**REPUBLIC OF TURKEY**

**MINISTRY OF HEALTH**

**HEALTH SYSTEM STRENGTHENING AND SUPPORT PROJECT (HSSSP)**

**(LN:8531-TR1111111111111111111111111111111111111111111111111111111111111111111111111111111111111111111111111111111111111111111111111111111)**

**Consultancy Service Procurement for Environmental and Social Impact Assessment and Its Sub-Management Plans, Environmental and Social Management Plan, Resettlement Plan and Stakeholder Engagement Plan of Ankara Akyurt Vaccine Production Center,** **Experimental Animal Production Center and ABSL3 Level Laboratory Project**

**TERMS OF REFERENCE**

|  |  |
| --- | --- |
| **Project Component/Part:** | Part III: Improving the Effectiveness of Overall Health Sector Administration |
| **Project Sub-Component/Part:** | (D) (i) Supporting the Project Management and Support Unit in project implementation, including in the areas of financial management, procurement, disbursement, and monitoring and evaluation |
| **Procurement Plan No:** | PYDB/2021/CS/P.4/CQS/1 |
| **Job/Assignment Title:** | Environmental and Social Impact Assessment and its sub-management plans for Ankara Akyurt Vaccine Production Center, Experimental Animal Production Center and ABSL3 Level Laboratory Project (**Activity 1)** |
| **Job/Assignment Objectives:** | In accordance with the Environmental and Social Framework (ESF) of the World Bank, environmental and social risk classification for "Vaccine Production Center (VPC), Experimental Animal Production Center and ABSL-3 level laboratory” (together “Activity 1”) under Component 4 to be built in Ankara, is proposed to be "*Substantial*". Within this frame, it is obligatory to conduct a detailed Environmental and Social Impact Assessment (ESIA) as per the provisions of the World Bank ESF and Turkey legislation, including Environmental and Social Management Plan (ESMP). |
| **Job/Assignment Duration:** | 8 (eight) months |
| **Procurement/Consultancy Type:** | Consultancy Services – Consultancy Company |
| **Procurement/Selection Method:** | Selection Based on Consultants' Qualifications (CQS) |
| **Market Approach** | International - Open |
| **Prior Review:** | No |
| **Reporting to (Implementing Agency):** | Project Management and Support Unit (PMSU) |

## BACKGROUND

The Republic of Turkey has received a loan from International Bank for Reconstruction and Development (IBRD) in the amount of 134.3 million US Dollars equivalent (EUR 120 million) to finance the *Health System Strengthening and Support Project – Parent Project* (*HSSSP*). Part of the proceeds will be applied to payments for goods, works, related services and consultancy services to be procured under this project.

The Parent Project consists of the following parts:

* Part I: Primary and Secondary Prevention
* Part II: Increasing Efficiency of Public Hospital Management
* Part III: Improving the Effectiveness of Overall Health Sector Administration
* Part IV: Strengthening Capacity to Respond to COVID-19

Part I: Primary and Secondary Prevention

Raising awareness (both of the population in general and among health care providers) on risk factors related to Non-Communicable Diseases (NCDs) and promoting healthy lifestyles and behavior changes, through the following activities:

1. (i) Developing public outreach materials, methodologies and targeting to raise population awareness about NCDs and the importance of healthy living; (ii) promoting healthy living activities, including staffing and provision of equipment of Healthy Living Centers; and (iii) implementing a nationwide campaign on substance addiction and strengthening the infrastructure of the treatment and research centers for adults and children suffering from alcoholism and substance addiction.
2. (i) Improving the capacity of post-screening diagnosis centers; and (ii) introducing and maintaining national cancer registry software and provision of training to health workers on said software.
3. Strengthening the Family Physician Training Program, including through expanding the infrastructure and hardware of the distance learning system to nationwide coverage.

Part II: Increasing Efficiency of Public Hospital Management

1. Strengthening public hospital management and clinical operations in: (i) hospital pharmacy; and (ii) clinical care processes (e.g. cardiovascular surgery, microsurgery, laparoscopy) by providing training to public hospital staff.
2. Strengthening the capacity of the General Directorate of Health Investments in managing public-private partnership (“PPP”) contracts; and in developing in-house capacity in legal, financial, operational, and structural aspects of contract management.

Part III: Improving the Effectiveness of Overall Health Sector Administration

1. (i) Institutionalizing health sector performance assessments and harmonizing health sector data; (ii) developing and adopting national e-health standards and reviewing applicable legislation to improve quality of health data; (iii) developing and implementing a health management information system; and (iv) enhancing the technical audit capacity of MoH and widening the use of evidence-based medical practice to improve the quality of health services.
2. (i) Developing a model for raising awareness about the Borrower's health sector.
3. Strengthening capacity for the health technology assessment.
4. Supporting (i) Project Management and Support Unit in project implementation, including in the areas of financial management, procurement, disbursement, and monitoring and evaluation; and (ii) the establishment of a data collection and processing system to strengthen MoH’s strategic and management capacity for making key policy decisions in the health sector.

Part IV: Strengthening Capacity to Respond to COVID-19

Provision of drugs for the treatment of COVID-19 patients, and procurement of equipment for the Sub-Projects within MoH which are:

* Ankara - Ankara Akyurt Vaccine Production Center, Experimental Animal Production Center and ABSL3 Level Laboratory **(Activity 1)**
* Istanbul - Istanbul Experimental Research Center (IDEA) **(Activity 2)[[1]](#footnote-2)**

Relevant World Bank Environmental and Social Safeguards Policies applied to the Parent Project

The Parent Project runs under the World Bank’s Safeguards policies. However, the Environmental and Social instruments required under this TOR will also benefit and incorporate a number of important and relevant principles and elements of the Bank’s new Environmental and Social Framework (ESF), as good practice (ie. SEP to be prepared in line with the COVID-19 SEP template).

The Parent Project has triggered mainly the following safeguards policies:

* OP 4.01 Environmental Assessment (EA)
* OP 4.04 Natural Habitats
* OP 4.12 Involuntary Resettlement

As per OP 4.01, the Parent Project’s EA category is set as Category B and has updated its draft ESMF and SEP to cover Activity 1 and Activity 2.

For sake of easiness, the remaining of the TOR will refer to World Bank Environmental and Social Standards of its new ESF. The expected deliverables of this TOR will be based on the WB ESF.

The Activity 1 is categorized as Cat B (Substantial risk in ESF). The EA category of the Project will be reconsidered based on the results of the ESIA studies, as needed.

### **Location of Activity 1**

Activity 1 is planned to be established in the Balıkhisar Neighborhood of the Akyurt District in the Ankara Province (Figure 1).

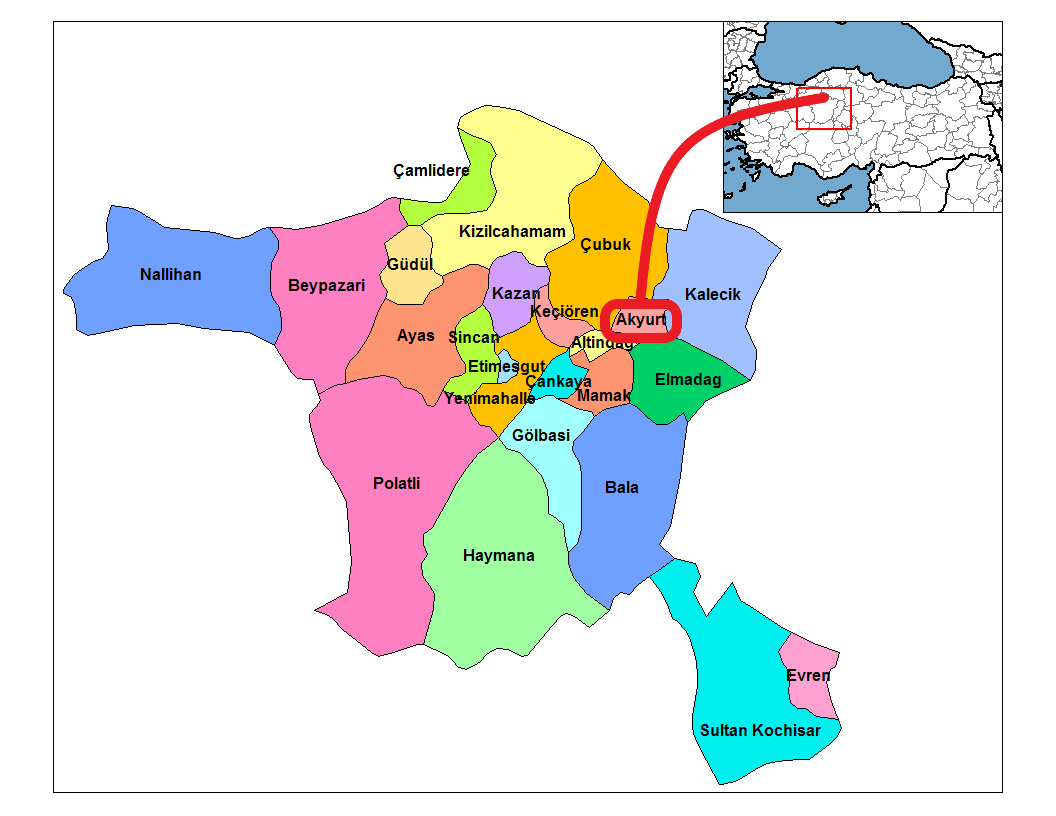


Figure 1: Map of Ankara and Akyurt

The Project area is owned by Ministry of Treasury and Finance and allocated to the Ministry of Health (MoH). There are two parcels adjacent to each other allocated for MoH are currently being used by General Directorate of Public Health (GDPH). There is a warehouse constructed on the parcel and being used currently to store equipment related to vaccines. This is the parcel where Activity 1 will be constructed. The adjacent parcel (1555/5) is also allocated for GDPH and currently being used as a vaccine warehouse including cold storages for -80 and -20 degrees where COVID-19 vaccines are currently being stored. Since the parcel is currently being used, infrastructure of energy, water, waste water and road systems in the Project area will be used. Satellite view of the Project area and its surroundings is provided in Figure 2.



Figure 2: General View of Activity 1 Parcel in Ankara

Distance of the Ankara Province center to the Project area are approximately 20 km. Esenboğa Airport is located approximately 3 km away from the Project area. The nearest settlement to the Project area is the Balikhisar Neighborhood which is located approximately 3 km south east of the Project area. In 1 km diameter, the closest places are OTONOMI (Land vehicle sales point), YDS (well-known shoe manufacturer particularly for people working in Health and Safety sector), ISBIR Bedding, OSYM (national exam center), BORUSAN Automotive and MAN Turkey. The closest housing area is located 500 meters away across Özal Boulevard – the highway with bird’s eye view (Figure 3). In addition, for the last years pharmaceutical and medical device companies started to be operated in the area which are Vilsan Veterinary and Pharmaceutical Industry, Turkish Pharmaceutical and Serum Industry, TTS Turktıpsan A.Ş, Turkish Plast Medical Products A.Ş. The area started to become ***bio-technology investment zone***. According to Akyurt Municipality Zoning Plan, the area was approved as “Serum Area”.



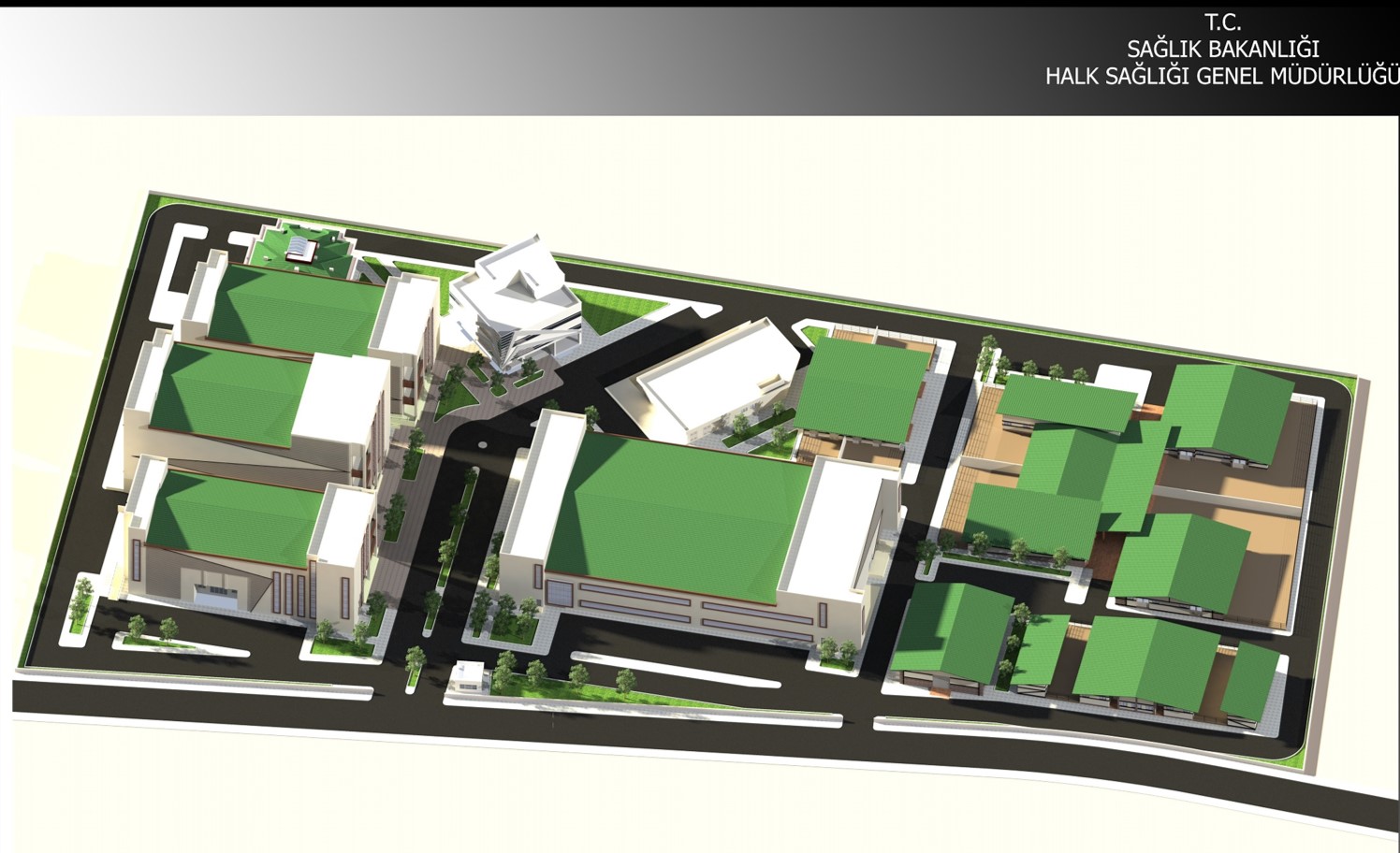
Figure 3: Structures in 1 km Diameter for Ankara Vaccine Center

### **Description of Activity 1**

In the scope of Activity 1, which is subject to ESIA of this ToR, a complex will be constructed by MoH including (i) a vaccine production center, (ii) an experimental animal production center and (iii) an ABSL 3 level laboratory. The level of the laboratory is designated after the internal assessment of MoH.

