Appendix no. 2 to ToR

**DESCRIPTION OF THE SUBJECT OF THE PROCUREMENT**

**Case No. PO.271.39.2022**

**“****Expert supervision of rebuilding and retrofitting the BSL-3 laboratory in Łukasiewicz - PORT”**

Definitions

**Contracting Party** – Łukasiewicz Research Network – PORT Polish Center for Technology Development (abbreviated Łukasiewicz – PORT).

**Contractor** – an expert in planning, evaluation of design, supervision of construction works and commissioning of biosafety level 3 (BSL-3) laboratories, selected in the procurement “Expert supervision of rebuilding and retrofitting the BSL-3 laboratory in Łukasiewicz – PORT”.

**Designer** – a participant of the building process, whose tasks is to prepare comprehensively the design documentation.

**Contract Engineer** – a group of people who are specialists in different aspects of construction works, who control the quality and progress of construction works, supervise documentation, enforce provisions of the contract with the construction works contractor and coordinate the activities of the building process participants.

1. **Description of the construction investment project**

The Contractor- an expert in the design evaluation, construction works supervision and commissioning of Biosafety Level 3 (BSL-3) laboratories will be responsible for the supervision of rebuilding and retrofitting of dedicated laboratories in Łukasiewicz – PORT to BSL-3 standards. The laboratories are situated in building no. 4, which is part of Łukasiewicz Research Network – PORT Polish Centre for Technology Development, located on Kampus Pracze, at Stabłowicka 147, Wrocław. The Łukasiewicz – PORT complex, including building no. 4, has been entered into the register of monuments- decision no. 460/Wm of 12.08.1991r.

Building no. 4 is a three-storey freestanding brick-built building with a basement. It was built using traditional technology- brick walls with gable roof covered with ceramic tiles. The building was modernized and commissioned in 2014, and the laboratories were finished a year later. Currently, two independent laboratories and additional rooms on the second floor are dedicated to operate to BSL-3 standard with a total area of 175,5 m2. On the ground floor, there is a chemical effluent decontamination system (EDS) associated with the laboratory. Heating, ventilation and air conditioning system (HVAC) connected to the laboratory is situated on the third floor and in the attic of the building.

Łukasiewicz – PORT BSL-3 laboratories have never been commissioned, as the required air pressure differences between the laboratory rooms and the rest of the building cannot be kept stable. Gap analysis, conducted by external experts in 2021, demonstrated numerous incompatibilities between the current state of laboratories in Łukasiewicz - PORT and the best practices and standards in engineering and architecture of BSL-3 laboratories. In the Gap Analysis Report, the experts pointed out the necessity of rebuilding and retrofitting the existing laboratories, in order that the laboratory suite meets the requirements of BSL-3, and to allow for optimal functionality regarding planned activities, while keeping the running costs of the laboratory optimal.

The Contracting Party is planning significant rebuilding of the laboratories, in order that the suite meets the highest standards of BSL-3. The scope of the necessary modernization works was estimated in Gap Analysis Report (the Contracting Party will provide the copy of Gap Analysis Report to the Contractor). Expected modernisation works include:

* layout rearrangement connected and relevant changes in electrical installation, other utilities and panel system building;
* HVAC installation change;
* HVAC system automation installation changes;
* removal of effluent decontamination system (EDS) from the ground floor;
* replacement of step-through showers connected to EDS by a single shower with local decontamination system.

We do not foresee any changes in land use plan.

The Contractor will be responsible for expert supervision of the rebuilding project, regarding compliance of planned and executed works with BSL-3 standards and regulations, as well as best practices applicable to the design and functioning of BSL-3 laboratories (see section 8, points a-h).

1. **Responsibilities of Contractor**

Responsibilities of the Contractor during the rebuilding project are listed below. Depending on the availability of funding, the Contracting Party reserves the right of option, based on which the range of responsibilities of the Contractor in the project will be defined:

* Basic order: Stages I, II, Part 1 of Stage III;
* Option: Part 2 of Stage III, Stages IV-VI.

**Stage I:** **The procedure for selecting the contractor for the design**

This stage will be divided into two parts: 1) preparation of the concept of laboratory and preparation of the procurement documentation and 2) selecting the Designer based on the appropriate procedure of PPL.

Part 1. Preparation of the concept of laboratory and preparation of the procurement documentation.

