Medical Equipment and Pharmaceuticals import Permit

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1. PURPOSE /SCOPE

The purpose of this procedure is to provide all prospective clients with:

- A description of application procedure for Medical Equipment and Pharmaceuticals Import Permit ensuring compliance with applicable Local and International laws.
- Details of the package documents which should be enclosed in the application pack

The Procedure describes common rules, sequence and procedures for Medical Equipment and Pharmaceuticals Import Permit application for equipment and material to be imported for any operation of BP Az SPU for its projects within the Azerbaijan Republic.

The Procedure has been developed in accordance with International Regulations and applicable local legislation as given in "REFERENCES" chapter below.

2. DEFINITIONS

Refer to document AzSPU-HSSE-DOC-00021-2 HSE Definitions for definitions common to this Procedure. Definitions specific to the Procedure are included below.

BP Az SPU	BP Azerbaijan Strategic Performance Unit
CAM	Contract Accountable Manager
HSE & TD	Health, Safety, Environment and Technical Directorate
P&RA	Permitting and Regulatory Affairs
PU	Performance Unit
PUL	Performance Unit Leader
SPA	Single Point of Accountability
VP	Vice President

"Medical Equipment and Pharmaceuticals" are meant as:

"Medical equipment" means medical equipment, products, items and materials, instruments, chemical agents and optical instruments used in diagnosing, prevention and treatment of diseases shall be deemed equal to pharmaceuticals.

"Pharmaceuticals" means natural (of herb, animal, mineral and other origin), synthetic, biotechnological pharmaceutical agents or their mixtures, including immune-biological pharmaceutical agents, possessing biological and pharmacological effect and used in diagnosing, prevention and treatment of diseases, prevention of pregnancy, rehabilitation of patients, changing the condition of a human organism or its physiological functions.

3. GENERAL REQUIREMENTS

This procedure is applicable for all BP Az SPU construction and operation activity in Azerbaijan and obligatory for BP Az SPU, as well as all legal entities regardless of the type of ownership or organizational and legal structure (hereinafter "Organization"), which act as contractors/ subcontractors to BP Az SPU and implement activities which requires availability of Medical Equipment and Pharmaceuticals.

BP Az SPU, as well as their contractors operating under the given below PSAs and HGAs conditions and whose operations shall require import of Medical Equipment and Pharmaceuticals should have available all papers and documents which required for Medical Equipment and Pharmaceuticals Import Permit in accordance with established BP Internal Procedures, Local and International laws, including:

- Law No. 933 of the Azerbaijan Republic approving the "Agreement on the Joint Development and Production Sharing for the Azeri and Chirag Fields and the Deep Water Portion of the Guneshli Field," dated 2 December 1994.
- Law No. 160-IQ of the Azerbaijan Republic approving the "Agreement on the Exploration, Development Production and Sharing for the Shah Deniz Prospective Area in the Azerbaijan Sector of the Caspian Sea," dated 4 October 1996.
- Law 885-IQ of the Azerbaijan Republic approving the "Agreement among the Azerbaijan Republic, Georgia and the Republic of Turkey relating to the Transportation of Petroleum via the territories of the Azerbaijan Republic, Georgia and the Republic of Turkey through the Baku-Tbilisi-Ceyhan Main Export Pipeline," dated 26 May 2000.
- Law 211-IIQ approving the of the Azerbaijan Republic approving the "Agreement between Georgia and the Azerbaijan Republic Relating to the Transit, Transportation and Sale of Natural Gas In and Beyond the Territories of Georgia and the Azerbaijan Republic Through the South Caucasus Pipeline System," dated 26 October 2001.

4. ROLES AND RESPONSIBILITIES

BP Az SPU Vice President

BP Az SPU VP shall be responsible for:

- Sanctioning PU/Contractor's application for Permit for Medical Equipment and Pharmaceuticals;
- Providing direct instructions to corresponding Assets, Project and Operations Managers and other responsible staff to comply with the current procedure for Medical Equipment and Pharmaceuticals import
- Being addressee for sending and receiving documents from the State Authorities and its further distribution.

