



SPECIFICATION

Ventilation and Temperature Control Equipment for Air Cleaning System for Microbiology Laboratory at the Institute for nuclear research of NAS of Ukraine

1. Scope

These specifications describe the requirements for the supply of ventilation and temperature control equipment (hereinafter referred to as ‘the Equipment’) for an air handling system for the microbiology laboratory at the Institute for nuclear research of NAS of Ukraine (hereinafter referred to as “the End-User”). The laboratory will be used for environmental control testing by determining microbial burden during production of radiopharmaceuticals as well as for biological quality control testing of finished products by determining sterility and apyrogenicity of injectable radiopharmaceutical products.

2. Applicable Documents

The following documents shall be applicable as guidelines for this Specification to the extent specified hereinafter:

- (i) World Health Organization Report Series no. 961, 2011 Annex 2 : WHO good practices for pharmaceutical microbiology laboratory; and
- (ii) USFDA Inspection guidelines: microbiological pharmaceutical quality control laboratories (7/93).

3. Definitions, Acronyms, and Abbreviations

The following definitions, acronyms, and abbreviations shall apply throughout this Specification unless defined otherwise hereinafter:

- Pa: Pascal
- INR: Institute for Nuclear Research
- FDA: Food and Drug Administration
- QA: Quality Assurance
- QC: Quality control

4. Requirements

4.1. Functional and Performance Requirements

The Equipment shall meet the following functional and performance requirements:

- 4.1.1. The Supplier shall provide a ventilation and temperature control equipment for a total laboratory area of 34.45 m², with a height of 2.5 m, and consisting of 5 (five) rooms with area sizes as follows:



- Room 1 – 6.3 m²
- Room 2 – 5.15 m²
- Room 3 – 5.95 m²
- Room 4 – 8.20 m²
- Room 5 – 8.85 m²

4.1.2. The equipment shall be designed in accordance with the following parameters:

- (i) The lowest calculated temperature of the outdoor air during the cold period of the year is -22°C;
- (ii) The highest calculated temperature of the outdoor air during the warm period of the year is +35°C
- (iii) The supply air temperature during the cold period of the year is 22°C;
- (iv) The supply air temperature during the warm period of the year is 16°C;
- (v) The relative humidity range in the premises during the cold period of the year is 30-50%; and
- (vi) The free pressure of the P1 V1 facilities is 1000 Pa.

4.1.3. The Supplier shall provide all required accessories to allow immediate operation of the Equipment.

4.1.4. The Supplier shall provide a complete set of cables for interconnection of all Equipment components.

4.2. Technical Requirements

The equipment should be designed as per provided drawing and the photographs of existing laboratory areas. The Equipment shall include inflow and outflow (exhaust) ventilation units, which will be installed on the exterior wall of the building as seen in the photograph. The video of the existing laboratory area is available in the following link <https://drive.google.com/file/d/1Wd5UPGAbtrQ3b91-U2Z12fUjiB2AP8l/view?usp=sharing>

The Equipment shall meet the following technical requirements:

4.2.1. The Equipment shall include an automatic inflow ventilation system which shall:

- (i) enable the maintaining of a specified temperature and humidity level, and include:
- (ii) an air dampers control;
- (iii) a filter clogging control;
- (iv) provide an indication of operation of fans; and
- (v) an emergency notification alarm system.

4.2.2. The Equipment shall include an output ventilation system which shall provide for an automatic activation of the reserve fan, in the case of main fan failure.

4.2.3. The inflow air ventilation system (P1) and outflow ventilation system (V1) shall be designed and installed as per attached drawings to fulfill the final requirements of class of clean air quality for the entire room area as mentioned below:



- Room 1, Grade D equivalent to class 100000,
- Room 2, Grade D/C equivalent to class 10000,
- Room 3, Grade C equivalent to class 10000,
- Room 4, Grade C/B equivalent to class 100,
- Room 5, Grade B equivalent to class 100.