1. On the basis of documents provided by the Contracting Party: Laboratory Strategy, User Requirements Brief, Needs Assessment, Risk Assessment and Gap Analysis Report, as well as taking into account regulations and best practices for BSL-3 laboratories (see section 8, points a-h), the Contractor will prepare a concept of the laboratory and the guidelines for the design, including:

* The final version of User Requirements Specification (URS), which – taking into account planned laboratory functions – will detail, amongst others:
* precise layout of equipment planned within the laboratory with precisely defined detailed specification (dimentions, series etc.), ensuring optimal use of equipment and maintaining the principles of ergonomics of their use and appropriate width of passages;
* the model of laboratory usage;
* the characteristics of personnel, equipment and materials flow;
* the characteristics of the possibility of future changes and modernisation of the laboratory;
* User Design Brief (UDB), together with exact guidelines for the architecture and installation characteristics.

The URS and UDB will be basis to prepare the Description of the Subject of Procurement for the procurement procedure for the preparation of the laboratory design. During preparation of the above documents, the Contractor will consult the solutions proposed in them with the Contracting Party, taking into account remarks and comments of the Contracting Party, and (if necessary) proposing alternative solutions, under the condition that implementing those alternative solutions will be possible without compromising norms and standards required for BSL-3 laboratories (section 8, points a-h).

1. The Contractor will actively assist the Contracting Party in the preparation of procurement documentation (Terms of Reference); especially they will be responsible for:

* preparation of the Description of the Subject of Procurement- which in a clear and exhaustive way will describe the subject of procurement, but not compromise fair competition (i.e. without mentioning trademarks, patents, producers, and if this is impossible, describing their equivalence characteristics);
* evaluation of the rest of procurement documentation, including acceptance of agreement template and appendices to the agreement in the scope of provisions related to the proper execution of the contract (e.g. timetable for the execution of the contract);
* preparation of the criteria and weights of offers evaluation (together with justification) and the conditions for participation in the procedure for selecting the contractor for the design documentation (in accordance with the Public Procurement Law (PPL) of 11 September 2019, in particular Articles 112, 116, 242).

The Contractor will prepare the documentation described in points a and b within a maximum of 8 weeks from the date of signing the agreement.

Part 2. Selecting the Designer based on the appropriate procedure of PPL legislation

During the procurement procedure for selecting the contractor for design documentation (the Designer), the responsibilities of the Contractor will include:

* preparation of answers to the questions connected with the technical and/or design documentation, in the deadlines resulting from PPL;
* checking the compliance of obtained tenders with the Terms of Reference and submitting to the Contracting Party the comments on submitted tenders;
* drawing up a proposal for the evaluation of tenders and presenting it in a report, which will contain, scores given to submitted tenders based on the criteria of the tenders evaluation and an indication of the most advantageous offer;
* substantive support in appeal proceedings before the National Chamber of Appeal (if an appeal is lodged).

The basis for signing the Acceptance Protocol for Part 1 of Stage I by the Ordering Party will be the preparation of the laboratory concept and preparation of procurement documentation to the required extent. The basis for signing the Acceptance Protocol for part 2 of Stage I by the Ordering Party will be the conduct and conclusion of the procedure for selection of the Designer.

**Stage II:** **Agreeing the final version of the design**

The Contractor will evaluate the design (and potentially its different variants) as delivered by the Designer selected in the procurement. The Contractor will focus especially on the area of their expertise and give their opinion on:

* Fulfillment of requested standards indicated in the description of the subject of procurement and evaluation of proposed solutions from the perspective of technologies used in BSL-3 laboratories;
* Meeting the requested functionality of the laboratory and assessing the optimality of the adopted solutions for the planned activities;
* Evaluation of the architectural solutions for installation of HVAC, sanitary installation, electrics and automation, and other installations which are required, indicated and/or planned in the laboratory, as well as detailed design solutions (in the scope of Expert’s knowledge);
* Evaluation of the quality of proposed materials and equipment (in the scope of Expert’s knowledge);
* Evaluation of economic aspects of the proposed design (the influence of proposed solutions on the running costs of laboratory).

The Contractor will work together with the Contract Engineer and/or Technical Depatrment Łukasiewicz – PORT and will present their evaluation relying on their expert knowledge and experience. The Contractor will evaluate the design in the scope of fulfillment of the requirements specified in the Description of the Subject of Procurement, and also relating it to other functioning BSL-3 laboratories. If relevant, the Contractor will point out any shortcomings of the design which violate the BSL-3 standards or regulations, or proposed solutions which can negatively impact the functionality of the laboratory. Where it is within their competence, the Contractor will present specific propositions for alternative solutions. If corrections to the design are necessary, the Contractor will evaluate the subsequent versions of it, until the final design is agreed on. The Contractor will take part in the receipt of design documentation together with the Ordering Party.