Az SPU HSE & Technical Directorate Vice President

Az SPU HSE & Technical Directorate Vice President shall approve any update and revision of the current Procedures.

BP Az SPU HSE&TD Permitting & Regulatory Affairs Manager or his delegate

BP Az SPU HSE&TD P&RA Manager shall be responsible for:

- Controlling the process of Permit issuing
- Updating this Procedure
- Assigning person to coordinate application package collating, controlling content and compliance with procedures, submission to State Authority and following up

PUL and/or Project Director

PUL and Project Director shall remain responsible for assignment of SPA (CAM) from his/her team for preparation of the application pack and coordination of Contractor's compliance with this procedure.

BP Contractor

Should Contractor require import permit to be issued to own name then Contractor shall be responsible for preparation of application pack in accordance with this procedure.

5. PROCEDURE/PROCESS

Application pack shall contain following content and order both in English and Azerbaijani language:

1. Agreement (between the importing company and the shipper or manufacturer, copied from the original).
2. Invoice.
3. Manufacturer's quality certificate.
4. Certificate of origin (including certificates issued by other responsible organizations).
5. Application letter to BP's name (in a case the permit to be issued to Contractor's name).

This section provides the "step by step" process of obtaining Permit for import of Medical Equipment and Material and clearly demonstrates the roles and responsibilities of all.

Stage 1 – BP's application to the Ministry of Health signed by BP Az SPU VP

Stage 2 – Internal readdressing of the application to the Analytical Expertise Center for Medicines

Stage 3 – Issuing of Permit by the Analytical Expertise Centre for Medicines to the Main Customs Department on Civil Aviation's name

5.1 TIMETABLE

The following timetable shall be observed while planning import of Medical Equipment and Materials on a routine basis. It is also important to note that the table is compiled based on work practice since there is no time indication for application review by State Authorities in applicable laws of Azerbaijan. However, pursuant to HGAs State Authorities must, on a priority basis, issue necessary permits and approvals within 30 days of application, which period can be extended to 60 days in extraordinary circumstances.

Stage	Action by:	Durations

Review of documents pack, translation, preparation of application for BP Az SPU VP signature and sending application to MH	P&R Affairs, BP	1 week[1]
Review of documents pack, preparation for internal forwarding of the application to Analytical Expertise Center for Medicines	Ministy of Health	1 week
Review of documents, preparation of the request for Main Customs Department on Civil Aviation's name	Analytical Expertise Center for Medicines	1 week

6. DOCUMENTS/REFERENCES

Requirements of this procedure are based on the documents constituting the present-day scientific recommendations, local skills and the experience of other countries.

This document, together with those listed below represent an integrated regulatory management system of pharmaceuticals and medical equipment.

No	Document No	Title
1.	Law of the Azerbaijan Republic dated 22 December 2006 N 208 –IIIQ Changes to the Law "On pharmaceuticals" dated 1 October 2007 N 416 –IIIQD	"On pharmaceuticals"
2.	Decree of the President of the Azerbaijan Republic dated 23 November 2007 N 663.	"On the introduction of additions and amendments to the Law of the Azerbaijan Republic on pharmaceuticals"
3.	Order of the President of the Azerbaijan Republic dated 24 June 1997 N 609. Rules for regulating import–export operations in the Azerbaijan Republic approved by Order of the President of the Azerbaijan Republic dated 24 June 1997 N 609	"Further Liberalization of Foreign Trade in the Azerbaijan Republic"
4.	Procurement, Supply Chain Management Handbook, BP Az SPU	
5.	Other applicable laws and regulations as may be adopted from time to time.	

[1] It requires a day to review and prepare application for BP Az SPU VP's signature provided all the documents sent to Permitting and Regulatory Team are translated.

Revision/Review Log

Revision Date	Authority	Custodian	Revision Details
02 April 2009	Greg Mattson	Rovshan Guliyev	Initial Issue
08 April 2010	Greg Mattson	Rovshan Guliyev	Title Changed