Activity 1 will compose of *12 main buildings* (Figure 4) which are:

1. Experimental Animals Production/Test Building (Scorpion, Fish, Rat, Snake, Rabbit and Guinea Pig)
2. Immunoserum Purification/Filling Building (Vaccine Labeling Storage and Shipment, Ampoule Filling, Ampoule Sterilization, Lyophilization and Vial Hood, Sterilization, Purification, Process Control Laboratory)
3. Antigen-Antiserum Diagnostic Product/Quality Control Laboratory Production Building (Live Virus and Bacteria Vaccine Quality Control Laboratories, Rabies Vaccine Quality Control Laboratory, Sterilization, Research and Biological Control Laboratories and other units)
4. Vaccine - Antigen Production Building (Sampling, Sample Storage/Rejection, Distilled Water, Tetanus-Hepatitis A- Diphtheria and Rabies Vaccine Production)
5. Administrative Building (Storages, Security, Cafeteria, Administrative Office)
6. Researcher Building
7. Transformer Heating Central Building
8. Security Building
9. Horse Experimental Animal Production Building
10. Sheep and Goats - Poultry Experimental Animal Production Building
11. Non-Human Primate-Pig Experimental Animal Building
12. Feed Storage Building



**6**

**3**

**4**

**2**

**5**

**7**

**11**

**1**

**9**

**12**

**10**

**8**

Figure 4: Draft Plan of Activity 1

Electricity, water, wastewater, natural gas, transportation infrastructure of the project area already exists, therefore construction of any associated facility is not foreseen.

Since the Project site is close to the Ankara city center, construction of a worker accommodation camp is not expected. Although the proposed site is a state treasury land with no issues of involuntary resettlement and has been utilized by MoH for vaccine storage purposes. As per the World Bank’s environmental and social standards, a Resettlement Action Plan (RAP) is added for precautionary measures in case additional associated facilities lead to such involuntary land take. This will be determined once the Consultant is on board and does the initial scoping for the ESIA studies.

Since the procurement of equipment for Activity 1 will be financed under the 4th Component of Parent Project HSSSP, documents prepared for the Parent Project will guide the Consultant for conducting all related works defined in this ToR that is prepared in line with the requirements of the World Bank safeguards policies and environmental and social framework. An Environmental and Social Framework (ESMF) and a Stakeholder Engagement Plan (SEP) have been prepared for Component 4 describing processes and procedures for the preparation of site-specific environmental and social studies and documents. ESIA including ESMP, sub-management plans, Resettlement Action Plan (RAP) (TBD) and SEP to be prepared for Activity 1 by the Consultant should include the construction and operation phases of Activity 1; therefore, this document will need to cover detailed information about specific conditions of Activity 1 including Project specific environmental and social mitigation measures, detailed analysis of stakeholders, stakeholder mapping, grievance mechanism and etc.

## DEFINITIONS

**Activity 1**: Ankara Akyurt Vaccine Production Center, Experimental Animal Production Center and ABSL3 Level Laboratory

**Activity 2**: Istanbul Experimental Research Center

**ESS**: Environmental and Social Standards

**ESIA**: Environmental and Social Impact Assessment

**EHS**: Environmental, Health and Safety

**EHS Guidelines**: Environmental, Health and Safety Guidelines

**ESF:** Environmental and Social Framework

**ESMF**: Environmental and Social Management Framework

**ESMP**: Environmental and Social Management Plan

**GIIP:** Good International Industry Practices

**HSSSP**: Health System Strengthening and Support Project – The Parent Project

**IDEA**: Istanbul Experimental Research Center

**MoH**: Ministry of Health

**OHS**: Occupational Health and Safety

**Parent Project**: Health System Strengthening and Support Project

**RAP:** Resettlement Action Plan

**SEP:** Stakeholder Engagement Plan

**ToR**: Terms of Reference

**VPC**: Vaccine Production Center

**WB:** World Bank

## OBJECTIVE

The Government of Turkey intends to build a new “Vaccine Production Center (VPC), Experimental Animal Production Center and an ABSL3 level laboratory” (together “Activity 1”) in Ankara. Procurement of equipment for Activity 1 will be financed under the 4th component of HSSSP given in detail in Section A of this ToR.

Activity 1 will be constructed in Balıkhisar Neighborhood of the Akyurt District in Ankara on the parcel number 1555/4 with a 47,589 m2 area composing 12 main buildings mentioned in Section A-II.

MoH would like to use the proceeds of the World Bank (IBRD) loan to undertake environmental and social impact assessment studies required to assess potential risks and propose appropriate mitigation measures. In accordance with the World Bank Environmental and Social Framework (ESF), the environmental and social risks of the construction and operation of the **Activity 1** are proposed to be rated as “**Substantial**”, in accordance with the WB ESF and project revised ESMF, as mentioned above. Therefore, it is necessary to conduct a detailed **Environmental and Social Impact Assessment (ESIA)** as per the provisions of the Bank ESF and Turkey legislation, including **Environmental and Social Management Plan (ESMP), Resettlement Action Plan (RAP)** (to be determined during ESIA studies)**, and Stakeholder Engagement Plan (SEP)** as well as sub-management plans which are expected to include but not necessarily limited to:

1. Chemical and Hazardous Materials Management Plan
2. Air Quality and Noise Management Plan
3. Waste and Wastewater Management Plan (including Hospital/Medical Waste Management Plan)
4. Pollution Prevention Plan
5. Traffic Management Plan
6. Human Resources Management Plan
7. Community Health and Safety Plan
8. Occupational Health and Safety Plan
9. Resource Efficiency Management Plan
10. Labor Management Plan
11. Biodiversity Management Plan
12. Emergency Response and Action Plan
13. Animal Welfare Management Plan
14. Security Management Plan

Risk level of the Activity will be assessed by the Consultant during Scoping Stage and this information should be indicated in the ESIA.

Above mentioned plans will be separately prepared for construction and operation phases, as relevant. Related plans should specify mitigation measures addressing to COVID-19 risks particularly for workers and communities.

The Consultant will conduct two Public Participation Meetings, one for the disclosure of this Terms of Reference before ESIA preparation process, and another after preparation of draft ESIA. The engagement and consultations with stakeholders will not be limited by the disclosure and consultations on this ToR and draft ESIA, ESMP, RAP and SEP, but will also be held by MoH throughout the entire stages of construction and operation, as per the procedures specified in SEP. The consultations will adhere with the COVID 19 measures introduced by the MoH a that time. The Consultant will also conduct required environmental baseline measurements, analysis and surveys which include but are not limited to biodiversity survey, air quality, noise measurements, soil, surface water and ground water analysis.

## SCOPE OF THE WORK

The Consultant will carry out the Environmental and Social studies through primary surveys and in depth consultations with affected communities and for disclosure purposes conduct at least 2 public meetings to discuss the terms of reference of the ESIA and after the preparation of the ESIA to share the findings with stakeholders. In preparing the above listed environmental and social studies and documents, the consultant is required to follow the related laws and regulations of Turkey (not limited thereto) as well as below documents of the World Bank and WHO:

* [World Bank Environmental and Social Framework (ESF) and Guidance Notes for Loan Beneficiaries;](https://thedocs.worldbank.org/en/doc/837721522762050108-0290022018/original/ESFFramework.pdf)
* [World Bank Group General Principles of Environmental, Health and Safety Guidelines (EHS);](https://www.ifc.org/wps/wcm/connect/29f5137d-6e17-4660-b1f9-02bf561935e5/Final%2B-%2BGeneral%2BEHS%2BGuidelines.pdf?MOD=AJPERES&CVID=jOWim3p)
* [World Bank Group EHS Guidelines for Health Care Facilities](https://www.ifc.org/wps/wcm/connect/960ef524-1fa5-4696-8db3-82c60edf5367/Final+-+Health+Care+Facilities.pdf?MOD=AJPERES&CVID=jqeCW2Q&id=1323161961169);
* [World Bank Group EHS Guidelines applicable to Water and Sanitation;](https://www.ifc.org/wps/wcm/connect/83217cd8-b9a5-4383-97b5-5af26182b3b8/2007+Water+and+Sanitation.pdf?MOD=AJPERES&CVID=m3CdtQr)
* [World Bank Group EHS Guidelines applicable to Electric Power Transmission and Distribution;](https://www.ifc.org/wps/wcm/connect/7b65ce6b-129d-4634-99dc-12f85c0674b3/Final%2B-%2BElectric%2BTransmission%2Band%2BDistribution.pdf?MOD=AJPERES&CVID=jqeI4Rs&id=1323162154847)
* [World Bank Group EHS Guidelines applicable to Gas Distribution Systems;](https://www.ifc.org/wps/wcm/connect/88f41d8f-bd85-4535-a689-066d41b7ee29/Final%2B-%2BGas%2BDistribution%2BSystems.pdf?MOD=AJPERES&CVID=jqezuZM&id=1323162128496)
* [World Bank Group EHS Guidelines applicable to Pharmaceuticals and Biotechnology Manufacturing;](https://documents1.worldbank.org/curated/pt/151641489556364662/pdf/113495-WP-ENGLISH-Pharmaceuticals-and-Biotechnology-Mnfg-PUBLIC.pdf)
* [WHO Laboratory Bio-Safety Manuel (LBM), fourth edition, 2020;](https://www.who.int/publications/i/item/9241546506)
* [WHO Biorisk Management: Laboratory Biosecurity Guidance, 2006, WHO/CDS/EPR/2006.6;](https://www.who.int/csr/resources/publications/biosafety/WHO_CDS_EPR_2006_6.pdf)
* [UN Model Regulations for the Transport of Dangerous Goods;](https://shop.un.org/series/recommendations-transport-dangerous-goods-model-regulations)
* [DIRECTIVE 2010/63/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 22 September 2010, on the protection of animals used for scientific purpose ( Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes Text with EEA relevance (europa.eu) ).](https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2010:276:0033:0079:en:PDF)

Related requirements of the EHS Guidelines will be applied to the tasks. In cases where the level of requirements and required measures in Turkey differ from those required in the EHS Guidelines, more stringent requirements shall apply in accordance with project specifications (such as the strict discharge and emission standards) as per the ESSs of the World Bank ESF.

In preparing the above-mentioned environmental and social studies and documents, the Consultant will fully comply with the ESS requirements. ESSs, which are expected to be relevant for the Activity 1 and to be considered within the scope of the ESIA, are summarized below.

The legislation and institutional structures for the establishment and management of facilities dealing with pathogens, are currently under development by the Government of Turkey. In order to ensure that the VPC in Ankara meets the internationally accepted standards for design, construction, operation and oversight system for ABSL-3 facility, the MoH will put in place and will follow procedures and measures which are in line with international good practices. The ESIA will assess the applicability of relevant national legislation, relevant guidelines and GIIP concerning the siting of the A-BSL in its current location. The proposed system for accreditation and oversight as specified in **Annex-5** to this TORs also envisages an engagement with an independent biosafety expert to verify the design and construction and carry out annual audit during operation.

In order to manage significant risks to workers and communities, the Consultant will undertake a detailed review of this proposed system for accreditation and oversight of the Ankara ABSL-3 facility. The findings of such review should be reflected in ESIA which should address, inter alia: the standard(s) to which the lab will be certified (e.g. WHO, CDC); organizations accredited to carry out the certification process (or in the case of independent experts, qualifications these specialist are required to meet); detailed steps and elements of the certification process , such as period of validity of the initial certification, requirements for annual renewal and interim inspections, etc.

**ESS-1 Assessment and Management of Environmental and Social Risks and Impacts:**

Potential environmental and social risks are expected to be environmental disturbances associated with construction and operation activities, habitat degradation, generation and disposal of various streams of wastes, including medical and hazardous, air pollution due to dust, noise and vibration, storage and use of laboratory reagents and infectious samples, use of laboratory equipment, land acquisition and resettlement, OHS/personal protection of health workers, and contextual risks related to contractor safety and community safety. In addition, during the operation of the facilities under Activity 1, there will be risks associated with the need to handle infectious materials and ensure infection containment as well as risks associated with animal testing/welfare. Associated facilities (electric power transmission lines, connecting/access roads, water/wastewater networks etc.) and cumulative impacts will be fully addressed within the scope of the assessments.

Social risks and impacts will also be considered in environmental and social assessments, including but not limited to land acquisition requirements. For example, the impacts on disadvantaged and vulnerable groups, community health and safety risks during construction and operation works, labor flow toward communities, (especially women and young girls), discrimination risk among groups in the provision of projects benefits, impacts on workers' health, safety and well-being, and risks on the cultural heritage sites.

Indicative outlines of ESIA and ESMP have been provided respectively in **Annex-1** and **Annex-2**.

**ESS-2 Labor and Working Conditions:**

Project workers include people employed directly, contracted workers and primary supply workers. Turkey is a party to many ILO conventions, and these conventions comply with ESS-2 requirements. The Labor Act of the country includes provisions on non-discrimination, freedom of association, minimum working age and minimum wage, child labor and forced labor, worker health and occupational safety and dispute resolution. The risks associated with child labor and forced labor are not envisaged in this project. ESIA will aim at identifying the risks such as sexual harassment in the workplace and violation of the principle of the equal opportunities in the workplace and at proposing a number of preventive measures. Within the scope of the ESIA, measures will be determined in accordance with this risk category and with the World Bank gender-based harassment and abuse guidelines[[2]](#footnote-3):

Labor Management Plan and Occupational Health and Safety Plan (separately for construction and operational works) will be prepared in line with the World Bank Group EHS Guidelines, national legislation/standards and more specific internationally recognized standards, (to be proposed by the Consultant and agreed with PMSU), and incorporated into the ESMP including a Code of Conduct.

The Consultant will consider the risks related to labor and working conditions and worker health and occupational health and safety within the scope of environmental and social assessments and carry out a Preliminary Supply Chain Risk Assessment.

**ESS 3 - Source Efficiency and Prevention and Management of Pollution:**

The Activity 1 is considered as a complex that will require the use of water and other resources such as electricity, natural gas and construction materials. Significant pollution-related risks of the activity are related to improper waste and land management, negative impacts of construction activities on any possible nearby water bodies, air quality impacts of construction and operation phases. In addition, management of hazardous wastes including medical wastes and other pollution risks related to experimental animal use and vaccine production are important issues during the operation phase. These anticipated impacts will be analyzed and evaluated in detail within the scope of the ESIA and related management plans. Pollution Prevention Plan, Chemical and Hazardous Materials Management Plan, Air Quality and Noise Management Plan, and Waste and Wastewater Management Plan (including Hospital/Medical Waste Management Plan) will be prepared which will include management and monitoring requirements for any water, air, noise and soil pollution and resource efficiency requirements.

**ESS-4 Public Health and Safety:**

It is anticipated that the Activity 1 will bear different risks during the planning, construction and operation periods.

The basic environmental aspects to be considered in relation with the activity are, **including but not limited to**, those associated with (i) the operation of ABSL3 and other labs, including storage and use of laboratory reagents and infectious samples and use of laboratory equipment, management of medical/laboratory wastes, OHS/personal protection of health workers and community safety, (ii) animal testing, and (iii) environmental and social risks associated with construction and installation of the equipment in the Activity 1.