4.2.4. The inflow air ventilation system (P1) shall provide the automatic regulation: (as per attached drawing specification)

- fan with the variable rotation rate,
- capacity: 3500 m³/hour,
- calculated thermal capacity of the electric heater: 50kW,
- design capacity of the air cooler: 35 kW,
- fan electric motor power: 1.7 kW,
- first stage filter F5, second stage filter F9,
- condensing compressor on Freon R410A: nominal cold productivity: 35 kW,
- required power consumption: 17 kW.

4.2.5. Outflow air ventilation system (V1) should provide with the automatic regulation:

- fan with the variable rotation rate,
- two fans: working and standby, productivity: 3200 m³/hour, power consumption: 1.1 kW, filter section H14.

4.2.6. The ventilation system should provide clean air of categories as mentioned below:

- Room 1, Grade D equivalent to class 100000,
- Room 2, Grade D/C equivalent to class 10000,
- Room 3, Grade C equivalent to class 10000,
- Room 4, Grade C/B equivalent to class 100,
- Room 5, Grade B equivalent to class 100.

4.2.7. The ventilation system should provide the variable air flow regulators as mentioned below for each room:

Variable air flow regulators

1. Room 1 - Ø125 P = 12.5 Pa,
2. Room 2 - Ø160 P = 22.5 Pa,
3. Room 3 - Ø200 P = 32.5 Pa,
4. Room 4 - Ø200 P = 32.5 Pa,
5. Room 5 - Ø250 P = 42.5 Pa.

4.2.8. The ventilation system should provide the regulators of constant air flow as mentioned below for each room:

Regulators of constant air flow

1. Room 1 - Ø125 L = 220 m³/hour,
2. Room 2 - Ø160 L = 440 m³/hour,
3. Room 3 - Ø200 L = 570 m³/hour,
4. Room 4 - Ø200 L = 730 m³/hour,
5. Room 5 - Ø250 L = 940 m³/hour.



5. Marking

The Equipment shall have all safety markings in the Ukrainian language.

6. Packing and Shipping

The Equipment, for the shipment by air to the End-User, shall be packed in accordance with international standards that are applicable for the shipment by air of this kind of equipment.

7. Quality Requirements

- 7.1. The Equipment shall be manufactured, shipped and installed in accordance with the Supplier's ISO quality assurance system or an equivalent quality assurance system.
- 7.2. The Supplier shall document the compliance with this quality assurance system.

8. Testing and Acceptance

- 8.1. The Equipment, prior to shipment, shall be tested for conformance with manufacturer's performance specifications and the minimum requirements specified herein.
- 8.2. The Equipment, after installation, shall be tested by the Supplier together with the End-User to demonstrate that the performance meets the manufacturer's performance specifications and the minimum requirements specified herein as determined by the IAEA and the End-User.
- 8.3. The results of the Equipment testing shall be documented by the Supplier in an acceptance protocol that shall be signed by the End-User.

9. Installation and Training

- 9.1. The Supplier shall install the Equipment at the End-User site, and in coordination with the End-User. No installation activities shall commence unless prior agreement with the End-User.
- 9.2. The Supplier shall provide on-site training program in the operation, maintenance, and proper handling of the Equipment for three technical persons for two days immediately after the equipment is installed at the site.