The basis for signing off the Acceptance Protocol for Stage II will be the report on conducting the Design Qualification (DQ).

**Stage III:** **Selecting the contractor of construction works based on the appropriate procedure of PPL.**

This stage will be divided into two parts: 1) preparation of the documentation for the procurement of the construction works and 2) selection of the contractor for the construction works based on appropriate procedure of PPL legislation.

Part 1. Preparation of the documentation for the procurement of the construction works

The Contractor will be supporting preparation of procurement documentation for construction works in the scope of issues connected specifically with BSL-3, including design documentation, client budget estimate and *Technical specification of execution and acceptance of construction works* document (PL: *Specyfikacja techniczna wykonania i odbioru robót budowlanych*- STWIORB), which will indicate for example, but not exclusively:

* preparation of the construction site;
* process management;
* architectural aspectsof installations HVAC, electrical, plumbing, automation and fire protection;
* required certification for rooms, equipment, craftsmanship and installations;
* technical specification for execution and acceptance of construction works;
* financial and progress timetable for project execution;
* qualification and validation of laboratory (including thorough testing of HVAC system at the stage of acceptance of construction works);
* employee training and preparation of operational procedures for laboratory;
* post-commissioning warranty services.

The abovementioned documentation will be prepared together with the Contracting Party and the Contract Engineer, on the basis of appropriate legislation. The Contractor will also assess from the BSL-3 perspective, the criteria and weights of the tender evaluation in the procurement procedure, as well as the conditions of taking part in the procurement proposed by the Contract Engineer.

The Contracting Party is estimating 20 hours of substantive consultations considering the input to the construction works procurement documentation in the scope of BSL-3-specific requirements.

Part 2. Selection of the contractor for the construction works based on appropriate procedure of PPL legislation.

During the procurement procedure for selection of construction works contractor, the Contractor (Expert) will actively support the Contracting Party and contract engineer in the scope of answering the questions connected with project documentation, if they are linked to the specificity of BSL-3, in the deadlines resulting from PPL.

The basis for signing off the Acceptance Protocol for Part 2 of Stage III will be the conclusion of procedure for selection of the contractor of construction works.

**Stage IV:** **Supervision of execution of construction works and commissioning of the laboratory**

The construction works will be divided into three parts: 1) demolition works, 2) building works (architecture and installations) and 3) final acceptance of works and commissioning of the laboratory. The Contractor will take part in parts 2 and 3 of construction works.

Part 2. Building works (architecture and installations).

The Contractor will be responsible for supervision of execution of part 2 of construction works in the scope of BSL-3-specific regulations, including:

* quality control of undertaken works according to BSL-3 standards;
* acceptance of successive stages of construction work in accordance with BSL-3 standards;
* inspection of construction site documentation as related to BSL-3 requirements and BSL-3 certification standards;
* supervision of project execution (including architecture, installations) in the scope of requirements of BSL-3 standards, professional opinions of potential alternative solutions and substitute materials selection, especially, but not exclusively, from the perspective of compliance with BSL-3 standards, operational cost consumption, ergonomics and usage and functional optimality;
* interpretation and assessment of test results of all installations as they are being finished, if necessary validation of the tests using own methods/equipment/personnel (obligatory for HVAC system).

The Expert will personally supervise the project execution and works acceptance, in the extent necessary to properly deliver the service.

If tests of completed laboratory installations prove it necessary to implement further changes by the contractor for building works, the Contractor will also participate in further tests, until the successful acceptance of the work.

Part 3. Final acceptance of works and commissioning of the laboratory.

Should all of the construction works be completed, the Contractor will take part in final acceptance of the construction works, including:

* technical acceptance of completed works;
* verification and validation with their own means and methods results of final tests, especially of the HVAC system in accordance with standards agreed with the Contracting Party (e.g. ANSI Z9.14-2020).

If tests of laboratory installations prove it necessary to implement further changes by the building contractor, the Contractor will participate in further tests, until the commissioning of the laboratory.

The basis of signing the Acceptance Protocol by Contracting Party for Stage IV: preparation of Installation Qualification (IQ) and Operational Qualification (OQ) protocols, signed final protocol of completed construction works (if applies), obtaining the use permit for the laboratory (if applies).