The Consultant will identify potential impacts of the stakeholders on public health and safety of the construction and operation phases, mitigation measures, monitoring and reporting requirements through the ESIA studies and prepare Community Health and Safety Plan and other relevant plans in accordance with the World Bank Group EHS Guidelines, national legislation/standards and more specific internationally recognized standards. In these studies, site-specific risks arising from natural hazards such as flood, earthquake and landslide and their scales for both construction and operation phases will be addressed in Emergency Response and Action Plan. One of the potential emergencies is a release of highly infectious disease organisms, accidentally or through deliberate malfeasance. Emergency Response and Action Plan for operation phase will address these risks as well. The need of a security presence associated with such risks will be assessed and addressed in the Security Management Plan, particularly for the operation phase, as appropriate.

In addition, the Consultant will identify appropriate risk management measures related to labor influx in the ESIA. When constructing large facilities, workforce requirements can be significant and if not managed properly there could be opportunistic migration to the area hoping for work in these construction sites.

The relevant plans in relation with ESS 4 should describe a Community Liaison Board, that is enforced by MOH with relevant scientists and experts on board in order to help the local communities in the vicinity to comprehend what this facility entails and ensure accuracy in the information shared with public, as such facilities could lead to misinformation and reactive communications if the community engagement part is not managed well. The Community Liaison Board should not only be considered for pre-construction but should cover all 3 phases: planning, construction and operation phase.

**ESS-5 Land Acquisition, Land Use Restrictions and Involuntary Resettlement:**

None of the facility and its auxiliary components (ETL, roads, camps etc.) are expected to cause any involuntary land acquisition. The site in Akyurt is a State Treasury Land and currently being utilized by MoH and is not located within residential area, it is mainly surrounded by buildings of businesses in automotive and pharmaceuticals However, the Consultant will assess the impacts that might arise due to land acquisition and land use of Activity 1 in accordance with ESS 5 and inform PMSU for the need to prepare a RAP. This information should be included in ESIA studies and related mitigation measures should be given in ESIA and also related plans. If required the stand-alone RAP will be prepared for Activity 1 to include all involuntary land acquisition and/or restrictions arising from the planned activity and related associated facilities (Energy transmission line, water-wastewater transmission line, etc.) The RAP will clearly identify land-based impacts, the groups impacted by the projects land take requirements, define the entitlements for each impact group, prepare an Entitlement Matrix that includes additional measures to bridge gaps between national law and ESS5, outline the process and institutional arrangements for land acquisition, provide a budget and time line for the implementation of RAP. The preliminary E&S screening conducted by the MoH PMSU’s E&S specialists does not indicate presence of any informal users on the impacted land. During the preparation of RAP, should any formal or informal users/landowners who might be affected from Activity 1 and its Associated Facilities be identified, the facilities will also be determined and included in RAP. The RAP will also include measures related to livelihood support, transitional allowances and assistance as required, in addition to identifying vulnerable and providing measures for them.

Terms of Reference and indicative outline of RAP have been provided in **Annex-3.**

**ESS-6 Conservation of Biodiversity and Sustainable Management of Living Natural Resources:**

Activity 1 will be screened for potential impacts on biodiversity and natural resources in accordance with the project ESMF. A biodiversity survey will be conducted by the Consultant within the scope of ESIA studies. The site-specific environmental and social assessments will include a detailed analysis of the significance of flora and fauna species, habitats, identify potential adverse impacts and suggest site-specific mitigation and monitoring. If required based on the baseline data regarding biodiversity, ecosystems, ecosystem services and habitats, as well as respective findings of the ESIA, the Consultant will prepare a Biodiversity Management Plan including additional and targeted measures to avoid, minimize and manage risks to biodiversity and ecosystems and ecosystem services. The existence of critical habitats, natural habitats and modified habitats will be determined or confirmed (in accordance with ESS-6 definitions) within the scope of ESIA. The baseline and impact assessment studies and management mitigation measures will include possible impacts on biodiversity features in Çubuk stream wetland habitat. The ESIA should also provide some information on the stream, including why it is or might be an ecologically (or socially) sensitive site, whether it has any legal protections or relevant regulations, and whether there are specific potential impacts that the ESIA should focus on.

**ESS-8 Cultural Heritage:**

Potential culturally important assets (tangible and/or intangible cultural heritage) that might be found at the Activity 1 site during the ESIA, will be evaluated in consultation with the Provincial Directorate of Culture and Tourism. During the stakeholder consultation process, the existence of any intangible cultural heritage that may be affected by the Activity 1 will also be determined and evaluated.

Since the Activity 1 includes construction works, it is possible to encounter chance findings during the excavation works. Therefore, a Chance Find Procedure will be, as per the provisions envisaged by the national laws and regulations.

**ESS-10 Stakeholder Engagement and Disclosure of Information:**

The purpose of the Stakeholder Engagement Plan (SEP) is to establish a systematic stakeholder engagement approach that will help the implementing institution identify key stakeholders (project affected parties and other interested parties) and establish and maintain a constructive relationship with them, particularly with the project affected groups. SEP will also assess the level of stakeholder interest and support for the Activity 1, ensure that stakeholder opinions are taken into account in design, environmental and social performance and will encourage an inclusive participation throughout the activity life and provide the necessary tools for this, provide the necessary activity information to stakeholders in a timely, understandable, accessible and appropriate manner, provide citizens with accessible and inclusive means to convey their problems and complaints, and ensure that the implementing institution of the activity respond to and manage these complaints.

The Consultant will prepare a project specific SEP in accordance with Parent Project’s SEP and hold the necessary (2) public consultation meetings described in the Purpose section. SEP will include the following key elements (see detailed master plan in **Annex-4**):

* Introduction/Project Description
* Regulations and Requirements
* Brief Summary of Past Stakeholder Engagement Activities
* Stakeholder Identification and Analysis
* Stakeholder Engagement Program
* Roles, Responsibilities and Resources of the Stakeholder Engagement Process
* Grievance Mechanism
* Monitoring and Reporting
* References

Annexes will include sample minutes of interviews and stakeholder engagement meetings held; Complaint Application Form; Stakeholder Map or Chart; correspondence or minutes of other consultation meetings, workshops, round tables, regional events, etc.

Apart from the ESS requirements described above, the ESIA and ESMP to be prepared for the Activity 1 will also address gender issues, which are more general. As mentioned in the ESS-2, risks of gender-based violence in the workplace will be evaluated under the heading of labor and working conditions. Other gender issues such as the vulnerability of women's social status or the risks of labor flow during construction works will be evaluated in the context of the issues addressed in the ESS-1, ESS-4, ESS-5 and ESS-10.

## RESPONSIBILITIES AND QUALIFICATIONS OF KEY PERSONNEL

E.1 Project Manager

General Responsibilities

S/he will be responsible for the coordination of the entire project.

Qualifications and Responsibilities

* Minimum 20 years of professional experience,
* To have managed the ESIA process in compliance with the relevant Turkish Legislation and international standards in the last 10 years,
* To have managed the environmental and social assessment, environmental and social due diligences and monitoring processes in health facility projects in the last 5 years,
* Environmental or Social Specialist, preferably with a master's degree.

E.2 Senior Social Impact Assessment Specialist

General Responsibilities

S/he will identify all social risks of the project at local, regional and national levels and provide recommendations for the elimination and/or mitigation of risks, facilitate implementation of ESIA and relevant ESMPs.

Qualifications and Responsibilities

* Minimum 10 years of experience in Social Impact Assessment analysis in line with the relevant Turkish Legislation and international standards,
* Social Scientist, preferably with a master's degree.
* Knowledge and experience in involuntary land take, resettlement issues in country is highly preferable

E.3 Land Acquisition and Resettlement Specialist

General Responsibilities

S/he will prepare the RAP; in doing so s/he will identify issues that may result in physical or economic loss of land based assets and livelihoods prior to and during the construction and operation process of the project and its associated facilities, provide actions to avoid, and/or mitigate risks in accordance with ESS5.

Qualifications and Responsibilities

* Social Expert with minimum 5 years of experience in involuntary resettlement, especially in international social safeguard policies related to economic resettlement (restoration of land-based income sources).
* Minimum of 5 years of relevant experience in preparing RAPs in line with international standards (IFC/WB/EBRD etc.)
* Knowledge and experience on Turkish expropriation legislation is preferable

E.4 Senior Environmental Specialist

General Responsibilities

S/he will identify the environmental risks of the project at local, regional and national levels and provide recommendations for the elimination and/or mitigation of risks.

Qualifications and Responsibilities

* Minimum 10 years of experience in Environmental Impact Assessment in line with the relevant Turkish Legislation and international IFI standards,
* • Environmental Specialist to have worked in minimum 1 health facility project in services provided on Environment and Social issues in accordance with national and international requirements.

E.5 Bio Safety Expert

General Responsibilities

S/he will identify the bio-safety risks of the project at local, regional and national levels and provide recommendations for the elimination and/or mitigation of risks.

Qualifications and Responsibilities

* PhD in Microbiology or Biotechnology
* Minimum 5 years of experience as a biosecurity consultant
* Minimum 10 years of experience at least in 3 labs as an ABSL-3 / BSL-3 / BSL-2 biosafety expert
* Regular participation in biosafety conferences
* Experience in review and approval of ABSL-3 / BSL-3 / BSL-2 facility designs
* Experience in supervising constructions of ABSL-3 / BSL-3 / BSL-2 facilities
* Experience in commissioning Biosecurity facilities
* Field training experience in biosecurity and animal biosecurity

E.6 Biodiversity Expert

General Responsibilities

S/he will identify the biodiversity related risks of the project at local, regional and national levels and provide recommendations for the elimination and/or mitigation of risks.

Qualifications and Responsibilities

* Minimum 10 years of professional experience,
* A Biologist familiar with WB ESF requirements and preferably with the relevant Turkish Legislation,
* Have worked in at least 10 projects funded by international donors including WB/IFC.

E.7 Cultural Heritage Expert

General Responsibilities

S/he will identify the archeological risks of the project at local, regional and national levels and provide recommendations for the elimination and/or mitigation of risks.

Qualifications and Responsibilities

* Minimum 10 years of professional experience,
* An Archeologist familiar with the relevant Turkish Legislation and preferably with WB ESF requirements.

E.8 OHS Specialist

General Responsibilities

S/he will identify the Occupational Health and Safety risks of the project and provide recommendations for the elimination and/or mitigation of risks.

Qualifications and Responsibilities

* Minimum 10 years of professional experience,
* Having a BSc degree from relevant departments and familiar with the relevant Turkish Legislation and preferably with the WB ESF requirements.
* HS experience in health sector facilities with biosafety levels is preferable

E.9 Biomedical Waste Management Specialist

General Responsibilities

S/he will identify the risks related to biomedical waste management of the project and provide recommendations for the elimination and/or mitigation of risks.

Qualifications and Responsibilities

* Minimum 10 years of relevant experience,
* Having a BSc degree from relevant departments and familiar with the relevant Turkish Legislation and preferably with the WB ESF requirements.

E.10 Stakeholder Engagement Specialist

General Responsibilities

S/he will prepare the site specific Stakeholder Engagement Plan to include stakeholder analysis, stakeholder engagement program, any specific needs of the potential impacted vulnerable groups, grievance mechanism and a communication strategy to inform public on community health risks related to the project.

Qualifications and Responsibilities

* Minimum 5 years of relevant experience,
* Having a BSc degree from relevant departments and familiar with the relevant Turkish Legislation and preferably with the WB ESF requirements.

E.11 Animal Welfare Specialist

General Responsibilities

S/he will prepare the Animal Welfare Management Plan and provide recommendations for the elimination and/or mitigation of risks related to animal welfare.

Qualifications and Responsibilities

* Minimum 10 years of relevant experience,
* Having a BSc degree from relevant departments and familiar with the relevant Turkish Legislation and preferably with the WB ESF requirements.

E.12 Environmental Engineer

General Responsibilities

S/he will provide specific contribution to the design, specifically to the ventilation system with increased air change rates and additional HEPA filtration systems.

Qualifications and Responsibilities

• Minimum 5 years of relevant experience

• Having a BSc Degree from relevant environmental engineering departments

## REPORTING LIABILITIES OF THE CONSULTANT

The Consultant will prepare all reports in both English and Turkish. The reports will be reviewed by the relevant consultants within the MoH PMSU in 15 calendar days after the submission of each deliverable and the World Bank will be supporting the MoH on review of these outputs. The reports expected as deliverables from the consultant will be delivered according to the following schedule:

1. Scoping Report: This report, which will be submitted *within 1 month* from the beginning of the work and will be prepared in both English and Turkish languages, will include scope and table of content of the ESIA, problems that have arisen as of that date, significant incompatibilities regarding the Terms of Reference. In this report, important issues that may affect the progress of the work will be brought to the attention of PMSU.

As the Scoping Report will also serve as an “Inception Report, it will include a work plan, description of methodologies to be used, and will also identify aspects of the TOR which the Consultant feels need to be clarified or modified, if any (e.g., if certain types of data are more difficult to obtain than anticipated, additional time and/or resources may be required or agreed that a different approach should be used).

1. Draft ESIA Report, ESMP, SEP, RAP and sub-management plans: Draft reports (including RAP which will be prepared if required) to be prepared in English and Turkish languages in accordance with the requirements/outline presented in Annex-1, Annex-2, Annex-3, Annex-4 and Annex-5 of this ToR will be submitted to PMSU *within 5 months at the latest* as of the delivery of the Scoping Report. PMSU will review the drafts and notify the Consultant of their opinions and change requests, if any.
2. Final ESIA Report, ESMP, SEP, RAP and sub-management plans: Draft reports prepared in English and Turkish languages and submitted for PMSU's opinion will be finalized in line with the PMSU's opinions and change requests, if any. Final ESIA, ESMP, SEP, RAP, and sub-management plans will be completed and submitted to the PMSU within 2 weeks at the latest after the PMSU’s opinions and change requests, if any, are notified to the Consultant. The results of the public participation meeting held after the submission of the draft reports will be reflected in the final documents. Final reports will be approved by the PMSU.

## SERVICES AND FACILITIES TO BE PROVIDED BY THE ADMINISTRATION

PMSU will provide the Consultant with all the information and documents requested by the Consultant for the proper execution and completion of the work.

## SUPERVISION OF THE WORK BY THE ADMINISTRATION

The reports prepared by the Consultant will be examined by the Social Specialist and Environmental Specialist working within the PMSU and corrective action can be requested when necessary.

## TIME, DURATION AND WORKPLACE

The work is expected to last 8 months. The site study will be carried out in the area of influence (to be determined during the scoping study) around the Project area where the Activity 1 will be established in Akyurt district in Ankara province.

Public Participation Meetings will be conducted in Ankara (at least 2 meetings, but continuous engagement is also expected in line with the development of SEP that would cover for all 3 phases-planning/preparation, construction and operation) and the relevant impacted settlement, if pandemic circumstances allow. In case physical meetings are not possible due to COVID-19 public health restrictions, then the SEP will formulate alternative channels to ensure feedback of the local communities and stakeholders in a timely manner. The SEP will include stakeholder engagement and public participation meetings that will cover the planning/preparation, construction and operation phases of the center.

