

DESCRIPTION OF THE SUBJECT OF THE PROCUREMENT
Case No. PO.271.23.2021
"An expert opinion (gap analysis) of the Łukasiewicz - PORT BSL-3 laboratory"

The **gap analysis** aims to identify inconsistencies between the current state of the BSL-3 laboratories at ŁUKASIEWICZ - PORT and state-of-art standards and good practices for the architecture and engineering of biosafety level 3 laboratories. Furthermore, the possibility of upgrading and adapting the premises to BSL-3 standard will be analysed and the costs of such adaptation estimated.

The analysis should include primarily, but not exclusively:

Analysis of the necessity and extent of reconstruction of heating, ventilation and air conditioning (HVAC) systems

Based on the Contracting Party's observations, the expert report should include, amongst others:

- Analysis of the problem of maintaining a stable pressure cascade. During the commissioning of the laboratory, a problem was encountered with the stability of the cascade, especially in emergency situations (switching fans, stopping the ventilation system). In addition, there are many doubts about the design of the cascade (only two stages) and the choice of reference site. The purpose of the expert opinion will be to analyse the causes and identify technical options for solving the problem.
- Analysis of the problem with the occurrence of critical overpressures and underpressures (e.g. when fans are switched on/over).
- Analysis of the necessity for duplicate fans in the HVAC system in the laboratory.
- Verification of the system building method in the BSL-3 laboratory for resistance to emerging pressure fluctuations (with particular attention to the ceiling fixing system).
- Analysis of the current mechanism for controlling and disconnecting ventilation in the BSL-3 laboratory during a fire emergency.

Analysis of necessary changes in the layout of individual rooms so that they are functional according to planned use

Based on the Contracting Party's observations, the expert report should include, amongst others:

- Analysis of the need for a one-way entry/exit system from the laboratory and possible changes to the system construction.
- Evaluation of the way in which bulky materials and equipment are brought in and out and, where changes are necessary, identification of the most appropriate solutions.
- Evaluation of the functionality of individual rooms in the context of their intended use and detailing any changes necessary for future use.

Analysis of the need for changes in the wastewater decontamination system

Based on the Contracting Party's observations, the expert report should include, amongst others:

- Evaluation of the designed wastewater discharge and decontamination system in the context of the planned works. If it has not been correctly selected or is not optimal, the expert opinion should include a



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comparison of available methods of wastewater decontamination in relation to tests planned in the laboratory and assess the technical feasibility of implementing these methods.

In the course of the opinion the current state of the laboratory is to be extensively analysed, the above issues only indicate the main technical problems identified by the Contracting Party. The recommendations contained in the expert opinion are expected to make maximum use of solutions and systems already in place. Systems should be designed for maintenance without entering the laboratory (including, for example, safe replacement of HEPA filters in the exhaust system).

1. Service elements

- a) Review of existing documentation (the Contracting Party will send documentation electronically, the Contractor will carry out a preliminary review of the documentation, prepare an inspection schedule and checklist - to be accepted by the Contracting Party)
- b) Site visit in the existing BSL-3 laboratory together with a check of compliance of the existing documentation with the actual state of the laboratory including carrying out the necessary measurements (minimum 2 days together with an opening and closing meeting). We exclude the option of a site visit in the form of an online meeting.
- c) Definition, with the participation of the Contracting Party, of basic operational parameters for the Laboratory.

The Contracting Party will provide an initial draft of the User Requirements Specification (hereinafter the URS). The Contractor will conduct a preliminary analysis of the URS and check its compliance with the norms and standards applicable to BSL-3 class laboratories, after which a final version of the document will be prepared together with the Contracting Party, which will form the basis for the next stage of the gap analysis and will include the identification of requirements in terms of:

