identified incompliances; * Management Review Report * Reports of final recommendations on elimination of incompliances and improvement of certain processes to be compliant with the requirements of ISO standards; * Agendas of workshops and Lists of participants; * Confirmation photo and video materials; * Information materials used during the workshops; * Decisions for approving the Report of identified incompliances and Report with final recommendations for each company; * Description of information activities and assistance for initiating certification procedures by the certification body. | **2 months since the submission of Deliverable 5** |
| **Deliverable 7: Final report. Finalization of Activities**  The Contractor shall submit a Final report, presenting the results of the consultancy, containing an executive summary, a detailed outline of actions and achieved results with lessons learned, good practices and recommendations for the Programme.  The Final Report will include the revised documents and annexes with all deliverables produced under this assignment. | **1 week since submission of Deliverable 6** |

**Note:** *The indicated tentative timeframe has been estimated as being sufficient/feasible for the envisaged volume of work to be completed successfully and is proposed as a guideline for the duration of the assignment. It cannot be and will not be used as a single criterion for contract/assignment fulfillment. The submission of envisaged deliverables approved by EU4Moldova: Focal Regions Programme will be the only criterion regarding the activity fulfilment by the Contractor and its eligibility for payment.*