## QUALIFICATION CRITERIA SOUGHT IN THE COMPANY

The qualification criteria sought in the Consultant Company that will provide consultancy services to perform the work requested within the scope of this Terms of Reference are as follows:

1. The Consultant will be a company that operates in environmental and social assessments for minimum 10 years in accordance with international standards (IFC/WB/EBRD etc.).
2. The Consultant will be a company that has previously performed minimum 5 approved environmental and social assessments/due diligences or related works in accordance
3. The Consultant Company shall demonstrate an acceptable level of qualifications and include the right national and/or international expertise on board as needed to support the operation.
4. International standards in the health sector and preferably has experience working with facilities including biosafety level 3.

## BUDGET AND PAYMENT PLAN

Estimated budget of the work is calculated as TRY 2.492.320, 00 TL + VAT (TRY 3.065.553,60 including VAT; USD 296,000. Based on the exchange rate of the Central Bank of the Republic of Turkey on 24.08.2021, 1 USD = 8.42 TRY) as a result of the market research, and the payment plan will be as follows. Payments will be made in the following tranches following the acceptance of the report(s) to be taken as a basis for the payment by the Administration after receiving the opinions of the World Bank's environmental and social team.

Following the delivery and acceptance of the 1st Report (Scoping Report), TRY 373.848,00 + VAT, which is 15% of the total amount

Following the delivery and acceptance of the 2nd Report (Draft ESIA Report and Sub-Plans), TRY 872.312,00 + VAT, which is 35% of the total amount

Following the delivery and acceptance of the 3rd Report (Final ESIA Report and Sub-Plans), TRY 1.246.160,00 + VAT, which is 50% of the total amount

### **Annex 1: Indicative Outline of Environmental and Social Impact Assessment (ESIA):**

(a) Executive Summary

* A brief description of key findings and recommended actions.

(b) Legal and Institutional Framework[[3]](#footnote-4)

* The legal and institutional framework, which is applicable to the project and taken as a basis in the realization of the environmental and social assessment including the issues referred to in paragraph 26 of ESS-1, is analyzed.
* The current environmental and social framework of the Borrower is compared with ESAS and the gaps between them are identified.
* The environmental and social requirements of the co-financiers are determined and evaluated.
* The ESIA will assess the applicability of relevant national legislation, relevant guidelines and GIIP concerning the siting of the A-BSL in its current location.
* A detailed review of the proposed system for accreditation and oversight of the Ankara ABSL-3 facility (Annex 5) is undertaken. Adequacy of existing systems and capacity is assessed as part of this task and specific recommendation for strengthening are proposed. Such review should address, inter alia: the standard(s) to which the lab will be certified (e.g., WHO, CDC); organizations accredited to carry out the certification process (or in the case of independent experts, additional qualifications requirements for these specialists); additional elements or details of the certification process involve (e.g., duration of validity of the initial certification, requirements and process for annual renewal and interim audits).

(c) Project Description

* The geographical, environmental, social and temporal context (e.g. project-specific pipelines, access roads, electricity supply, water supply, accommodation, raw material and product storage facilities), including the off-site investments that may be required by the proposed Project, and the main suppliers of the project are briefly described.
* Taking into account the project details, it is determined whether a plan is needed to meet the requirements of ESS 1 - 10.
* A map presenting sufficient detail about the project site, area of influence and other areas that may be affected by the direct, indirect and cumulative impacts of the project.

(d) Baseline Data

* Baseline data relevant to the project location, design, operation or mitigation measures are presented in detail. They should contain information on project identification, planning and implementation dates, as well as a discussion about the accuracy, reliability and sources of these data.
* Measures and quality of existing data, key data gaps and uncertainties related to projections are identified and predicted.
* Based on the available information, the scope of the subject area is evaluated and the relevant physical, biological, demographic and socioeconomic conditions are disclosed, including the changes envisaged to be made before the project begins.
* Existing and proposed zoning activities included in the project area that are not directly related to the project are taken into consideration.

(e) Environmental and Social Risks and Impacts

* All relevant environmental and social risks and impacts of the project are taken into account. Environmental and social risks and impacts specifically specified in ESS 2-8, as well as other environmental and social risks and impacts that may arise as a result of the specific feature and context of the project, are determined together with the risks and impacts specified in paragraph 28 of ESS-1.

(f) Mitigation Measures

* Mitigation measures and significant negative residual impacts that cannot be mitigated are identified and the acceptability of these negative residual impacts is evaluated to the extent possible.
* Differentiated measures are established so that adverse impacts do not disproportionately affect disadvantaged or vulnerable groups.
* The applicability of environmental and social mitigation measures, the capital and current expenditures of the proposed mitigation measures, their compliance with local conditions, as well as institutional, training and monitoring requirements for the proposed mitigation measures, are evaluated.
* Considerations that do not need further attention are determined and the justifications for this determination are presented.

(g) Analysis of Alternatives

* Applicable alternatives to the proposed project regarding location, technology, design and operation, not only limited to including the no-project situation, are systematically compared but also discussing the pros and cons of potential locations in terms of their potential environmental and social impacts.
* The applicability of environmental and social mitigation measures of alternatives, the capital and current expenditures of the alternative mitigation measures, their compliance with local conditions, as well as institutional, training and monitoring requirements for the alternative mitigation measures, are evaluated.
* For each alternative, environmental and social impacts are quantified and, where possible, assessed economically.

(h) Design Measures

* The justification for the selection of a particular proposed project design is provided and the relevant EHS Guidelines are specified, or if the EHS Guidelines are found to be not applicable for the project, pollution prevention and reduction approaches are justified in line with recommended emission levels and good international industry practices.

(i) Environmental and Social Management Plan (ESMP) (see Annex 2)

(j) Appendices

* List of the individuals or organizations that prepared or contributed to the environmental and social assessment.
* References—setting out the written materials both published and unpublished, that have been used.
* Record of meetings, consultations and surveys with stakeholders, including those with affected people and other interested parties. The record specifies the means of such stakeholder engagement that were used to obtain the views of affected people and other interested parties.
* Tables presenting the relevant data referred to or summarized in the main text.
* List of associated reports or plans.
* Official letters received from relevant ministries, provincial directorates and other public institutions.

### **Annex 2: Indicative Outline of Environmental and Social Management Plan (ESMP):**

An ESMP consists of the set of mitigation, monitoring, and institutional measures to be taken during implementation and operation of a project to eliminate adverse environmental and social risks and impacts, offset them, or reduce them to acceptable levels. The ESMP also includes the measures and actions needed to implement these measures. General Directorate of Infrastructure Investments (a) identifies the set of responses to potentially adverse impacts; (b) determines requirements for ensuring that those responses are made effectively and in a timely manner; and (c) describes the means for meeting those requirements.

ESMPs are prepared as stand-alone documents. The content of the ESMP includes the following:

(a) Mitigation

* The ESMP identifies measures and actions in accordance with the mitigation hierarchy that reduce potentially adverse environmental and social impacts to acceptable levels. The plan will include compensatory measures, if applicable. Specifically, ESMP;

1. identifies and summarizes all anticipated adverse environmental and social impacts (including those involving but not limited to land acquisition, involuntary resettlement worker and public health and safety, vulnerable groups and cultural heritage), or;
2. summarizes—with technical details—each mitigation measure, including the type of impact to which it relates and the conditions under which it is required (e.g., continuously or in the event of contingencies), together with designs, equipment descriptions, and operating procedures, as appropriate;
3. estimates any potential environmental and social impacts of these measures; and takes into account, and is consistent with, other mitigation plans required for the project (e.g., for involuntary resettlement, workforce, stakeholder engagement, or cultural heritage).

(b) Monitoring

* The ESMP identifies monitoring objectives and specifies the type of monitoring, with linkages to the impacts assessed in the environmental and social assessment and the mitigation measures described in the ESMP. Specifically, the monitoring section of the ESMP provides (a) a specific description, and technical details, of monitoring measures, including the parameters to be measured, methods to be used, sampling locations, frequency of measurements, detection limits (where appropriate), and definition of thresholds that will signal the need for corrective actions; and (b) monitoring and reporting procedures to (i) ensure early detection of conditions that necessitate particular mitigation measures, and (ii) furnish information on the progress and results of mitigation.

(c) Capacity development and training

* To support timely and effective implementation of environmental and social project components and mitigation measures, the ESMP draws on the environmental and social assessment of the existence, role, and capability of responsible parties on site or at the agency and ministry level.
* Specifically, the ESMP provides a specific description of institutional arrangements, identifying which party is responsible for carrying out the mitigation and monitoring measures (e.g., for operation, supervision, enforcement, monitoring of implementation, remedial action, financing, reporting, and staff training).
* To strengthen environmental and social management capability in the agencies responsible for implementation, the ESMP recommends the establishment or expansion of the parties responsible, the training of staff and any additional measures that may be necessary to support implementation of mitigation measures and any other recommendations of the environmental and social assessment.

(d) Implementation schedule and cost estimates

* For all three aspects (mitigation, monitoring, and capacity development), the ESMP provides (a) an implementation schedule for measures that must be carried out as part of the project, showing phasing and coordination with overall project implementation plans; and (b) the capital and recurrent cost estimates and sources of funds for implementing the ESMP. These figures are also integrated into the total project cost tables.

### **Annex 3: Terms of Reference and Indicative Outline of Resettlement Plan (RAP):**

The objective of this assignment is to prepare a Resettlement Plan (RAP)[[4]](#footnote-5) for Activity 1 described above by following relevant national laws and the World Bank ESF and its relevant ESSs (in particular ESS 5) to ensure adverse land-based impacts (resulting in economic and/or physical displacement) induced by project activities resulted by are mitigated, livelihoods livelihood of Project Affected Peoples (PAPs) are restored in a manner acceptable to the Bank.. The RAP will include detailed information on PAPs who whose livelihoods are likely to be adversely affected by the project activities, during pre-construction, construction and operation. The key principles for RAP preparation and implementation are the following:

• When possible, resettlement plans should be conceived as development opportunities, so that those affected may also benefit from project activities.

• Setting Cut-off date—Date of completion of the census and assets inventory of persons affected by the project. Persons occupying the project area after the cut-off date are not eligible for compensation and/or resettlement assistance. Similarly, fixed assets (such as built structures, crops, fruit trees, and woodlots) established after the date of completion of the assets inventory, or an alternative mutually agreed on date, will not be compensated.

• Lack of legal rights does not bar displaced persons in peaceful possession from compensation or alternative forms of assistance.

• Compensation rates refer to amounts to be paid in full at replacement cost to the individual or collective owner of the lost asset, without deduction (i.e. depreciation costs) for any purpose.

• When cultivated land is acquired, as best practice suggests; civils works should be commenced after harvest. Where not possible standing crops should be paid at full replacement cost. In cases where land-based income is not the primary source and proportionately less compared to other sources of income, alternative measures such as payment of cash or provision of employment are acceptable if preferred by the persons losing agricultural land.

• In cases where physical displacement is unavoidable, replacement house plots, sites for relocating businesses, or redistributed agricultural land should be of equivalent use value to the land that was lost.

• Transition periods should be minimized. Compensation should be paid prior to the time of impact, so that new houses can be constructed, fixed assets can be removed or replaced, livelihoods restored and other necessary measures can be undertaken before displacement begins.

• Displaced persons are consulted during the planning and implementation of the RAP, and pre-construction, construction and operation processes of the project, so their preferences regarding resettlement arrangements are considered and applied into project design and implementation. RAP is disclosed in a publicly accessible manner also taking into consideration needs of vulnerable and any prevailing government restrictions related to the Covid19 pandemic.

• The previous level of community infrastructure and services and access to resources will be maintained or improved after resettlement.

• The borrower is responsible for meeting costs associated with land acquisition and resettlement, including contingencies.

• RAP includes include adequate institutional arrangements to ensure effective implementation of resettlement measures.

• Resettlement plans include arrangements for internal and external monitoring of resettlement implementation.

• Resettlement plans include procedures by which displaced persons can freely and when preferred anonymously log grievances.

**Tasks of the RAP Assignment**

The assignment will involve the following tasks:

• **Review relevant project documents**. The documents to be reviewed would include but not limited to draft project feasibility study, the preliminary project design, and relevant socioeconomic and legal documents, any plans and studies carried out on the land impacts of the project, lists of ownership status, maps, cadastral documents and inventories etc. produced up to date;

• **Carry out census and various socioeconomic surveys and studies**. The international standards on Involuntary resettlement (WB ESS5) require that where land acquisition or restrictions on land use are unavoidable, the Borrower will, as part of the environmental and social assessment, conduct a census to identify the persons who will be affected by the project, to establish an inventory of land and assets to be affected, to determine who will be eligible for compensation and assistance, and to discourage ineligible persons, such as opportunistic settlers, from claiming benefits.

Various studies need to be carried out for preparation of the resettlement plan, including socioeconomic survey and inventory survey. The socioeconomic studies will gather data on livelihoods and income in order to establish a baseline for developing the measures of rehabilitating the livelihood and income pre-land acquisition. The studies will be carried out in gender sensitive approach and should also pay special attention to vulnerable households to be affected. The RAP should include the results of a census survey on all individuals, households, infrastructure, businesses (large or small, licensed or non-licensed), farms and agricultural concerns, herding pastures impacted by the project activities. The RAP should also contain photographs and GIS coordinate information on each of the potentially adversely affected entities or PAPs, together the with names of individuals and/or household heads, owners of each entity, names of regular employees, descriptions of the size and composition of all structures; a description of the function of the structure/entity (e.g., gas station, restaurant, market, dwelling, etc.); and information on the value of the structure and average monthly income from the concerns;

Turkish Law requires preparation of inventory of assets. Land acquisition through expropriation requires the preparation of a census (full count) of affected immovable assets, and a full list of their owners. However, national requirement is limited to census of immovable assets and legal titleholders. Census and baseline information on Project affected populations as defined by ESS5, including tenants, users of communal land, land holders/occupants without legal or customary title is not required. As a remedy to bridge this gap, census baseline information would need to be complied by the Consultant for all categories of affected PAPs, titleholder and other land users (non-title holders).

• **Carry out socioeconomic studies in a gender sensitive approach**. The socioeconomic studies and consultations should be carried out in a gender sensitive manner. The different needs and demands of men and women will need to be taken into account in the survey, studies, consultations and designed mitigation measures. To extent possible, gender disaggregated data would be collected. If needed, consultation with women should be organized separately.

• **Pay special attentions to vulnerable groups**. The studies should help identify and gather information on vulnerable households/people and households/people who will be severely impacted, in order to be able to design specific assistance measures for these groups.