**Stage V:** **Certification of the laboratory in accordance with EN12128 and Genetically Modified Microorganisms (GMM) regulation for GMM III**

The Contractor will prepare the laboratory for the certification, as well as provide additional supervision over functional commissioning of the laboratory, including:

* assessment of procedures proposed by the Contracting Party, in connection of laboratory functionality and BSL-3 standards;
* assessment of proposed laboratory use model in connection with future research activities (specified by the Contracting Party)
* evaluation of technical and procedural compliance with EN 12128 (or equivalent) standard;
* preparation of the laboratory for obtaining approval from Ministry of Climate and Environment as a leading category 3 genetic engineering (GMM 3) laboratory (according to Polish law; the Contracting Party will make all relevant legislative documentation available to the Contractor);
* evaluation of established documentation necessary for proper functioning of BSL-3 laboratory and its management according to ISO 35001:2019 (or equivalent).

The Contractor will dedicate a sufficient amount of time necessary to run the final tests of the laboratory and to properly supervise functional commissioning of the laboratory. The Contractor will also support the Contracting Party in preparation of appropriate documentation connected to the above-mentioned certification.

The Contractor will obtain the certificate of compliance of the BSL-3 laboratory with the EN 12128 standard. The certificate will be issued by a person with appropriate expertise, as confirmed by an independent institution from a country within the European Union, European Free Trade Association, United Kingdom, USA or Canada (for example Registered Biosafety Professional or Certified Biological Safety Professional certified by Association for Biosafety and Biosecurity International). The person issuing the certificate should be able to demonstrate granting minimum of 3 certificates for the BSL-3, ABSL-3, BSL-4 or ABSL-4 laboratories in the last 10 years in three different organisations.

The basis for signing the Acceptance Protocol by Contracting Party for Stage V: obtaining of the certificate of compliance of the laboratory to EN12128 and obtaining GMM 3 category (according to regulations of Ministry of Climate and Environment) for the laboratory.

**Stage VI:** **Consultations after commissioning of the laboratory**

The Contractor will provide support for the Contracting Party via on-line consultations regarding the BSL-3 standards functioning in the laboratory after laboratory commissioning (40 hours through the first 6 months after the completion of Stage V).

1. **Implementation timeline**

The agreement for the expert services will be signed for the period of 37 months from the date of signing, of which it is estimated:

* 16 months within the basic order:

Stage I: 4 months

Stage II: 9 months

Stage III, Part 1: 3 months

* 21 months within the right of option:

Stage III, Part 2: 4 months

Stage IV: 10 months

Stage V: 3 months, of which the first two months overlap with the last 2 months of Stage IV

Stage VI: 6 months

During the execution of the agreement, in Stages I-V, the Contractor will make a minimum of three visits in person to the construction site at time points agreed with the Contracting Party (including one during the final acceptance of construction works and testing of installations). In addition, if necessary, the Contracting Party may call on the Contractor for another 3 visits as part of the single source procurement pursuant to Article 214(1)(7) of the PPL, i.e. after negotiations with the Contractor and signing of the contract between the parties.

1. **Existing documentation**

Where necessary, after signing the agreement, the Contracting Party will make available all existing design documentation for the rooms to be modernised. As-built documentation for the building where the laboratory is placed will be available for inspection at the Contracting Party's premises or in electronic form.

1. **Subcontracting**

The Contractor may entrust performance of part of the contract to a subcontractor (subcontractors). The Contractor takes full responsibility for the subcontractors (including the timeliness and quality of their work).

The Contracting Party reserves the obligation for the Contractor to personally perform the key parts of the contract, concerning: 1) preparation of the documentation (as described in Section II, description of Stage I) for the procurement to select the Designer; 2) evaluation of tenders submitted in the procurement for selection of the Designer; 3) evaluation of design documentation proposed by Designer and agreeing the final version of the design; 4) taking part in the acceptance of completed works of all the stages and in the final acceptance of construction works; 5) verification of tests qualifying the laboratory to work in BSL-3 standard; 6) preparation of the laboratory for certification.

1. **Language of correspondence, documents**

The Contracting Party accepts English as the language of correspondence and communication with the Contractor during the execution of the contract (after signing the agreement with the Contractor). The documentation will be prepared in Polish or English.

1. **Information on currencies in which settlements between the Contracting Party and the Contractor can be made**

Settlements between Contracting Party and Contractor will be carried out in Polish zlotys (PLN). The Contracting Party also admits the possibility of settlements with the Contractor in Euro or CHF.

