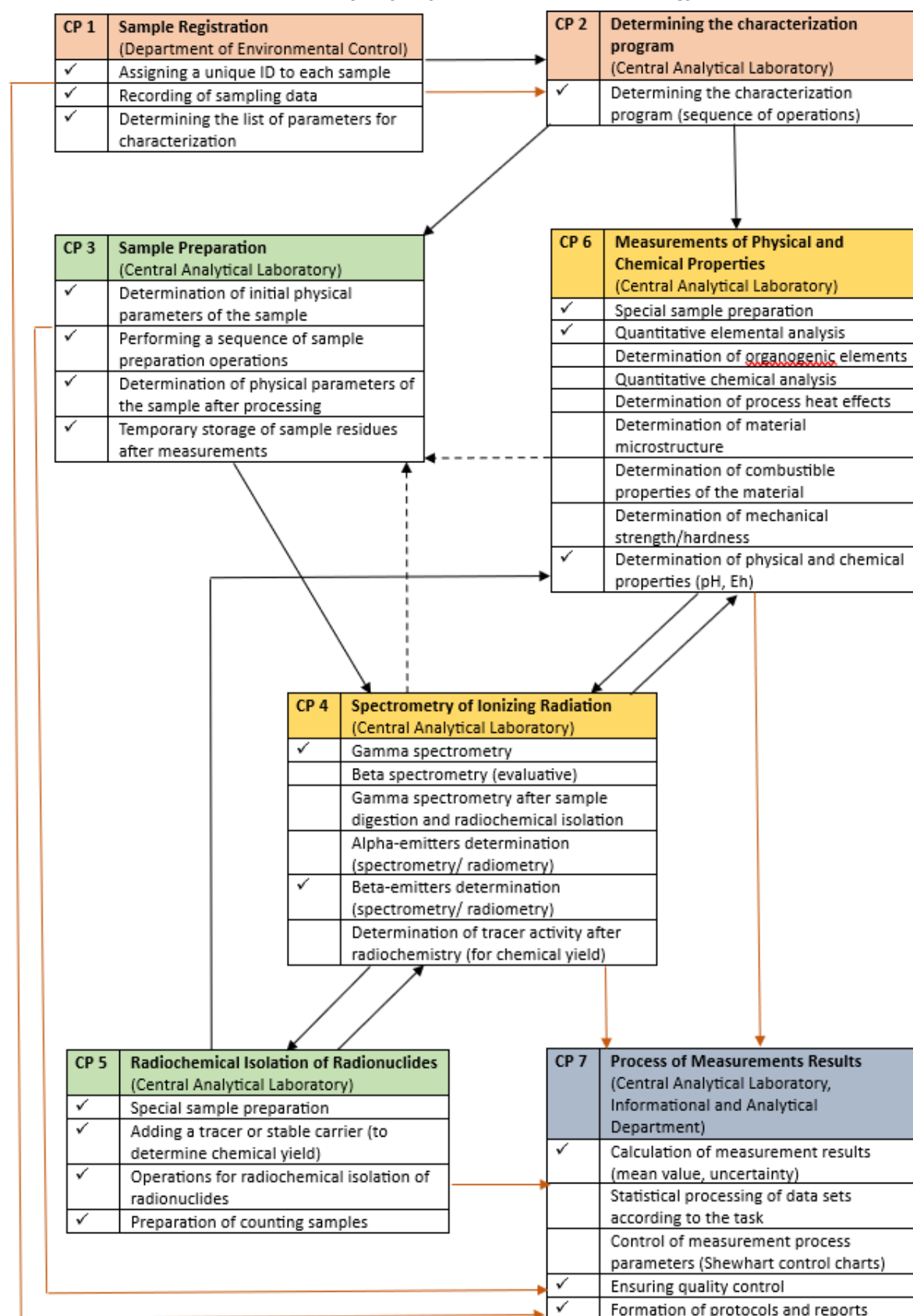**UKR9040 Task 4.2.3 LIMS Procurement**

Bidders Questions

1. *How many users will be using the system at the same time (on keyboards)? It is best to consider peak time operations. The reason I ask is that our software is priced on a concurrent user basis.*
   The maximum is expected to use the system at the same time is 10 users (7 control points, and 3 user interfaces (other computers) for managers & technicians). The total number of users that are will be registered for access to the LIMS is up to 75 i.e. only 10 of the 75 will be using the system at anyone time. The LIMS should be configured to allow the level of access to be specified for each user.