**• Develop the methods for valuing the affected assets**. The consultant shall develop and describe in detail the methods used in valuing those assets that will be eligible for compensation as per World Bank ESS5 on involuntary resettlement. This process should capture the methodology for taking of inventory of assets, values assigned and agreement reached with each identified PAP and consider inflationary realities in the final determination of values. Compensation value should reflect fully the replacement cost of acquired assets;

• **Carry out consultations with various project stakeholders**, including project affected people, on resettlement options, compensation standards, livelihood and income restoration measures; institutional arrangements, and grievance mechanisms. It needs to summarize the outcomes from public consultations held with communities and PAPs along the road and include in an Annex summary minutes of each consultation meeting, signed lists of attendance, photographs of the consultations; and the Agenda for the meeting. The consultant should note that following the preparation of the Draft RAP, further Public Consultations should be held with the PAPs to inform them of the findings and conclusions, and confirm there is general acceptance by the PAPs of the proposed mitigation measures. PAPs who are determined to be eligible for mitigation should (if they agree with the mitigation) sign;

• **Develop the resettlement measures**. In addition to the compensation, the consultant will need to design a package of resettlement measures for income restoration, livelihood rehabilitation, and relocation for each category of eligible displaced persons to achieve the resettlement policy. The RAP should also include the feasibility analysis of the proposed resettlement measures;

• **Enhance/Improve and Ensure Project Grievance Mechanism incorporates local social context (particularly resettlement)**. The consultant shall describe the options available to PAPs for grievance redress they may have about the process, the identification of eligible people for compensation, the valuing and compensation and any other complaints they may have with the entire process. The RAP shall indicate how these would be disseminated and accessible to them in a way that is clear and comprehensible to the PAPs. The grievance mechanism should also have an in-built monitoring mechanism to check on responsiveness to complaints or grievances lodged. The different forms of receiving the complaints should be clearly described together with the different stages of going through the process. In addition, the mechanism shall indicate alternatives, in case the proposed mechanism, for any reason, does not respond to all grievances and complaints;

• **Prepare resettlement plan (RAP).** The consultant will prepare the RAP based on the findings and results of documentation reviews, socioeconomic studies, and consultation with project stakeholders and project affected persons. The RAP will clearly present detailed information on the proposed mitigation measures for each affected entity/PAP with reasoning for the type and level of mitigation being offered. The contents of the RAP would include but not limited the following:

**1. Introduction**

* Project location (province, district, neighborhood)
* Amount and type of land required for the project (private/public ownership), etc.
* The reasons for the selection of the land
* Project description: description of the project impact area, project components and land acquisition needs by project phases
* Information on other assets (physical structures, businesses, facilities, trees, etc.), if any, and their current status (used/unused/active, etc.).
* Information on the land acquisition approach to be applied (changes that can be made in the project design to prevent or minimize the need for land acquisition, use public lands, and take a negotiation approach instead of direct expropriation are indicated.)

**2. Potential Impacts and Affected Persons**

* Description of the project impacts (temporary/permanent land acquisition)
* The method to be applied for land acquisition (depending on whether the land owner is a public or a private person; establishment of permanent right to property, establishment of right of easement, allocation, transfer, permit, etc.)
* If the selected land belongs to private individuals, information on the number of legal right holders and how they use the land
* If there are existing structures on the selected land, information on who uses these structures and how and for how long they will be affected by the project.
* If there is a non-agricultural use on the selected land (residential, agricultural industry, other businesses, etc.), information on who the affected people are and how and for how long they will be affected by the project
* Identification of impacts on land-based livelihoods, depending on the type of land use, i.e. identification of specific groups or vulnerable persons affected by project activities.
* Eligibility criteria for compensation in accordance with national legislation or ESS-5.

**3. Legislative Framework**

* Brief information on national legislation (only laws and regulations applicable to the project)
* Summary of the Bank's ESS5 standard
* Gaps between the Legal Framework and the Bank's ESS5 standard and measures to be taken to eliminate these gaps

**4. Implementation, Compensation and Other Assistance**

Detailed description of the land acquisition process; legal obligations of the Borrower; methods and duration of land acquisition; entitlements to the project impacts, including the types of persons and losses to be compensated; other assistance/support to be provided during the project implementation process (if livelihoods are affected, whether additional measures will be implemented for the recovery of income). This section will include an Entitlement Matrix for any land-based impacts caused by the construction works of each component.

**5. Consultation and Participation**

The summary of the consultation process with the owners and users of the land subject to the acquisition, the parties responsible for the consultation, the channels and tools to be used to inform the people affected by the project, the actions to be taken to ensure or increase the participation of the vulnerable groups, if any.

**6. Project Grievance Mechanism (GM)**

Information about complaint or demand collection system of Ministry of Health. Detailed information on the tools and methods to be used to receive grievances throughout the life of the project; registration and resolution of complaints, how long complaints will be resolved, monitoring of open and closed complaints, methods used by Ministry of Health to introduce the project grievance mechanism to stakeholders, parties responsible for the management of the Grievance Mechanism, etc.

**7. Monitoring and Reporting**

Disclosure of the approach adopted by Ministry of Health to monitor implementation of RAP, and frequency of monitoring, evaluation and reporting

8. RAP Budget and Implementation Schedule

Tables showing categorized cost estimates for all resettlement activities, including allowances for inflation, population growth, and other contingencies; timetables for expenditures; sources of funds; and arrangements for timely flow of funds, and funding for resettlement, if any, in areas outside the jurisdiction of the implementing agencies. A budget breakdown for all items that are available during RAP preparation.

An implementation schedule providing anticipated dates for displacement, and estimated initiation and completion dates for all resettlement plan activities. The schedule should indicate how the resettlement activities are linked to the implementation of the overall project.

### **Annex 4: Indicative Outline of Stakeholder Engagement Plan (SEP)[[5]](#footnote-6):**

Acronyms and Abbreviations

1. Introduction / Project Description
   1. Introduction
   2. Project Overview
   3. Objectives of SEP
   4. Summary of Analysis of Alternatives
2. Regulations and Requirements
   1. Local requirements in Turkey
   2. World Bank requirements
3. Brief Summary of Previous Stakeholder Engagement Activities
   1. *E.g. Consultations prior to the SEP*
   2. *E.g. Consultations carried out within the scope of a past project that could be meaningful for the SEP activities of the current project*
   3. *E.g. Communication with NGOs, etc.*
   4. *E.g. lessons learned from past projects*
   5. *E.g. Other documented stakeholder engagement activities - interviews, workshops, etc. where feedback from relevant stakeholders is collected.*
4. Stakeholder Identification and Analysis
   1. Project affected parties
   2. Other interested parties
   3. Disadvantaged/vulnerable individuals or groups
   4. Brief information on the interest and impact of the stakeholders on the project
5. Stakeholder Engagement Program
   1. The purpose and timing of the stakeholder engagement program (the main objectives of the stakeholder engagement program and the program envisaged for various stakeholder engagement activities)
   2. Suggested strategy for disclosure of information (what information will be disclosed, in what format, and which methods will be used to communicate this information to each of the relevant stakeholder groups)
   3. Suggested strategy for consultation (methods to be used for consultations with each stakeholder group)
   4. Suggested strategy for receiving opinions of vulnerable groups
   5. Deadlines (information is provided regarding deadlines for project phases and key decisions. Deadlines for the submission of opinions are specified)
   6. Review of opinions
   7. Project phases in the future (explaining that people will be informed as the project progresses, including reporting on the project's environmental and social performance, implementation of the stakeholder engagement plan, and the grievance mechanism)
6. Resources and Responsibilities for Implementing Stakeholder Engagement Activities
   1. Implementation Arrangements
   2. Deadlines
   3. Roles and Responsibilities
   4. Estimated Budget
7. Grievance Mechanism
   1. Grievance process (receiving, processing and directing complaints to the relevant units, resolving complaints and intervening as required, monitoring and reporting)
   2. Contact information for Grievance Mechanism
8. Monitoring and Reporting
   1. Monitoring reports to be prepared during the project (by components, if applicable)
   2. Ensuring the participation of stakeholders in monitoring activities
   3. Reporting back to stakeholder groups
9. References

Attachments: records of meetings or consultations, stakeholder map analysis or charts, detailed budget, grievance application form, etc.

### **Annex 5: Laws and Regulations about BSL facilities and Certification Process of the Labs**

# Certification Process

The labs will be certified in accordance with WHO requirements as specified in the Laboratory Biosafety Manual (4th edition) of WHO. Accordingly, there are specific requirements with respect to ventilation standards, hygiene standards, clean room standards in the manual. The design, construction and operation of the labs will be following these requirements.

According to the WHO Manual Chapter 8, laboratory certification is the systematic examination of all safety features and processes within the laboratory (engineering controls, personal protective equipment and administrative controls). Biosafety practices and procedures are also examined. Laboratory certification is an on-going quality and safety assurance activity that should take place on a regular basis. Adequately trained safety and health or biosafety professionals may conduct laboratory certification activities. Institutions may consider engaging or be required to engage a third party to provide inspections. Biomedical research and clinical laboratory facilities may develop audit, survey or inspection tools to help ensure consistency in the certification process.

The ABSL2 and ABSL3 labs will be certified by a third party.

Accreditation and certification process will be conducted in line with “the survey” defined in the WHO Laboratory Biosafety Manual. The survey is given in Annex 3 that will be used for the accreditation audit. Findings of the audit, survey or inspection should be discussed with laboratory personnel and management. Within the laboratory, an individual should be identified and made responsible for ensuring that corrective actions are taken for all deficiencies identified during the audit process. Certification of the laboratory should not be completed, and the laboratory should not be declared functional, until deficiencies have been adequately addressed.

**Main Steps of Accreditation Process are:**

* Architectural and engineering plans, commissioning testing documents and equipment validations and verifications for BSL-2 and 3 facilities will be reviewed and approved in advance by Contractor’s EHS Environmental Health & Safety Expert and Bio Safety Expert to ensure that they in compliance with the CDC/NIH’s Biosafety in Microbiological and Biomedical Laboratories (BMBL) 5th edition requirements. (See Annex 3 for Key Personnel Requirements)
* Completion of the accreditation process by the Facility Certification Specialist in line with WHO Laboratory Biosecurity Guidance and CEN/CWA 15793 Laboratory Bio Risk Management Standard and CWA 16393:2012 which is the “Guidelines for the implementation of CWA 15793:2008”.

After completion of installation and refurbishment activities, validation tests will be conducted by an independent third-party. Validation test will include seal test for HEPA filters, determination of clean room classification, air alterations, pressures of rooms, temperature and moisture of rooms and sound pressure level of rooms.

**Main Steps of the Certification process are:**

**I. Evaluation of Administrative Controls and ability to facilitate Maintenance Operations to ensure occupant safety and facility integrity**

1. Review background materials that affect maintenance operations:
2. Inspect and Evaluate
3. Inspect room layout, placement of equipment and equipment condition
4. Evaluate maintenance frequency and review maintenance logs

**II. Validation of Engineering Controls**

1. Validate that extra capacity is present on both supply and exhaust systems and quantify the estimated spare capacity (must document how extra capacity was calculated or estimated)
2. Ensure single pass air flow
3. Measure directional air flow, pressure relationships, air changes and record data
4. Directional air flow must be established from clean areas into contaminated areas.
5. Develop heating, ventilation, and air conditioning (HVAC) system and electrical systems failure tests consistent with laboratory design parameters.
6. Assess HVAC equipment condition
7. Perform smoke tests to demonstrate directional airflow
8. Inspect and challenge door interlock systems and automatic door closers
9. Test all alarms
10. Discharge exhaust assessment (as a measure of performance)
11. Verification of air change rates (ACR) in containment spaces
12. Review biological safety cabinet (BSC) certification data including serial number validation
13. Building Services Validation (also known as MEP Validation)
14. Validate autoclave availability, operations and bioseal integrity

**III. Review Standard Operation Procedures (SOPs)**

1. Autoclave & Decontamination
2. Safety SOPs
3. Occupational Health Monitoring (Policy and records of implementation), if appropriate
4. Biohazardous Materials Use Authorization (e.g., Human Pathogen Registration, Recombinant DNA Registration, Select Agent, etc.)

“Biosafety Level 3-Laboratory Certification Requirements” are given in detail in Annex 1. During the certification process, a compliance checklist to be filled in by the independent Facility Certification Specialist during the certification process is given in Annex 2.

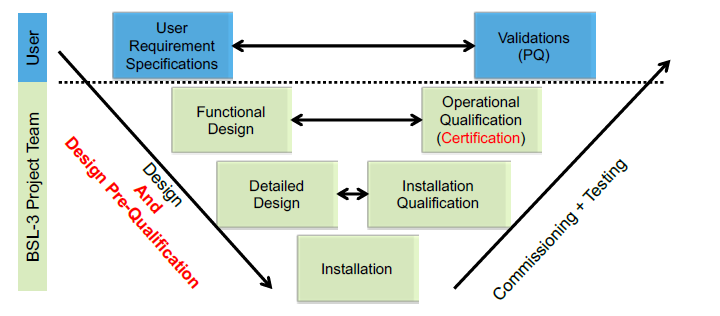
The independent Facility Certification Specialist to work as an advisor for MoH and the biosafety expert of the CC should be experienced with the certification of at least 3 labs and should have 10 years of experience in certification and operation of a BSL3 level laboratory. Both the independent Facility Certification Specialist and CC’s biosafety expert must have an experience on review and approval of ABSL-3 / BSL-3 / BSL-2 facility designs, supervising constructions of ABSL-3 / BSL-3 / BSL-2 facilities, experience in commissioning Biosecurity facilities.

The Biosafety Expert will be responsible for conducting risk assessment in accordance with the WHO Laboratory Biosafety Manual and CEN/CWA 15793 Laboratory Bio Risk Management Standard, and will provide recommendations to minimize the risks. In this respect, the design documents will be evaluated, the execution phase will be supervised, and interim audit reports will be prepared. The Biosafety Expert will also be responsible for training the users and maintenance staff of the facility with respect to principles and safe working practices within ABSL-3/BSL-3/BSL-2 facilities. The standards required for establishment of the labs are described in Chapter 3: Regulatory Framework. The Biosafety expert will work for CC and will make all preparations for the independent facility certification. The independent Facility Certification Specialist will assess the BSL2 and BSL3 labs and will work for Ministry of Health as a consultant.

If the Lab management could not achieve closing all non-conform items and the certification fails, the independent facility certifier issues an official letter to the lab management indicating that the labs are not certified (certification process failed) and all risks for operating the labs under these conditions shall be the sole responsibility of the Lab management. BSL2 and BSL3 labs shall not be operated without certification. There are different certification procedures in each country. Certification is mandatory in the US and Canada for work with select agents and exotic animal pathogens, respectively. Singapore and Australian governments maintain an official certification scheme for BSL-3 labs, or quarantine facilities, respectively. In the US any person with experience and expertise can certify labs. In Canada certifications are done by government experts. In Singapore and Australia, certifiers are approved or accredited by the competent authority. In all other countries, the certifier is a recognized biosafety professional or biocontainment engineer with extensive experience and expertise in certification of biosafety facilities, including facility-related and organizational risk controls (e.g., biorisk management systems according to CWA 15793 or ISO 31000). World Health Organization (WHO) and World Animal Health Organization (OIE) do not accredit or certify certifiers.

**The V-Model for Biosafety Labs**

Certification of biosafety laboratories should follow the qualification process as described by the V-model (Figure 3).



