Terms of Reference

for

Provision of COVID19 Diagnostics Quality Management Training

The CONTRACTOR shall perform and be responsible for providing COVID19 Diagnostics Quality Management Training for different facilities and conditions aimed at specialists working either in and/or with medical facilities or laboratories. The to-be-trained specialists are from the Central Asian (CA) and South-East and Eastern European (SEEE) regions of the EU CBRN Centres of Excellence Initiative (Albania, Afghanistan, Armenia, Azerbaijan, Bosnia and Herzegovina, Georgia, Kazakhstan, Kyrgyzstan, Moldova, Mongolia, Montenegro, North Macedonia, Pakistan, Serbia, Tajikistan, Ukraine and Uzbekistan).
This activity is supported under EU CBRN Centres of Excellence Project 53.

1.0 PARTIES

1.1 CONTRACTOR: to be selected by competitive open tender as per standard ISTC terms and conditions.

1.2 CONTRACTING AGENCY: The International Science and Technology Center (ISTC); an inter-governmental organisation with status of a diplomatic mission, headquartered in Nur-Sultan, Kazakhstan. Its Member countries include Armenia, Georgia, Kazakhstan, Kyrgyzstan and Tajikistan

1.3 OTHER PARTIES:

1.3.1 European Commission (EC), namely those parts of the EC associated with the European Union Chemical, Biological, Radiological and Nuclear Risk Mitigation Centres of Excellence Initiative (EU CBRN CoE), such as (but not limited to): Service for Foreign Policy Instruments (FPI), European External Action Service (EEAS), and the EC Joint Research Centre (JRC);

1.3.2 Governmental officials from various ministries of participating countries;

1.3.3 Relevant organizations in participating countries that deal with diagnostics of infectious diseases (including public and private medical clinics and hospitals, or public and private, diagnostics and/or research, medical or veterinary laboratories).

2.0 AIM OF CONTRACT

2.1 Under previous funding activities by the EU and other international funders (like the United States of America, Canada and others) many workshops on diagnostics of infectious human, animal or plant diseases have been provided to specialists from the CA and SEEE regions' partner countries. Often these workshops' primary aim was to provide experts the technical skills to perform diagnostics of infectious diseases, with quality management (QM) mainly focused on conducting these tests properly;

2.2 As part of the response by the Central Asian and South-East and Eastern European Regions partner countries of the EU CBRN CoE to ongoing COVID-19 crisis, they identified the need for training in quality management for the <u>full</u> process of diagnostics;

2.3 In order to assist experts from these partner countries to address these needs, the aim of this contract is to provide online training to experts from the CA and SEEE regions' partner countries on quality management of infectious disease diagnostics based on WHO standards and guidelines, in order that the to-be-trained experts will have the necessary tools to implement the required procedures to assure a good QM system within their respective facilities.

3.0 SCOPE OF WORK AND DELIVERABLES

Responsibilities and Activities to be covered by the CONTRACTOR:

3.1 Training will be conducted to train 2-3 local experts per participating country on Quality Management of Diagnostics from medical and laboratory facilities, particularly with regards to COVID-19 but also in general.

3.2 Training should be focused primarily to personnel of a regulatory institution or control department of hospital or laboratory (but not regular lab personnel) to assist these personnel to enhance qualification of control in the overall institution.

3.3 The CONTRACTOR will conduct a virtual course for local country experts that includes modules focused on:

- Description of various aspects of quality management for the full cycle of diagnostics of infectious diseases, including (but not limited to):
  - Sample collection and labelling;
  - Sample transport;
  - Sample processing;
  - Sample testing;
  - Sample disposal;
  - Data collection, analysis and management;
  - How Biosafety and Biosecurity principles affects each of the above issues.
- Introduction to and instruction on how to develop and implement quality assurance elements such as:
  - Documentation
  - Standard Operating Procedures (SOP's),
  - Quality Control samples
  - External Quality Assessment Scheme

  Where feasible provide template documents for each of the steps
- Provide theoretical and practical skills on developing and implementing a quality control system, including;
  - Developing a framework and the necessary components for quality management;
  - Creating a QM training program within a facility;
  - Basic principles of how to review and/or assess compliance to the developed and implemented quality management system;
  - Developing strategies and measures to continually improve and/or strengthen the quality management system, and compliance thereof;
- review by the CONTRACTOR's experts of a small case study that each trainee is required to conduct of a facility in their country as part of the training activities, to provide the trainees with the opportunity to apply the learned skills to their environment and receive feedback from the CONTRACTOR's tutors.

The course will conclude with a module focused on how to use the material and knowledge gained to train others and a final testing and evaluation portion to ensure that all local experts are proficient in the material and will be able to train others effectively.

3.4 The delivery mode of the virtual training activities is expected to be a mix of downloadable materials for self-study by the recipients, case studies, assignments, pre-recorded instructional videos, interactive webinars and/or discussion forums using various online conference, training platforms or other capabilities;

3.5 The total hours that trainees are expected to dedicate to this training program, covering all delivery modes described under Article 3.4, should be at least 40 hrs spread out over the duration of the training program, which is expected to be 8-10 weeks. Of this at least 10

hours should be interactive directly with the tutors of the workshop, either through live webinars, forums or other interactive formats.

3.6 The CONTRACTOR will provide necessary materials for the local experts to conduct in-country training in the local language for personnel from medical or laboratory facilities. Materials will include access to virtual course or power point presentations and case studies for practical exercises, and short training videos translated into the local language. Where materials are not available in local languages, they will be made available to the ISTC for translation, see also Article 7.1.