2. *It seems that only manual result entry is required as links to instruments is not mentioned. Is this   correct?*
   No, where possible direct connection of instruments is expected. Provision should be made for at least 30 instruments. See attachment for current list of equipment in the laboratory which should be recognized in the LIMS. This list is likely to change over the next 12 months and new equipment replaces that which has been damaged or stolen. Three data entry modes are envisaged:
   a. Automatic data push from the instrument to the LIMS during measurements.
   b. Export of data from the instrument (e.g. in xls file) and user upload into LIMS.
   c. Manual entry of data by the user.

3. *Is it imperative that we supply bar-code hardware as it may be better to source this locally?   Our   software   supports   bar-code   operation.*
   Local procurement is still currently difficult. Therefore, the proposal should include the provision for the bar-code hardware.

4. *The required LIMS system seems to be on premises. Is also accepted a SaaS (software as a services) solution on a certified cloud platform? The world trends are based on cloud solution and not anymore on client/server on premises solution.*
   For this procurement, the client is requesting a system for installation on a server at the client's premises given the current situation in Ukraine. However, in the next 2-4 years the client will investigate the options to move to a cloud-based platform. Therefore, the bidder should state whether it is possible to transition the LIMS software proposed in response to this RfQ to a cloud-bases SaaS in the future.

5. *Is a web-based system acceptable for IAEA (instead of on-premise)?*
   Please see the response above to Question 4.

6. *Total number of end-users please?*
   Please see the response to Question 1 above.

7. *(Compliance matrix ref: 4.1.1) Where are the samples first registered? In the field without access to the main server or in the lab where the main server is accessible?*
   Not in the field, the sample in first registered when it arrives at the laboratory.

8. *(Compliance matrix ref: 4.1.3) Could you please describe the overall process of sample collection, registration, processing analysis, and reporting (the entire workflow) and provide sample documentation generated at each stage?*
   See diagram below.

Legend:

 	Registration activity
 	Activity of sample preparation for measurement
 	Measurement activity
 	Analytical activity
⟶	Sample flow
⟶	Information flow
╌╌╌⟶	Flow of spent samples

The sequence of work procedures for determining the radiological, physical and chemical properties of samples (sample flow chart in the laboratory)

CP 1 — Sample Registration (Department of Environmental Control)
- ✓ Assigning a unique ID to each sample
- ✓ Recording of sampling data
- ✓ Determining the list of parameters for characterization

CP 2 — Determining the characterization program (Central Analytical Laboratory)
- ✓ Determining the characterization program (sequence of operations)

CP 3 — Sample Preparation (Central Analytical Laboratory)
- ✓ Determination of initial physical parameters of the sample
- ✓ Performing a sequence of sample preparation operations
- ✓ Determination of physical parameters of the sample after processing
- ✓ Temporary storage of sample residues after measurements

CP 6 — Measurements of Physical and Chemical Properties (Central Analytical Laboratory)
- ✓ Special sample preparation
- ✓ Quantitative elemental analysis
- Determination of organogenic elements
- Quantitative chemical analysis
- Determination of process heat effects
- Determination of material microstructure
- Determination of combustible properties of the material
- Determination of mechanical strength/hardness
- ✓ Determination of physical and chemical properties (pH, Eh)

CP 4 — Spectrometry of Ionizing Radiation (Central Analytical Laboratory)
- ✓ Gamma spectrometry
- Beta spectrometry (evaluative)
- Gamma spectrometry after sample digestion and radiochemical isolation
- Alpha-emitters determination (spectrometry/ radiometry)
- ✓ Beta-emitters determination (spectrometry/ radiometry)
- Determination of tracer activity after radiochemistry (for chemical yield)

CP 5 — Radiochemical Isolation of Radionuclides (Central Analytical Laboratory)
- ✓ Special sample preparation
- ✓ Adding a tracer or stable carrier (to determine chemical yield)
- ✓ Operations for radiochemical isolation of radionuclides
- ✓ Preparation of counting samples