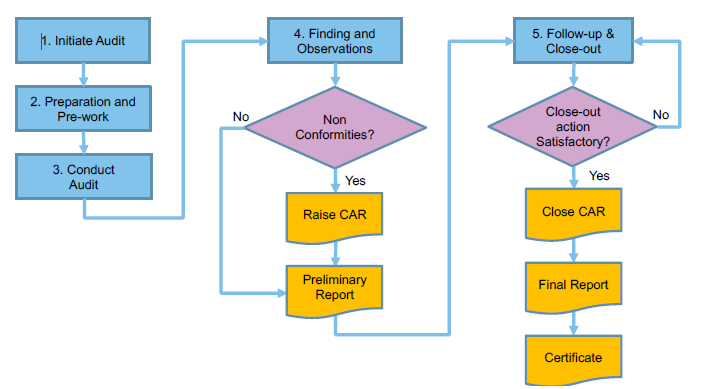
*Figure 1: V-model for Biosafety Laboratories*

Often high biocontainment facilities are designed and built without precise user requirement specifications (URS) or qualification requirements (IQ, OQ) agreed at the start of a project. Accordingly, at handover, the facility may (i) not conform to the chosen biosafety standard, guideline or national regulations, (ii) not be efficient to work in it, and (iii) be expensive to build, operate and maintain. The V-model as shown in ***Figure 1*** illustrates how biosafety labs should be designed, built, and tested. The left side of the V-model represents when the requirements get defined (“are you building the right lab?”), and the right side shows the construction and installation of systems and parts and when to verify them against the requirements (IQ, OQ, or “are you building it right?”). It is important to note that the verification process starts with reviewing the URS. Subsequently, all design specifications, equipment, and materials of construction should get thoroughly reviewed and pre-qualified by the certifier to the chosen biosafety standard, guideline or the applicable regulations as well as to the URS to ensure certification worthiness. Because, most requirements set by biosafety standards and guidelines are vague, descriptive, or goal-oriented, or all of the before-mentioned, without detailed and precise specification of methods of construction and performance parameters required to pass the certification inspection and tests. The independent third-party certifier’s role is to steer the user and the design team towards a certification-worthy facility. Without pre-qualification, design failures could emerge only during construction, commissioning or testing, or – worst case – at the certification inspection and tests.

Once initial certification is provided, according to the WHO Manual all biological research and clinical laboratories should be regularly certified. Laboratory certification is an on-going quality and safety assurance activity that should take place on a regular basis.

**Audit and Certification Process**

The audit and certification process includes five steps as shown in Figure 2.



**Figure 2**: 5-step audit and certification process flowchart

**Certification audit initiation and preparation/pre-work** is performed by the independent assigned certifier in their office. The submittals to the certifier include all drawings, schematics, and certificates of equipment items, materials, and parts. Commissioning and testing results performed by the builder, his sub-contractors and equipment specifications are to be submitted too. The users or lab operator submit biosafety policies and SOPs.

**Certification audit**

The on-site certification audit is normally carried out by an independent biosafety expert and includes the facility-related risk control measures as well as the biorisk management system. The audit includes visual inspections and testing of mechanical, electrical, sanitary and plumbing systems as well as primary and secondary containment equipment. Primary containment equipment includes biosafety cabinets and centrifuges, for example. Secondary containment equipment includes mechanical systems, autoclaves and effluent decontamination equipment, for example. Performance testing the mechanical ventilation is the toughest test. It includes controlled shut-down and restoration of normal operation and single point of failure tests (loss of power, failures of ventilation equipment and systems).

After completion of the audit, the certifier summarizes and presents non-conformities and quality issues in a Findings Observation Report (FOR). Necessary actions are followed up in a Corrective Action Report (CAR). The CAR serves to keep track of non-conform findings and corrective solutions until close-out. After closing all non-conform items the certificate of compliance is issued. For facility related certifications, the current practice is to re-certify annually.

# Legal Framework

There are several national and international requirements that BSL2 and BSL3 laboratories need to follow during preparation, design, installation and refurbishment; and operation.

## National Laws and Regulations

National laws and regulations are evaluated within two sub-headings: “General Laws and Regulations” refer to all laws, regulations, legislations and etc. that the Activity is affiliated from a wider perspective. “Specific Laws and Regulations” heading gives more specific regulations and legislations which are about laboratory safety and biosafety issues.

### General Laws and Regulations

1. Constitution of the Republic of Turkey
2. Decree Law on Certain Regulations in the Field of Health **[[6]](#footnote-7)**
3. National Pandemic Plan
4. COVID-19 Risk Assessment and COVID-19 Guideline
5. The Turkish Environmental Law (Law No: 2872; Date of Ratification: 1983)
6. Regulation on the Control of Medical Wastes (No: 29959, Date: Jan 25th, 2017)
7. Regulation on Improvement and Assessment of Healthcare Services (lastly amended in 2017)
8. Regulation of Waste Management (No: 29314, Date: April 2nd, 2015)
9. Law on the Right to Information (No. 4982), published in the Official Gazette no. 25269 dated 24 October 2003
10. Labor Law (No. 4857), published in the Official Gazette no. 25134 dated 10 June 2003
11. Law on Occupational Health and Safety (No. 6331), published in the Official Gazette no. 28339 dated 30 June 2012
12. Regulation on Contractors and Sub-contractors, published in the Official Gazette no. 27010 dated 27 September 2008
13. Occupational Health and Safety No. 6331, put into force on 20 June 2012
14. Turkish Labor Law No.4857
15. Regulation on the Principles and Procedures for the Employment of Children and Young Persons 2004 (RPEC)
16. Regulations on Overtime and Extra Hours in Relation to the Labor Law (No: 25425, Date: April 6th, 2004)
17. Regulations on Working Conditions at Night for Women Workers (No: 28717, Date: July 24th, 2013)
18. Law on the Work Permit for Foreigners (No: 4817, Date: Feb 27th, 2013)
19. Law on Protection of Animals (Law No: 5199, Date: June 24th, 2004)
20. Welfare and Protection of Animals Used for Experimental and Other Scientific Purposes Regulation (No: 28141, Date: Dec 13th, 2011)
21. Practice Directive of Regulation on the Working Procedures and Principles of Animal Testing Ethical Committees (Basis approval No: E.3679106; Date: Dec 12th, 2018)
22. Regulation for Protection of Workers Against Biological Exposure” (No: 28678, Date: June 15th, 2013)

### Specific Laws and Regulations

1. Good Laboratory Practice (No: 27516; Date: March 9, 2010) (in compliance with OECD standards)
2. Standards of Accreditation in Health – Laboratory Kit
3. TS EN 12128 - Laboratories for research, development and analysis - Containment levels of micro biology laboratories, areas of risk, localities and physical safety requirements (February, 2020). This standard is structured on ISO 3864 (Safety colors and signs), ISO 7000 (Graphical symbols for use on equipment), ISO 8995 (Principles of visual ergonomics-The lightning of indoor work systems)
4. TS 12124 EN ISO 14644 Clean Rooms and Related Controlled Environments
5. EN 12237:2003
6. TS EN 12128: 2002: Biotechnology - Laboratories for research, development and analysis
7. TS EN 12469 Biotechnology – Performance Criteria regarding Microbiological Safety Cabinets
8. TS EN 12347 Biotechnology – Performance Criteria for Steam Sterilizators and Autoclaves
9. Prevention of Biologic Factors Exposures Regulation (In compliance with European Union: Directive 2000/54/EC on the protection of workers from risks related to exposure to biological agents at work)

The scope of activity at BSL 2 and BSL 3 are defined as “installation” according to Turkish laws and regulations; and excludes any construction activities. Therefore the Activity is not obliged to follow construction related laws and regulations.

## International Requirements

International requirements for the activities to be conducted in the scope of BSL2 and BSL 3 laboratories are as follows:

1. World Bank Safeguard Policy (OP) (BP 4.01)
2. WHO Laboratory Bio-Safety Manuel (LBM), fourth edition, 2020;
3. WHO Biorisk Management: Laboratory Biosecurity Guidance, 2006, WHO/CDS/EPR/2006.6
4. ISO 35001: 2009 Bio-risk Management for Laboratories
5. CEN/CWA 15793 Laboratory Bio Risk Management Standard
6. CDC/NIH’s Biosafety in Microbiological and Biomedical Laboratories (BMBL) 5th edition
7. DIN 1946 Ventilation and Air Conditioning (for the healthcare sector)
8. DIN EN 1886 Ventilation for Buildings – Air Handling Units – Mechanical Performance
9. EUROVENT Certification (third party product performance certification for Heat Ventilation Air Conditioning and Refrigeration products)
10. TS 12124 EN ISO 14644 Clean Rooms and Related Controlled Environments
11. EN 12237:2003 Ventilation for Buildings. Ductwork. Strength and Leakage of Circular Sheet Metal Ducts
12. 2010/63/EU numbered EU Directive on Protection of Animals Used for Scientific Purposes, and
13. EU Commission Recommendation on guidelines for the Accommodation and Care of Animals Used for Experimental and other Scientific Purposes
14. Council Directive 2000/54/EC. On the protection of workers from risks related to exposure to biological agents at work (seventh individual directive within the meaning of Article 16(1) of Directive 89/391/EEC) Official Journal L262, 43, 21-45
15. FAO, 2018. Biosafety Primer 2018. Bangkok. 120 pp.
16. OIE, 2012. Biosafety and biosecurity in the veterinary microbiology laboratory and animal facilities.Terrestrial Manual Chapter 1.1.3.
17. OIE, 2018. Standart for managing biological risk in the veterinary laboratory and animal facilities Terrestrial Manual 2018 Chapter 1.1.4.

ANNEX 1: Biosafety Level 3-Laboratory Certification Requirements

**I. Evaluation of Administrative Controls and ability to facilitate Maintenance Operations to ensure occupant safety and facility integrity**

1. Review background materials that affect maintenance operations:

* Obtain and review Commissioning Report
* Review architectural and mechanical drawings to ensure design intent is being met
* Review biosafety policies and procedures (SOPs) for the laboratory (facility) including training of occupants and maintenance staff
* Evaluate administrative and engineering procedures to determine if they meet the needs of the program.
* Review hazardous (infectious) waste management procedures
* Assess laboratory accident response protocols
* Evaluate decontamination procedures for appropriateness with respect to the protocols being conducted or anticipated
* Review integrated pest management program
* Review SOPs for document retention, maintenance and lab procedures

2. Inspect and Evaluate

* Finishes, penetrations & caulking integrity for architectural elements such as doors, around the ceilings, lighting fixtures, electrical devices, etc. within containment to meet requirements for:
  + Clean-ability of all surfaces including furniture
  + Smoothness of all surfaces
  + Sealed seams and penetrations
  + Monolithic, slip resistant floors
  + Surface impermeability to liquids
  + Resistance of surfaces to chemical (organic solvents, acids, alkalis), disinfectants and moderate heat
  + Gas tightness for decontamination
  + Pest management requirements
  + Non-operable windows
  + Bioseals

3. Inspect room layout, placement of equipment and equipment condition

* Evaluate autoclave verification testing procedures; inspect logs
* Evaluate access control and exit procedures
* Evaluate availability of:
  + Emergency equipment
  + Emergency two-way communication system
  + System provided for electronic transfer of information to outside of containment
  + Emergency lighting
  + Working fire extinguisher
  + Availability of chemical spill kit within containment
* Evaluate redundancy requirements for particular facility such as air handling units, exhaust fans, decontamination system components (e.g. pumps & HEPA filters)
* Assess location of BSL-3 labs in relation to BSL-2 support labs, offices and break rooms, elevators, loading docks, etc. for effects on laboratory pressurization and airflow. This includes operational condition of doors.
* Presence of an anteroom w/ or w/o a shower
  + Storage provided for donning clean protective clothing and safety equipment (e.g. Powered Air Purifying Respirators)
* Hands-free sink located near exit of laboratory
* Office location outside of containment
* Inspect signage for proper posting
* Biohazard sign
* Agents used
* Names and telephone number for lab director
* Special requirements such as required use of PPEs, personnel access
* Review list of all mechanical controls and their locations
* Review start up and shut down procedures in case of emergency

4. Evaluate maintenance frequency and review maintenance logs

* Autoclaves
* BSC filters
* Centrifuges
* Door/equipment locks
* HVAC balancing
* HVAC belts
* HVAC Motors/Sheaves
* Lights
* Plumbing

**II. Validation of Engineering Controls**

1. Validate that extra capacity is present on both supply and exhaust systems and quantify the estimated spare capacity (must document how extra capacity was calculated or estimated)

2. Ensure single pass air flow

3. Measure directional air flow, pressure relationships, air changes and record data

4. Directional air flow must be established from clean areas into contaminated areas. In the event that multiple containment zones exist within a laboratory or laboratory suite, sequentially more negative pressure differentials must be established so that the more contaminated spaces are maintained at a negative pressure with respect to less contaminated areas. Pressure differentials across doorways must be measured using a device calibrated against a primary standard. Ideally, at least -0.05 in WG (-12.5 Pa) should be maintained from clean areas to more contaminated areas. In no case should the differential be less than -0.03 in. WG (-7.6 Pa) when the door is closed.

5. Develop HVAC system and electrical systems failure tests consistent with laboratory design parameters. Perform tests and record data. To verify correct operations these tests should include at a minimum:

* Normal operations  emergency power
* Emergency power  normal operations
* Loss of supply fans (individual and in combination)
* Loss of exhaust fans (individual and in combination)
* Building automation system (BAS) maintains operational set points during all scenarios and return to normal operations.
* Upon reboot BAS must retain operational set points.
* If an uninterrupted power supply (UPS) is installed, verify operation of relays
* Provide UPS for BAS
* Assess if UPS is operational

Ensure that laboratories are maintained at negative pressure with respect to less contaminated areas.

6. Assess HVAC equipment condition

* Visually inspect
  + Belts
  + Belt guards
  + Wiring
  + Duct supports and connections
  + Guide wires (if applicable)
  + Dilution air dampers (if applicable)
  + Bearings (high pitched squealing)
  + Ductwork system workmanship, damage, etc.
* Ensure that motor operating temperatures are maintained within equipment specifications
* Ensure that interlock between supply and exhaust is operational
* Verify correct placement of biological safety cabinets with respect to supply and exhaust diffusers, doors and traffic patterns.
* Use smoke at the face of the cabinet to ensure that the air curtain is not being disrupted by supply or exhaust diffusers placed in proximity of the cabinet(s) or opening and closing doors and traffic patterns.