3.7 The CONTRACTOR will provide subject matter expert reach-back support for local experts for a duration of 6 months following the course. This may be in the form of a learning platform access for all trainers, direct e-mail communication, and/or one-on-one mentoring sessions.

3.8 The CONTRACTOR will achieve the following deliverables:

A. Develop curriculum and training materials that address subjects listed in 3.3;

B. Deliver these training online (e.g. web-based platform) that enables participants to communicate effectively and provide feedback to trainer;

C. Provide monitoring and subject matter expertise support for a period of 6 months following the course and assess the progress of the trainers and trainings they are providing.

4.0 REPORTING REQUIREMENTS

4.1 Technical reporting requirements:

4.1.1 CONTRACTOR is required to accurately report activities, milestone progress and deliverables (etc) on a monthly basis to the ISTC. Pending acceptance by the ISTC, the CONTRACTOR will receive payments as per the agreed milestone payment schedules prepared by the CONTRACTOR (payment terms to be negotiated during tender process).

4.2 Financial accounting and reporting requirements:

4.2.1 CONTRACTOR is required to report quarterly to ISTC on financial activities that were performed. Format of report will be agreed upon with ISTC, but objective is to have a report that clearly exhibits financial costs reported linked to activities the deliverables. Pending acceptance by the ISTC, the CONTRACTOR will receive payments as per the agreed milestone payment schedules prepared by the CONTRACTOR (payment terms to be negotiated during tender process).

4.2.2 CONTRACTOR shall keep accurate and regular records and complete accounts throughout the implementation of the Contract to internationally-accepted standards. All financial transactions and statements shall be subject to ISTC auditing procedures.

4.2.4 CONTRACTOR shall retain and make available all relevant financial information, in original format, for a period of five years from the end date of the contract for the purposes of audit. This shall include all activities involving third parties contracted to the CONTRACT. In exceptional cases, certified copies of original contract, procurement, grant agreement and financial support documents will also be acceptable.

5.0 SCHEDULE

Duration of the contract is to be 9 months, which is roughly broken into three phases, which potentially can have some overlap:

5.1 Preparation of training materials, 1 month:

5.2 Conduct of training activities to participating countries, 2 months;

5.3 Provision of reach-back support to newly trained experts from participating countries, 6 months.

6.0 TEAM OF EXPERTS REQUIREMENTS

6.1 The CONTRACTOR shall assemble a Team of Experts (ToE) capable of implementing the tasks as described in this Terms of Reference.

6.2 The ToE should contain minimally a Coordinator and two Quality Management Expert(s) with experience in quality management of diagnostics of infectious diseases in medical and laboratory settings. The ToE should include some redundancy to ensure continuity of implementation if key ToE members are absent. See Annex A for ToE specifications.

6.3 The Coordinator is responsible for liaising with ToE, ISTC, EC and local implementers. The Coordinator is responsible for coordination of work and reporting responsibilities of the ToE and any sub-contractors hired to implement the Contract.

6.4 The Coordinator will work directly for the main CONTRACTING organisation, i.e. is not working for a sub-contracting organisation.

6.5 All ToE experts and other team members (if applicable) must be independent and free from conflicts of interest in the responsibilities they undertake as part of the Contract.

6.6 All ToE members shall sign a confidentiality and non-disclosure agreement, which will be an integral part of their contract with their contracting organisation.

7.0 ROLE OF THE ISTC

Separately from this contract, but in support of the activities to be performed by the CONTRACTOR, the main responsibilities of the ISTC are to:

7.1 Coordinate with representatives of the participating countries in selecting the appropriate candidates for the training;

7.2 Contract the necessary interpretation and translation services for implementation of training activities, which are conducted by the CONTRACTOR. Including (but not limited to): synchronous interpretation during live, online training sessions, translation of training and supporting materials/documents, and translated transcripts or dubbing of instructional videos (prepared by the CONTRACTOR);

7.3 Provide access to training platforms and online meeting capabilities to the newly trained local experts (that were trained by the CONTRACTOR) to support the development of their national, sustainable training activities, based on the training received from the CONTRACTOR.

ANNEX A

SPECIFICATIONS FOR TEAM OF EXPERTS (ToE) MEMBERS

The Team of Experts (ToE) should contain minimally a Coordinator and two Quality Management Expert(s) with experience in quality management of diagnostics of infectious diseases in medical and laboratory settings. The ToE should contain some build-in redundancy, in order to assure continuity of implementation.
The Coordinator is responsible for liaising with ToE, ISTC, EC and local implementers. The Coordinator is responsible for coordination of work and reporting responsibilities of the ToE and any sub-contractors hired to implement the contract.
All ToE experts and other team members must be independent and free from conflicts of interest in the responsibilities they undertake.

It is essential that the Team of Experts cover the following skills:

- Experience in working in/with medical and/or laboratory facilities for more than 10 years
- Experience in the area of disease infection diagnostics for more than 10 years
- At least 5 years of experience in providing quality management training
- Proven knowledge of International Health requirements (treaties, conventions, regulations, guidelines, etc.) covering the full scope of best practices in the area of quality management
- Proven team management skills, within international and preferably multi-disciplinary teams
- Track record in providing online training activities
- Fluent in English

It is beneficial if the Team of Experts also has additional skills, such as:

- Previous working experience in countries of the CA and SEEE regions of the EU CBRN CoE is beneficiary;
- Knowledge of Russian is an asset.