CP 7 — Process of Measurements Results (Central Analytical Laboratory, Informational and Analytical Department)
- ✓ Calculation of measurement results (mean value, uncertainty)
- Statistical processing of data sets according to the task
- Control of measurement process parameters (Shewhart control charts)
- ✓ Ensuring quality control
- ✓ Formation of protocols and reports

9. *Regarding compliance matrix ref: 4.1.10 - Permit the tracking of progress of an analytical programme of work including generation of summary progress reports.*
    a. *How many control points are there at the moment? Is it / will it be 7 because 7 barcode scanners have been requested?*
       This is correct: seven control points, seven barcode scanners. Please refer to the work procedure diagram above which shows the activities / analyses carried out at each control point (CP).

    b. *Can a control point perform multiple sample tests (analytical processings) before transferring the sample to the next point?*
       Yes, at certain control points multiple sample tests/analyses may be performed. There are two control points where up to 15 different types of tests/analyses may be carried out. At these control points there could be simultaneous input of data from instruments and a user.

    c. *Is a workflow (transition of a sample through control points), always for a single sample or also possible for a batch of samples?*
       Both single samples and batch samples will be processed. Several instruments allow for batch measurement of samples.

10. *Regarding compliance matrix ref: 4.1.11 - Record user-defined details of each analytical procedure performed by the laboratory and include the SOP for the procedure in a downloadable form. Is this similar to a free form Lab Notebook with ability to inject the processed data?*
    The LIMS should have the ability to record relevant user-defined information relating to each sample including any deviations from SOP. An output of all information relating to a sample should be available in a downloadable form. The SOP should be accessible within the LIMS so it can be viewed at a checkpoint/user interface and also be available for download / printing to hardcopy.

11. *How 4.1.13 (Support inputting of user-defined analytical information entered manually by the end user including sample masses, chemical recoveries and measurement data arising from analytical instrumentation for a minimum of 100 analytical parameters) differs from 4.1.14 (Support the recording of user-defined supporting information for each data input (e.g. measurement date, instrument serial number, calibration file reference)? That is both seem to be user-defined custom meta-info, related to input data.*
    They are both forms of data to be entered by the user; 4.1.13 is concerned with sample measurement data (e.g. sample masses, chemical recoveries and measurement data); 4.1.14 is concerned with information about the sampling process (e.g. SOP and any deviations, the instrumentation used, calibration file reference, etc). Measurement data will be analyzed and evaluated and sampling procedure / instrumentation data will only be reported.

12. *Regarding compliance matrix ref: 4.1.15 - Support the recording of quality control data from each analytical instrument and the statistical analysis and display of such data as Shewhart plots in accordance with ISO7870-2:2013.*
    a. *Could you please describe the current quality control process, which data is being recorded, and what you are looking to implement additionally as a part of new system?*

       The laboratory is working towards accreditation to meet the requirements of ISO 17025, ISO 9001, and ISO 7870-2:2013 (2023). Therefore, the LIMS must support meeting these requirements. In terms of QC practices the laboratory currently / will soon implement:

- Analyzing blank samples.
- Analyzing duplicate or triplicate samples.
- Analyzing spiked samples - periodic intra-laboratory measurements (precision, reproducibility and stability) using non-certified control materials
- Instrument calibration.
- Participation in interlaboratory proficiency programmes.

The LIMS should support statistical analysis of QC data in accordance with ISO 7870-2:2013 and ISO 7870-2:2023 including inter-laboratory comparisons.

b. *Can we assume that one control point = one analytical instrument (so there are 7 analytical instruments at the moment)? Is it subject to change?*
No, please see the answer to question 9.

c. *The standard has been revised by ISO 7870-2:2023. Should we assume the new standard in the implementation?*
Although the new ISO standard has not yet been implemented in Ukraine it will be in the future and therefore the LIMS should accommodate the requirements under both ISO 7870-2:2013 and ISO 7870-2:2023.

13. *Regarding compliance matrix ref: 4.1.17 - Permit the conversion of results for each analyte into different units based on industry recognized or user-defined conversion factors. We would suggest that the system should persist data with a constant common denominator while the corrections be applied during input and for reporting.*
Noted; we assume that this means that the LIMS database will store data using a consistent unit, but the LIMS input and output interface will allow for entry and export of date in different formats i.e. the LIMS will do the conversion prior to storing in the database e.g. input interface allows input in mg but data is stored in the database as g.