7. Perform smoke tests to demonstrate directional airflow

* Doors
* Vents
* Windows
* Autoclave
* Other vented areas

8. Inspect and challenge door interlock systems and automatic door closers

* Door closers are required
  + Ensure that doors automatically close and latch
  + Interlocks required
  + Check operability
* Open and close doors in all possible sequences
* Ensure that delay set points are tight enough to preclude inadvertent over ride of interlock

9. Test all alarms

* HVAC Failure Alarm
* Availability of air flow alarms showing if the room has gone positive under normal conditions or if door is open for greater than 20 seconds.
* Availability of a visual indication for personnel to be aware if the room is under positive or negative pressure prior to entering into the lab
* Review fire alarm annual documentation
* Review security alarm annual documentation

10. Discharge exhaust assessment (as a measure of performance)

* Inspect rooftop landscape for re-entrainment opportunities

Min. 25 ft. from intake, 40 ft from boiler stacks and 15 ft. from plumbing stacks

* Laboratory exhaust stacks- minimum 3m height above highest point on roof
* Check Exhaust stack locations and discharge velocities
* Exhaust velocity = 15-20 m/s or 3000-4000 fpm
* Is all aerosol-producing equipment exhausted by certified HEPA filtration devices?
  + Ensure that continuous flow centrifuges or other equipment that may produce aerosols are contained in devices that exhaust air through HEPA filters before discharge into the laboratory
* Ensure that discharge of local exhaust ventilation (LEV) devices is removed from air intakes to prevent re-entrainment
* Consider local conditions (e.g., HEPA filters on exhaust, dilution air)

11. Verification of air change rates (ACR) in containment spaces

* ACR is determined during design based on sensible and latent heat loads contaminants and odors that require containment space usage
* Measure supply and exhaust air volumes using a device calibrated annually
* Calculate ACR; monitor trends
* In no case should the ACR be less than 6/hr for labs and 10/hr. for animal facilities

12. Review biological safety cabinet (BSC) certification data including serial number validation

* BSCs must be on an annual certification schedule
* Verify that BSCs are located away from doors and vents
* Verify that installation of BSC is correct for cabinet type.
* Inspect HEPA filter installations
* Review certification documentation for all exhaust HVAC HEPA installations
* Verify that HEPA filters are on portable air vacuum systems at point of use and at the barrier
* Visually inspect
  + Isolation valves for decon
  + Decon and challenge ports
  + Scanning access

13. Validate MEP

* Inspect for adequate illumination
* Verify that circuit breakers are outside of containment
* Backflow prevention for lab water system
* Sinks and drains properly marked
* Availability of emergency power for critical systems
* Availability of hands free emergency eyewash
* Availability of emergency shower
* Caulking and sealing requirements for electrical devices such as conduits, boxes, lights, etc.
* Validate provision for dedicated vacuum pump, if present
* Inspect effluent decontamination system, if present

14. Validate autoclave availability, operations and bioseal integrity

**III. Review SOPs**

1. Autoclave & Decontamination

* To decontaminate materials before removing them from the biosafety cabinet
* If an autoclave is available near but outside the BSL-3 facility, ensure adequate decontamination procedures in place for wet and dry biohazardous materials that leave the facility
* Assess the travel route to nearest autoclave avoid public corridors
* Assess procedures for use of and disposal of PPEs
* Assess procedures for decon of equipment that leaves the facility for repair or discontinuation of use
* Review storage and transport of biohazardous materials
* Assess type of disinfectant to be used and if it is of adequate strength and type for the biohazardous materials in use in the facility
* Validate schedule and frequency of changing HVAC filters on vacuum lines

2. Safety SOPs

* Identification of responsible official for BSL-3 facility
* Certification of all personnel working within containment and process used to certify them
* Use, storage and disposal of Personal Protective Equipment
* Documented limited personnel access to facility
* Procedures for maintenance to enter facility
* Hand washing procedures are in place
* Use of mechanical pipetting devices; NO mouth pipetting
* Use of sharps prohibited unless absolutely required and then use should be managed by protocol
* Procedures in place to minimize production of aerosols
* Decontamination procedures are in place
* Training program is in place and documentation available for training and refresher courses of all personnel allowed in the BSL-3 facility
* Baseline serum samples are collected as appropriate and stored for all laboratory and other at-risk personnel
* A biosafety manual specific to the laboratory has been prepared and adopted
* Biosafety precautions are incorporated into standard operating procedures
* If animals are housed under ABSL-3 conditions, all animal specific regulations and biosafety procedures are followed

3. Occupational Health Monitoring (Policy and records of implementation), if appropriate

* Blood/ Serum Storage
* Vaccinations
* High-risk (immune suppressed, pregnant, etc.) individuals
* Health screening
* Annual updates of Exposure Control Plan to include documentation of all locations where BSL-3 agents or materials are used or stored

4. Biohazardous Materials Use Authorization (e.g., Human Pathogen Registration, Recombinant DNA Registration, Select Agent, etc.)

* Current BUA
* Symptomology page
* Procedures for how samples are received
* Validate that a current Animal Subjects Committee approval is on file (if animals are used in the facility.

**IV. Requirements for the Independent Facility Certification Specialist:**

* PhD in Microbiology or Biotechnology
* Completed at least3 BSL3 labs certification process
* Minimum 5 years of experience as a biosecurity consultant
* Minimum 10 years of experience as an ABSL-3 / BSL-3 / BSL-2 facility certification specialist
* Regular participation in biosafety conferences
* Experience in biorisk assessment
* Experience in review and approval of ABSL-3 / BSL-3 / BSL-2 facility designs
* Experience in supervising constructions of ABSL-3 / BSL-3 / BSL-2 facilities
* Experience in commissioning Biosecurity facilities
* Field training experience in biosecurity and animal biosecurity

ANNEX 2: Biosafety Level 3-Laboratory Certification Checklist

|  |  |  |  |
| --- | --- | --- | --- |
| Date: | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | Contact: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Building: | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | Telephone: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Room #: | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | Inspector: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Initial (I): | ❑ | \* Determination must be made as to requirement for initial and / or annual validation | |
| Annual (A): | ❑ |
|  |  |  |  |

|  |  |
| --- | --- |
| 1. **Administrative Controls** | |
| A/I | **NOTES** |

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **1** | **Review and Assess Background Materials** | |  |  |  |  |  |
|  |  | SOPs for document retention, maintenance and lab procedures |  | ❑ Yes | ❑ No | ❑ N/A |  |
|  |  | Commissioning Report |  | ❑ Yes | ❑ No | ❑ N/A |  |
|  |  | Architectural and mechanical drawings to ensure design intent is being met |  | ❑ Yes | ❑ No | ❑ N/A |  |
|  |  | Biosafety policies and procedures (SOPs) for the laboratory (facility) including training of occupants and maintenance staff |  | ❑ Yes | ❑ No | ❑ N/A |  |
|  |  | Hazardous (infectious) waste management procedures |  | ❑ Yes | ❑ No | ❑ N/A |  |
|  |  | Integrated pest management program |  | ❑ Yes | ❑ No | ❑ N/A |  |
|  |  | Administrative and engineering procedures to determine if they meet the needs of the program |  | ❑ Yes | ❑ No | ❑ N/A |  |
|  |  | Laboratory accident response protocols |  | ❑ Yes | ❑ No | ❑ N/A |  |
|  |  | Decontamination procedures for appropriateness with respect to the protocols being conducted or anticipated |  | ❑ Yes | ❑ No | ❑ N/A |  |

|  |  |  |
| --- | --- | --- |
| **2** | **Inspect, & Evaluate Architectural Features for Maintenance, Operations (Finishes,**  **penetrations & caulking integrity such as doors, around the ceilings, lighting fixtures,**  **electrical devices, etc. within containment to meet requirements for:** |  |

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  |  | Clean-ability of all surfaces including furniture |  | ❑ Pass | ❑ Fail | ❑ N/A |  |
|  |  | Smoothness of all surfaces |  | ❑ Pass | ❑ Fail | ❑ N/A |  |
|  |  | Sealed seams and penetrations |  | ❑ Pass | ❑ Fail | ❑ N/A |  |
|  |  | Monolithic, slip resistant floors |  | ❑ Pass | ❑ Fail | ❑ N/A |  |
|  |  | Surface impermeability to liquids |  | ❑ Pass | ❑ Fail | ❑ N/A |  |
|  |  | Resistance of surfaces to chemicals (organic solvents, acids, alkalis,), disinfectants and moderate heat |  | ❑ Pass | ❑ Fail | ❑ N/A |  |
|  |  | Gas tightness for decontamination |  | ❑ Pass | ❑ Fail | ❑ N/A |  |
|  |  | Pest management requirements |  | ❑ Pass | ❑ Fail | ❑ N/A |  |
|  |  | Non-operable windows |  | ❑ Pass | ❑ Fail | ❑ N/A |  |
|  |  | Bioseals |  | ❑ Pass | ❑ Fail | ❑ N/A |  |

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| **3** | **Inspection of room layout, placement of equipment and equipment condition** | ❑ Pass | ❑ Fail | ❑ N/A |  |

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| **4** | **Autoclave verification testing procedures; inspect logs** |  | ❑ Pass | ❑ Fail | ❑ N/A |  |
| **5** | **Access control and exit procedures** |  | ❑ Pass | ❑ Fail | ❑ N/A |  |

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| **6** | **Evaluate availability of:** |  |

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|  |  | Emergency equipment |  | ❑ Pass | ❑ Fail | ❑ N/A |  |
|  |  | Emergency two way communication system |  | ❑ Pass | ❑ Fail | ❑ N/A |  |
|  |  | System provided for electronic transfer of information to outside of containment |  | ❑ Pass | ❑ Fail | ❑ N/A |  |
|  |  | Emergency lighting |  | ❑ Pass | ❑ Fail | ❑ N/A |  |
|  |  | Working fire extinguisher |  | ❑ Pass | ❑ Fail | ❑ N/A |  |
|  |  | Chemical spill kit within containment |  | ❑ Pass | ❑ Fail | ❑ N/A |  |

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| **7** | **Evaluate redundancy requirements (e.g. air handling units exhaust fans, decontamination system components)** | ❑ Pass | ❑ Fail | ❑ N/A |  |
| **8** | **Assess location of BSL-3 labs in relation to BSL-2 support labs, offices, break rooms, elevators, loading docks, etc. for effects on laboratory pressurization and airflow. This includes operational condition of doors.** | ❑ Pass | ❑ Fail | ❑ N/A |  |
| **9** | **Presence of an anteroom w/ or w/o a shower** | ❑ Yes | ❑ No | ❑ N/A |  |

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|  |  | Storage provided for donning clean protective clothing and safety equipment (e.g. PAPR) |  | ❑ Yes | ❑ No | ❑ N/A |  |
|  |  | Hands-free sink located near exit of laboratory |  | ❑ Yes | ❑ No | ❑ N/A |  |

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| **10** | **Office location outside of containment** | ❑ Yes | ❑ No | ❑ N/A |  |
| **11** | **Inspect signage and visual documentation for proper posting:** | ❑ Yes | ❑ No | ❑ N/A |  |

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|  |  | Biohazard sign |  | ❑ Yes | ❑ No | ❑ N/A |  |
|  |  | List of agents used |  | ❑ Yes | ❑ No | ❑ N/A |  |
|  |  | Names and telephone number for lab director |  | ❑ Yes | ❑ No | ❑ N/A |  |
|  |  | Special requirements such as required use of PPEs, personnel immunizations, etc. |  | ❑ Yes | ❑ No | ❑ N/A |  |
|  |  | Review list of all mechanical controls and their locations |  | ❑ Yes | ❑ No | ❑ N/A |  |
|  |  | Review start up and shut down procedures in case of emergency |  | ❑ Yes | ❑ No | ❑ N/A |  |

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| **12** | **Evaluate maintenance frequency and review maintenance logs** | ❑ Yes | ❑ No | ❑ N/A |  |

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|  |  | Autoclaves |  | ❑ Pass | ❑ Fail | ❑ N/A |  |
|  |  | BSC filters |  | ❑ Pass | ❑ Fail | ❑ N/A |  |
|  |  | Centrifuges |  | ❑ Pass | ❑ Fail | ❑ N/A |  |
|  |  | Door / equipment looks |  | ❑ Pass | ❑ Fail | ❑ N/A |  |
|  |  | HVAC balancing |  | ❑ Pass | ❑ Fail | ❑ N/A |  |
|  |  | HVAC belts |  | ❑ Pass | ❑ Fail | ❑ N/A |  |
|  |  | HVAC Motors / Sheaves |  | ❑ Pass | ❑ Fail | ❑ N/A |  |
|  |  | Lights |  | ❑ Pass | ❑ Fail | ❑ N/A |  |
|  |  | Plumbing |  | ❑ Pass | ❑ Fail | ❑ N/A |  |

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| 1. **Validation of Engineering Costs** | | | | | |
| **13** | **Exhaust systems and quantify the estimated spare capacity (must document how extra capacity was calculated or estimated)** | ❑ Pass | ❑ Fail | ❑ N/A |  |
| **14** | **Ensure single pass air flow** | ❑ Pass | ❑ Fail | ❑ N/A |  |
| **15** | **Measure directional air flow, pressure relationships, air changes and record data** | ❑ Pass | ❑ Fail | ❑ N/A |  |
| **16** | **Ensure directional air flow is established from clean areas into contaminated areas** | | | |  |

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|  |  | If multiple containment zones exist within a laboratory or laboratory suite, ensure that sequentially more negative pressure differentials are established so that the more contaminated spaces are maintained at a negative pressure with respect to less contaminated areas |  | ❑ Pass | ❑ Fail | ❑ N/A |  |
|  |  | Pressure differentials across doorways must be measured using a device calibrated against a primary standard. Ideally, at least -0.05 in WG (-12.5 Pa) should be maintained from clean areas to more contaminated areas. In no case should the differential be less than -0.03 in. WG (-7.6 Pa) when the door is closed. |  | ❑ Pass | ❑ Fail | ❑ N/A |  |

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| **17** | **Develop HVAC system and electrical systems failure tests consistent with laboratory design parameters. Perform tests and record data. To verify correct operations these tests should include at a minimum:** |  |

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|  |  | Normal operations  emergency power |  | ❑ Pass | ❑ Fail | ❑ N/A |  |
|  |  | Emergency power  normal operations |  | ❑ Pass | ❑ Fail | ❑ N/A |  |
|  |  | Loss of supply fans (individual and in combination) |  | ❑ Pass | ❑ Fail | ❑ N/A |  |
|  |  | Loss of exhaust fans (individual and in combination) |  | ❑ Pass | ❑ Fail | ❑ N/A |  |

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| **18** | **Building automation system maintains operational set points during all scenarios and return to normal operations** | ❑ Pass | ❑ Fail | ❑ N/A |  |
| **19** | **Upon reboot BAS must retain operational set points** | ❑ Pass | ❑ Fail | ❑ N/A |  |
| **20** | **If an uninterrupted power supply (UPS) is installed, verify** | ❑ Pass | ❑ Fail | ❑ N/A |  |
| **21** | **Assess if UPS is operational** | ❑ Pass | ❑ Fail | ❑ N/A |  |
| **22** | **Provide UPS for BAS** | ❑ Pass | ❑ Fail | ❑ N/A |  |
| **23** | **Assess HVAC equipment condition. Visually inspect the following:** | | | |  |

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|  |  | Belts |  | ❑ Pass | ❑ Fail | ❑ N/A |  |
|  |  | Belt Guards |  | ❑ Pass | ❑ Fail | ❑ N/A |  |
|  |  | Wiring |  | ❑ Pass | ❑ Fail | ❑ N/A |  |
|  |  | Duct supports and connections |  | ❑ Pass | ❑ Fail | ❑ N/A |  |
|  |  | Guide wires (if applicable) |  | ❑ Pass | ❑ Fail | ❑ N/A |  |
|  |  | Dilution air dampers (if applicable) |  | ❑ Pass | ❑ Fail | ❑ N/A |  |
|  |  | Bearings (high pitched squealing) |  | ❑ Pass | ❑ Fail | ❑ N/A |  |
|  |  | Ductwork system workmanship, damage, etc. |  | ❑ Pass | ❑ Fail | ❑ N/A |  |