- Regulatory issues:
 - guidelines and standards (as described at the end of section 1)
 - legal requirements (health and safety, fire safety)
 - process, product and waste characterisation
 - functional procedures, technical service procedures
- Processes:
 - personnel flow
 - material flow
- Staff-related issues:
 - emergency procedures
 - training of staff and technical services
- Technical specifications for the building:
 - room characteristics
 - technical installations (electrical, plumbing, HVAC, fire protection, automation and LV, metering, detection)
 - arrangement of utilities (gas, water, electricity) and installations for laboratory equipment
 - process installations (including industrial gas installations)
 - materials used (amongst others floors, walls, ceilings, doors, reception windows)



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- d) Comparison of the actual laboratory with the final URS, including an analysis of compliance with BSL-3 standards and requirements, an analysis of the quality of workmanship and an assessment of the adaptation of the premises to the planned functionality with particular reference to:

- HVAC installation,
- electrical installation,
- plumbing,
- automation and LV,
- fire protection installation,
- detection systems,
- metering,
- materials used,
- installed laboratory equipment,
- installed technical equipment.

This comparison should identify gaps for which corrective actions (if possible) will then be identified. The gap analysis should include a comparison of the compliance of the performance of the rooms and installations with the design, with appropriate standards/guidelines and with the requirements contained in the URS.

- e) Analysis report

The gap analysis/expert opinion will be concluded with a written Expert Opinion Report (in Polish and English or in English only). Minimum scope of the Expert Opinion Report:

- Introduction, purpose of the report, scope of the review
- Reference documentation, reference to legislation, standards and guidelines, glossary
- Audit report (also including findings, solutions and answers to questions and topics raised throughout the gap analysis process and the results of the measurements carried out)
- List of gaps and non-conformities, with an indication of the degree of impact of each gap on compliance with regulations and standards, as well as on achieving the functionality of each room in terms of its future use (as described in the URS), and with possible corrective actions for each gap and estimated costs for each modification proposal.

The proposed corrective action plan/concept proposal for the laboratory modernisation will address these issues:

- process issues within the laboratory;
- architectural and constructional issues within the laboratory (including an analysis of the possibility and necessity of separating additional locks/changing rooms or entrances to the laboratories so as to ensure a unidirectional flow of people, a description of the necessary modernisation work on all installations needed to separate the additional rooms, and an analysis of the selection of the correct system development);
- mechanical (HVAC and utility) issues, including identification of technically feasible solutions to achieve the correct pressure cascade and targeted airflow into the laboratory, taking into account possible changes in the HVAC system and control algorithms controlling the system. The report should also include an assessment of the impact of changes to the HVAC



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system on automation and laboratory layout, system development and functionality;

- sanitary issues (sanitary installations, including wastewater decontamination system);
- electrical and automation issues;
- qualification and validation issues in terms of compliance/non-compliance with the guidelines contained in the document referred to in (c) and other as indicated by the Contractor.

- Estimated costs of adapting the laboratory

Regulations, standards, norms and guidelines

The laboratory facility should be verified in accordance with local regulations, applicable standards, norms and guidelines (in consultation with the Contracting Party), including but not limited to:

- 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 e-mail address specified in the Agreement within no more than 7 working days.
 - 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.
 - 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 e-mail address indicated in the Agreement within no more than 7 working days.
 - 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*,
 - WHO Laboratory Biosafety Manual (4th edition)
 - Biosafety in Microbiological and Biomedical Laboratories, 6th Edition,
 - NIH Design Requirements Manual (DRM), 2016;
- as well as current best solutions and practices for the architecture and engineering of tertiary containment laboratories.

2. Implementation deadline - a maximum of 8 weeks (56 calendar days) from the date of conclusion of the agreement.

3. Form of documentation



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Report, drawings and all other documents created during the gap analysis should be provided in electronic form plus 1 paper copy. All electronic documents should be provided as source files in their original format and as PDF files.

4. 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. The gap analysis report will be prepared in Polish and English or in English only.

5. Software: acceptable software, necessary for analysis and creation of documents: Microsoft Office programs, Autocad, Autocad 3D, Microsoft Project or equivalent, allowing documents to be read in the above programs.

6. Existing documentation: The Contracting Party will make available existing design documentation for the rooms to be modernised. As-built documentation for the building containing the laboratory will be available for inspection at the Contracting Party's premises or in electronic form.



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