14. *Regarding compliance matrix ref: 4.1.19 - Maintain the electronic signature system for laboratory personnel. At which stages is the electronic signature applied?*
The electronic signature is specific to each user and enables the LIMS to record which user carried out a SOP e.g. preparation / test / analysis. The electronic signature should be maintained as a sample proceeds throughout the testing and analyses process.

15. *Regarding compliance matrix ref: 4.1.20 - Support the archiving and retrieval of all data in a csv or equivalent format. Staff training can be another big project. To which extent is staff training tracking required? E.g., only users assigned to trainings, mark as attended, calendar and notification system, training resources tracking, grading system, etc.*
As a minimum the LIMS needs to record which users are trained against each SOP e.g. preparation / test / analysis and the dates the training is valid. The LIMS should therefore know whether a user can apply their electronic signature for a given SOP i.e. only trained users data for a specific preparation / test / analysis.

16. *Regarding compliance matrix ref: 4.1.23 - Incorporate security features, such as individual user password-controlled log-in, to restrict and log database access and to log the identity of the user entering input data or modifying database functionality. Do you have an SSO service to integrate with?*
Assuming that SSO is 'single service sign-on' we do not currently have a SSO service in place.

17. *Regarding compliance matrix ref: 4.1.27 - Be compliant with any relevant requirements for record keeping and data management in testing and calibration laboratories as specified in ISO17025:2017.*

a. *Will laboratory calibration and testing also be a part of the new system?*
Note the function of the laboratory is the testing and analysis of environmental and waste samples, it is not a calibration laboratory. The LIMS should meet the requirements for relevant requirements for record keeping and data management as set out in ISO17025:2017 (see sections 7.5 & 8.4).

b. *If so, what does the current process of calibrating and testing the laboratories look like? Which parts are you looking to implement additionally for a new system?*
Refer to question 8 which provides an overview of the sample testing and analysis process. Prefer to question 12 a which provides information on the QC procedures used at the laboratory.

18. *Technical Requirement 4.1.24 states "Store all data in a centralised server accessible over a local area network and support simultaneous multiple-user access from up to 7 separate control points". How many individual users will the system be accessed by?*
Refer to question 1.

19. *For LIMS we would need the number of user licenses and number of instruments to be connected. This will allow us to bid for the licenses and the implementation charges.*
Refer to question 1 and 2.

20. *We have already had an internal review of the RFT requirements and from a technical perspective, the primary question I would have at this time is how many users of the LIMS system do you expect to have?*
Refer to question 1.

21. *Is a web-based system acceptable for IAEA? (instead of on-premise); what is the' total number of end-users please?*
Refer to question 4 and 1.

22. *We would like to know the number of user licenses required for the LIMS RFQ If instruments need to be integrated we would like to have a list of instruments or total number of instruments to be connected with LIMS.*
Refer to question 1 and 2.

23. *In Supplier Cover Letter document we have statement: "Alternatively, if a bidder is not able to register through the IAEA iSupplier portal, they may submit the completed Supplier Registration Form (including a copy of the Certificate of Incorporation), attached to this Request for Quotation (RFQ), as part of their quotation." - Do we have to translate to English "copy of the Certificate of Incorporation" with a sworn translator or a copy in original language and standard translation signed by members of the board will be enough?*
This is not necessary. A copy of the original and a signed translation by a member of staff is acceptable.

24. *In the Specification document there is a statement: " 4.1.28. Have been previously installed in a radioanalytical or analytical laboratory and demonstrated to operate effectively – evidenced through supporting statements from existing customers." Do we have to translate to English statements from customers with a sworn translator or a copy in original language and standard translation signed by members of the board will be enough?*
This is not necessary. A copy of the original and a signed translation by a member of staff is acceptable.

25. *In the Technical Compliance Matrix document there is point 10.2: "10.2. International calibration certificate or certificate of verification/calibration from the metrological centre of Ukraine." This kind of certificates are related to laboratory equipment   and subject of this tender is software plus scanners which are also not in scope of calibration certificate. Should we leave this point empty or setup "No" in a compliant column and describe reasons like we did in this question?*

Requirement has been added in error, please disregard and but a cross through the box.