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| **24** | **Ensure that motor operating temperatures are maintained within equipment specifications** | ❑ Pass | ❑ Fail | ❑ N/A |  |
| **25** | **Ensure that interlock between supply and exhaust is operational** | ❑ Pass | ❑ Fail | ❑ N/A |  |
| **26** | **Verify correct placement of biological safety cabinets with respect to supply and exhaust diffusers, doors and traffic patterns** | ❑ Pass | ❑ Fail | ❑ N/A |  |
| **27** | **Use smoke at the face of the cabinet to ensure that the air curtain is not being disrupted by supply or exhaust diffusers placed in proximity of the cabinet(s) or opening and closing**  **doors and traffic patterns** | ❑ Pass | ❑ Fail | ❑ N/A |  |
| **28** | **Perform smoke tests to demonstrate directional airflow** | | | |  |

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|  |  | Doors |  | ❑ Pass | ❑ Fail | ❑ N/A |  |
|  |  | Vents |  | ❑ Pass | ❑ Fail | ❑ N/A |  |
|  |  | Windows |  | ❑ Pass | ❑ Fail | ❑ N/A |  |
|  |  | Autoclave |  | ❑ Pass | ❑ Fail | ❑ N/A |  |
|  |  | Other vented areas |  | ❑ Pass | ❑ Fail | ❑ N/A |  |

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| **29** | **Inspect and challenge door interlock systems and automatic door closers** |  |

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|  |  | Door closers are required |  | ❑ Pass | ❑ Fail | ❑ N/A |  |
|  |  | Ensure that doors automatically close and latch |  | ❑ Pass | ❑ Fail | ❑ N/A |  |
|  |  | Interlocks required |  | ❑ Pass | ❑ Fail | ❑ N/A |  |
|  |  | Check operability |  | ❑ Pass | ❑ Fail | ❑ N/A |  |

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| **30** | **Open and close doors in all possible sequences** | ❑ Pass | ❑ Fail | ❑ N/A |  |
| **31** | **Ensure that delay set points are tight enough to preclude inadvertent over ride of interlock** | ❑ Pass | ❑ Fail | ❑ N/A |  |
| **32** | **Test all alarms** | | | |  |

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|  |  | HVAC Failure Alarm |  | ❑ Pass | ❑ Fail | ❑ N/A |  |
|  |  | Availability of air flow alarms showing if the room has gone positive under normal conditions or if door is open for greater than 20 seconds |  | ❑ Pass | ❑ Fail | ❑ N/A |  |
|  |  | Availability of a visual indication for personnel to be aware if the room is under positive or negative pressure prior to entering into the lab |  | ❑ Pass | ❑ Fail | ❑ N/A |  |
|  |  | Review fire alarm annual documentation |  | ❑ Pass | ❑ Fail | ❑ N/A |  |
|  |  | Review security alarm annual documentation |  | ❑ Pass | ❑ Fail | ❑ N/A |  |
| **33** | **Discharge exhaust assessment (as a measure of performance)** | |  | ❑ Pass | ❑ Fail | ❑ N/A |  |

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| **34** | **Inspect rooftop landscape for re-entrainment opportunities** |  |

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|  |  | Min. 25 ft. from intake, 40 ft from boiler stacks, 15 ft from plumbing stacks |  | ❑ Pass | ❑ Fail | ❑ N/A |  |
| **35** | **Laboratory exhaust stacks - minimum 3m height above highest point on roof** | |  | ❑ Pass | ❑ Fail | ❑ N/A |  |
| **36** | **Check exhaust stack locations and discharge velocities** | |  | ❑ Pass | ❑ Fail | ❑ N/A |  |
| **37** | **Exhaust velocity = 15-20 m/s or 3000-4000 fpm** | |  | ❑ Pass | ❑ Fail | ❑ N/A |  |
| **38** | **All aerosol-producing equipment exhausted by certified HEPA filtration devices** | |  | ❑ Pass | ❑ Fail | ❑ N/A |  |
| **39** | **Ensure that continuous flow centrifuges or other equipment that may produce aerosols are contained in devices that**  **exhaust air through HEPA filters before discharge into the**  **laboratory** | |  | ❑ Pass | ❑ Fail | ❑ N/A |  |
| **40** | **Ensure that discharge of local exhaust ventilation (LEV) devices is removed from air intakes to prevent re-entrainment** | |  | ❑ Pass | ❑ Fail | ❑ N/A |  |
| **41** | **Consider local conditions (e.g., HEPA filters on exhaust)** | |  | ❑ Pass | ❑ Fail | ❑ N/A |  |

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| **42** | **Verification of air change rates (ACR) in containment spaces** |  |

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|  |  | ACR is determined during design based on sensible and latent heat loads contaminants and odors that require containment space usage |  | ❑ Pass | ❑ Fail | ❑ N/A |  |
|  |  | Measure supply and exhaust air volumes using a device calibrated annually |  | ❑ Pass | ❑ Fail | ❑ N/A |  |
|  |  | Calculate ACR; monitor trends |  | ❑ Pass | ❑ Fail | ❑ N/A |  |
|  |  | In no case should the ACR be less than 6/hr. for labs and  10/hr. for animal facilities |  | ❑ Pass | ❑ Fail | ❑ N/A |  |

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| **43** | **Review biological safety cabinet (BSC) certification data including serial number validation** |  |

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|  |  | BSCs must be on an annual certification schedule |  | ❑ Pass | ❑ Fail | ❑ N/A |  |
|  |  | Verify that BSCs are located away from doors and vents |  | ❑ Pass | ❑ Fail | ❑ N/A |  |
|  |  | Verify that installation of BSC is correct for cabinet type |  | ❑ Pass | ❑ Fail | ❑ N/A |  |
|  |  | Inspect HEPA filter installations |  | ❑ Pass | ❑ Fail | ❑ N/A |  |
|  |  | Review certification documentation for all exhaust HVAC HEPA installations |  | ❑ Pass | ❑ Fail | ❑ N/A |  |
|  |  | Verify that HEPA filters are on portable vacuum systems at point of use and at the barrier |  | ❑ Pass | ❑ Fail | ❑ N/A |  |

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| **44** | **Visually inspect** |  |

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|  |  | Isolation valves for decon |  | ❑ Pass | ❑ Fail | ❑ N/A |  |
|  |  | Decon and challenge ports |  | ❑ Pass | ❑ Fail | ❑ N/A |  |
|  |  | Scanning access |  | ❑ Pass | ❑ Fail | ❑ N/A |  |

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| **45** | **Validate MEP** |  |

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|  |  | Inspect for adequate illumination |  | ❑ Pass | ❑ Fail | ❑ N/A |  |
|  |  | Verify that circuit breakers are outside of containment |  | ❑ Pass | ❑ Fail | ❑ N/A |  |
|  |  | Backflow prevention for lab water system |  | ❑ Pass | ❑ Fail | ❑ N/A |  |
|  |  | Sinks and drains properly marked |  | ❑ Pass | ❑ Fail | ❑ N/A |  |
|  |  | Availability of emergency power for critical systems |  | ❑ Pass | ❑ Fail | ❑ N/A |  |
|  |  | Availability of hands free emergency eyewash |  | ❑ Pass | ❑ Fail | ❑ N/A |  |
|  |  | Availability of emergency shower |  | ❑ Pass | ❑ Fail | ❑ N/A |  |
|  |  | Caulking and sealing requirements for electrical devices such as conduits, boxes, lights, etc. |  | ❑ Pass | ❑ Fail | ❑ N/A |  |
|  |  | Validate provision for dedicated vacuum pump |  | ❑ Pass | ❑ Fail | ❑ N/A |  |
|  |  | Inspect effluent decontamination system, if present |  | ❑ Pass | ❑ Fail | ❑ N/A |  |

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| **46** | **Validate autoclave availability, operations and bioseal integrity** |  |

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|  |  | Test interlocks |  | ❑ Pass | ❑ Fail | ❑ N/A |  |
|  |  | Confirm cycle – test load |  | ❑ Pass | ❑ Fail | ❑ N/A |  |
|  |  | Visually inspect bioseal |  | ❑ Pass | ❑ Fail | ❑ N/A |  |
|  |  | Smoke test bioseal |  | ❑ Pass | ❑ Fail | ❑ N/A |  |
|  |  | Validate maintenance of sterilization temp. of 121 degrees for 60 minutes |  | ❑ Pass | ❑ Fail | ❑ N/A |  |
|  |  | Autoclave-out capability directly from the BSL-3 facility in new facilities |  | ❑ Pass | ❑ Fail | ❑ N/A |  |
|  |  | In older facilities if autoclave-out is not available, an autoclave must be available near the BSL-3 facility so that containment of biohazardous waste is maintained. |  | ❑ Pass | ❑ Fail | ❑ N/A |  |
|  |  | Additional environmental protection (e.g., personnel showers, HEPA filtration of exhaust air, containment of other piped services and the provision of effluent decontamination) is considered if recommended by the agent summary |  | ❑ Pass | ❑ Fail | ❑ N/A |  |

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| 1. **Review SOPs** | | |
| **47** | **Autoclave & Decontamination** |  |

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|  |  | To decontaminate materials before removing them from the biosafety cabinet |  | ❑ Pass | ❑ Fail | ❑ N/A |  |
|  |  | If an autoclave is available near but outside the BSL-3 facility, ensure adequate decontamination procedures in place for wet and dry biohazardous materials that leave the  facility |  | ❑ Pass | ❑ Fail | ❑ N/A |  |
|  |  | Assess the travel route to nearest autoclave avoid public corridors |  | ❑ Pass | ❑ Fail | ❑ N/A |  |
|  |  | Assess procedures for use of and disposal of PPEs |  | ❑ Pass | ❑ Fail | ❑ N/A |  |
|  |  | Assess procedures for decon of equipment that leaves the facility for repair or discontinuation of use |  | ❑ Pass | ❑ Fail | ❑ N/A |  |
|  |  | Review storage and transport of biohazardous materials |  | ❑ Pass | ❑ Fail | ❑ N/A |  |
|  |  | Assess type of disinfectant to be used and if it is of  adequate strength and type for the biohazardous materials in use in the facility |  | ❑ Pass | ❑ Fail | ❑ N/A |  |
|  |  | Validate schedule and frequency of changing HVAC filters on vacuum lines |  | ❑ Pass | ❑ Fail | ❑ N/A |  |

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| **48** | **Safety SOPs** |  |

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|  |  | Identification of responsible official for BSL-3 facility |  | ❑ Pass | ❑ Fail | ❑ N/A |  |
|  |  | Certification of all personnel working within containment and process used to certify them |  | ❑ Pass | ❑ Fail | ❑ N/A |  |
|  |  | Use, storage and disposal of Personal Protective Equipment (PPE) |  | ❑ Pass | ❑ Fail | ❑ N/A |  |
|  |  | Documented limited personnel access to facility |  | ❑ Pass | ❑ Fail | ❑ N/A |  |
|  |  | Procedures for maintenance to enter facility |  | ❑ Pass | ❑ Fail | ❑ N/A |  |
|  |  | Hand washing procedures |  | ❑ Pass | ❑ Fail | ❑ N/A |  |
|  |  | Use of mechanical pipetting devices; NO mouth pipetting |  | ❑ Pass | ❑ Fail | ❑ N/A |  |
|  |  | Use of sharps prohibited unless absolutely required and then use should be managed by protocol |  | ❑ Pass | ❑ Fail | ❑ N/A |  |
|  |  | Procedures to minimize production of aerosols |  | ❑ Pass | ❑ Fail | ❑ N/A |  |
|  |  | Decontamination procedures |  | ❑ Pass | ❑ Fail | ❑ N/A |  |
|  |  | Training program and documentation available for training and refresher courses of all personnel allowed in the BSL-3 facility |  | ❑ Pass | ❑ Fail | ❑ N/A |  |
|  |  | Baseline serum samples are collected as appropriate and stored for all laboratory and other at-risk personnel |  | ❑ Pass | ❑ Fail | ❑ N/A |  |
|  |  | A biosafety manual specific to the laboratory has been prepared and adopted |  | ❑ Pass | ❑ Fail | ❑ N/A |  |
|  |  | Biosafety precautions are incorporated into standard operating procedures |  | ❑ Pass | ❑ Fail | ❑ N/A |  |
|  |  | If animals are housed under ABSL-3 conditions, all animal specific regulations and biosafety procedures are followed |  | ❑ Pass | ❑ Fail | ❑ N/A |  |

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| **49** | **Occupational Health Monitoring (Policy and records of implementation), if appropriate** |  |

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|  |  | Blood/ Serum Storage |  | ❑ Pass | ❑ Fail | ❑ N/A |  |
|  |  | Vaccinations |  | ❑ Pass | ❑ Fail | ❑ N/A |  |
|  |  | High-risk (immune suppressed, pregnant, etc.) individuals |  | ❑ Pass | ❑ Fail | ❑ N/A |  |
|  |  | Health screening |  | ❑ Pass | ❑ Fail | ❑ N/A |  |
|  |  | Annual updates of Exposure Control Plan to include documentation of all locations where BSL-3 agents or materials are used or stored |  | ❑ Pass | ❑ Fail | ❑ N/A |  |

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| **50** | **Biohazardous Materials Use Authorization (e.g., Human Pathogen Registration, Recombinant DNA Registration, Select Agent, etc.)** |  |

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|  |  | Current BUA |  | ❑ Pass | ❑ Fail | ❑ N/A |  |
|  |  | Symptomology page |  | ❑ Pass | ❑ Fail | ❑ N/A |  |
|  |  | Procedures for how samples are received |  | ❑ Pass | ❑ Fail | ❑ N/A |  |
|  |  |  |  |  |  |  |  |  |  |  |

1. Activity 2 is not subject of this Terms of Reference. ESMP of IDEA (Activity 2) can be reached from <https://pydb.saglik.gov.tr/TR-77176/8531-kapsaminda-yapilan-absl2-ve-absl-3-laboratuvarlari.html> [↑](#footnote-ref-2)
2. <http://documents.worldbank.org/curated/en/399881538336159607/Environment-and-Social-Framework-ESF-Good-Practice-Note-on-Gender-based-Violence-English.pdf> [↑](#footnote-ref-3)
3. This analysis also includes labor, health and safety legislation. [↑](#footnote-ref-4)
4. This is a sample TOR driven from IFC Handbook for Preparing a Resettlement Action Plan and <https://www.ifc.org/wps/wcm/connect/ee19f150-f505-41db-891f-6ef5557195b6/ResettlementHandbook.PDF?MOD=AJPERES&CACHEID=ROOTWORKSPACE-ee19f150-f505-41db-891f-6ef5557195b6-jkD0CRL> [↑](#footnote-ref-5)
5. See also ESS-10 Template: Disclosure of Stakeholder Engagement and Information, Stakeholder Engagement Plan and Stakeholder Engagement Framework, June 2018 and an update for the COVID 19 Stakeholder Engagement Template [↑](#footnote-ref-6)
6. With Article 25 of the Decree Law No. 703 dated 09.07.2018, the name of the Decree Law No. 663 has been changed into "Decree Law on Certain Regulations in the Field of Health" [↑](#footnote-ref-7)