1. **Regulations, standards, norms and guidelines**
2. PN-EN 12128:2000 *Biotechnology - Laboratories for research, development and analysis - Containment levels of microbiology laboratories, areas of risk, localities and physical safety requirements* - if necessary, the Contracting Party will provide a translated version of the Polish document in electronic form to the email address indicated in the Agreement within no more than 7 working days.
3. Act of 22 June 2001 on micro-organisms and genetically modified organisms, Regulation of the Minister of Environment of 11 April 2016 on detailed types of safety measures to be applied at genetic engineering facilities, Directive 2009/41/EC of the European Parliament and of the Council of 6 May 2009 on the contained use of genetically modified micro-organisms - if necessary, the Contracting Party will provide a translated version of the Polish document in electronic form to the email address indicated in the Agreement within no more than 7 working days.
4. Regulation of the Minister of Health of 22 April 2005 on biological agents harmful to health in the workplace and health protection of workers occupationally exposed to such agents, Directive 2000/54/EC of the European Parliament and of the Council of 18 September 2000 on the protection of workers from risks related to exposure to biological agents at work - if necessary, the Contracting Party will provide a translated version of the Polish document in electronic form to the email address indicated in the Agreement within no more than 7 working days.
5. ISO 35001:2019 Biorisk management for laboratories and other related organisations
6. ANSI Z9.14- 2020: *Testing and performance verification methodologies for ventilation systems for Biological Safety Level 3 (BSL-3) and animal Biological Safety Level 3 (ABSL-3) facilities*,
7. WHO Laboratory Biosafety Manual (4th edition or newer)
8. Biosafety in Microbiological and Biomedical Laboratories, 6th Edition,
9. NIH Design Requirements Manual (DRM), 2016
10. Polish Procurement Law of 11 September 2019, especially art.  112, 116, 242 connected with the Description of the Subject of Procurement - if necessary, the Contracting Party will provide a translated version of those articles of the Polish document in electronic form to the email address indicated in the Agreement within no more than 7 working days.
11. **Confidential nature of information**

Working in accordance with art. 133 par. 3 of PPL Act, the Contracting Party informs that they have not made available part of Terms of Reference in the scope of the Gap Analysis. The above-mentioned information is confidential.

In order to obtain the above-mentioned information, the Contractor may request the information from the Contracting Party by submitting a "Confidentiality statement" using the template from Appendix no 1 to the Description of the Subject of Procurement. The statement should be send to the e-mail address: anna.paziewska-harris@port.lukasiewicz.gov.pl The Contractor will answer within 2 days, with the proviso that in a situation where the Contractor does not submit the above-mentioned statement, the Contracting Party will not be obliged to provide confidential information.

1. **Measures to maintain the confidentiality of information**

The Contracting Party requests that the Contractor submits a statement, in which they commit to not make confidential information available to other entities, to not use confidential information for any purpose other than to participate in the procurement procedure and, possibly, to execute the agreement signed as the result of procurement, and to appropriate securing of the confidential information against unauthorised access by other entities. The Contracting Party will make the confidential information available after receiving the “Confidentiality statement”.

Appendix no. 1 to the Description of the Subject of Procurement

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(place, date)

**Confidentiality statement**

To the procurement procedure „Expert supervision of rebuilding and retrofitting the BSL-3 laboratory in Łukasiewicz – PORT” , case no. PO.271.39.2022

The Contractor, i.e. ……………………………………………………/name, address/, states to the Łukasiewicz Research Network – PORT Polish Centre for Technology Development in Worcław, called hereafter the Contracting Party, that they are aware, and have been informed by the Contracting Party that the information connected with the Gap Analysis Report in the procurement „Expert supervision of rebuilding and retrofitting the BSL-3 laboratory in Łukasiewicz – PORT”, which the Contracting Party will make available to the Contractor, is confidentional information.

Considering the above, the Contractor commits to:

1. Not make the information available to other entities (keep all confidential information in strict confidence),
2. Use the confidential information only in connection to procurement procedure, and possibly in connection with executing the agreement signed as a result of the procurement and not use the confidential information for other purposes,
3. Restrict disclousure of confidential information to those workers or co-workers of the Contractor, for whom the confidential information is necessary to execute the goals described in point b),
4. Secure the confidential information from unauthorised access of other entities.

The Contractor states that they are aware that the breach of the above obligations may be treated as an act of unfair competition, as described in Act of 16 April 1993 on combating of unfair competition and as crime, as described in art. 266 § 1 of the Act of 6 June 1997 r. Penal code, as well as it can result in the liability of the Contractor for the damages.

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/signature of an authorised person/