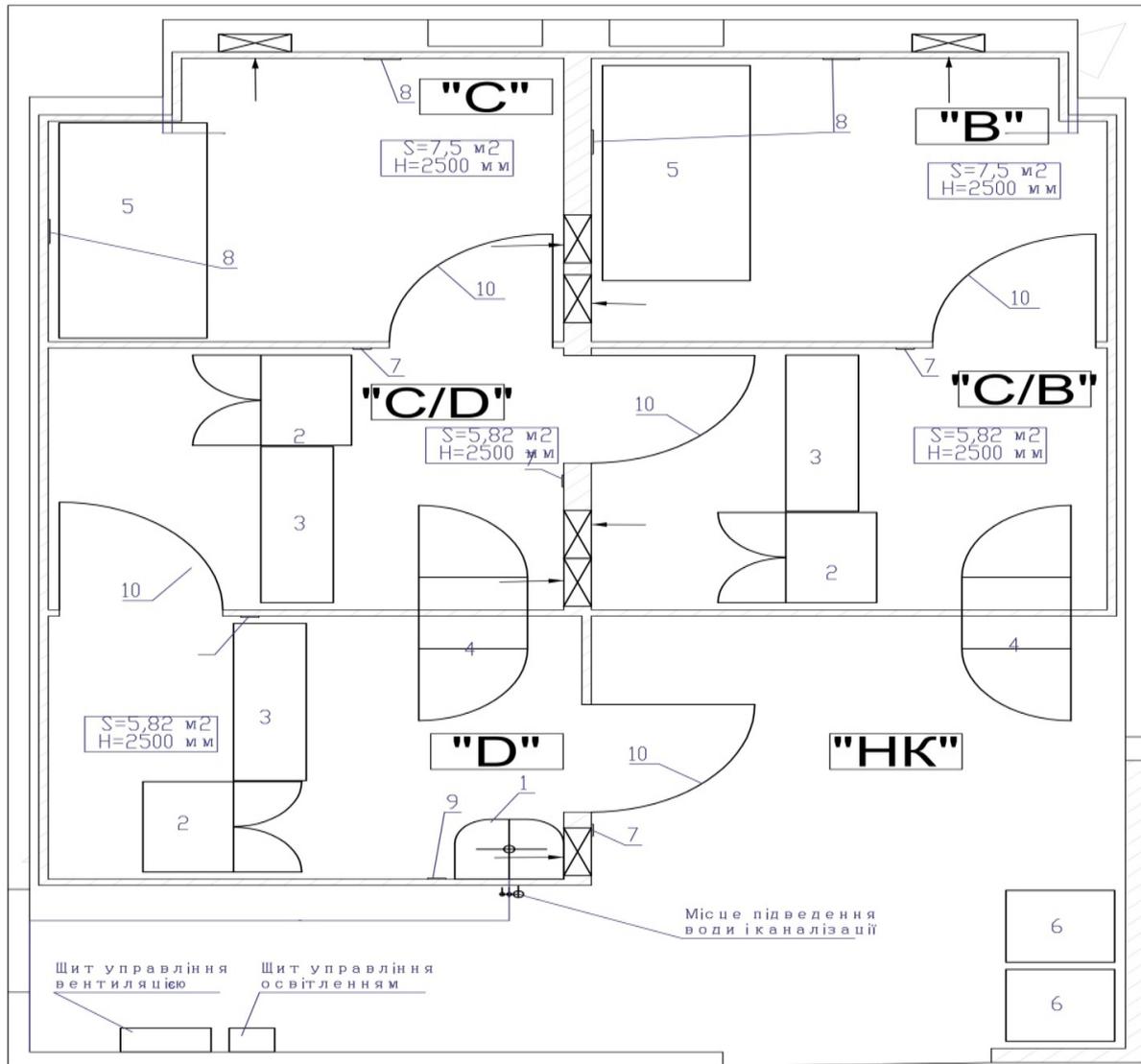
10. Warranty and Support

- 10.1. The Supplier shall provide a comprehensive warranty for 1 (one) year that shall begin on the date of signature of the acceptance protocol, referenced in Section 8.3. above.
- 10.2. The Supplier shall guarantee that Equipment consumables, components and spare parts will be available for a minimum of 5 (five) years, starting from the date of signature of the acceptance protocol, referenced in Section 8.3. above.



11. Deliverable Data Items

The Supplier shall provide 2 (two) complete sets of operation and servicing manuals and technical drawings in the English and Ukrainian language.



1. Умивальник (ШхГхВ: 600x500x900) - 1 шт..
2. Шафа для одягу (ШхГхВ: 755x500x1800) - 3 шт.
3. Лава поперечна (ШхГхВ: 1165x400x500) - 3 шт.
4. Шлюз передавальний (ШхГхВ: 400x600x400) - 2 шт.
5. Бокс ламінарний (ШхГхВ: 1800x815x2300) - 2 шт.

6. Термостат (ШхГ: 600x600) - 2 шт.
7. Вимикач освітлення IP54 (h 900) - 5 шт.
8. Розетка x2 IP54 (h300) - 4 шт.
9. Розетка x2 IP54 (h1500) - 1 шт.
10. Двері (ШхВ: 900x2100).

Laboratory plan of MBC RFP

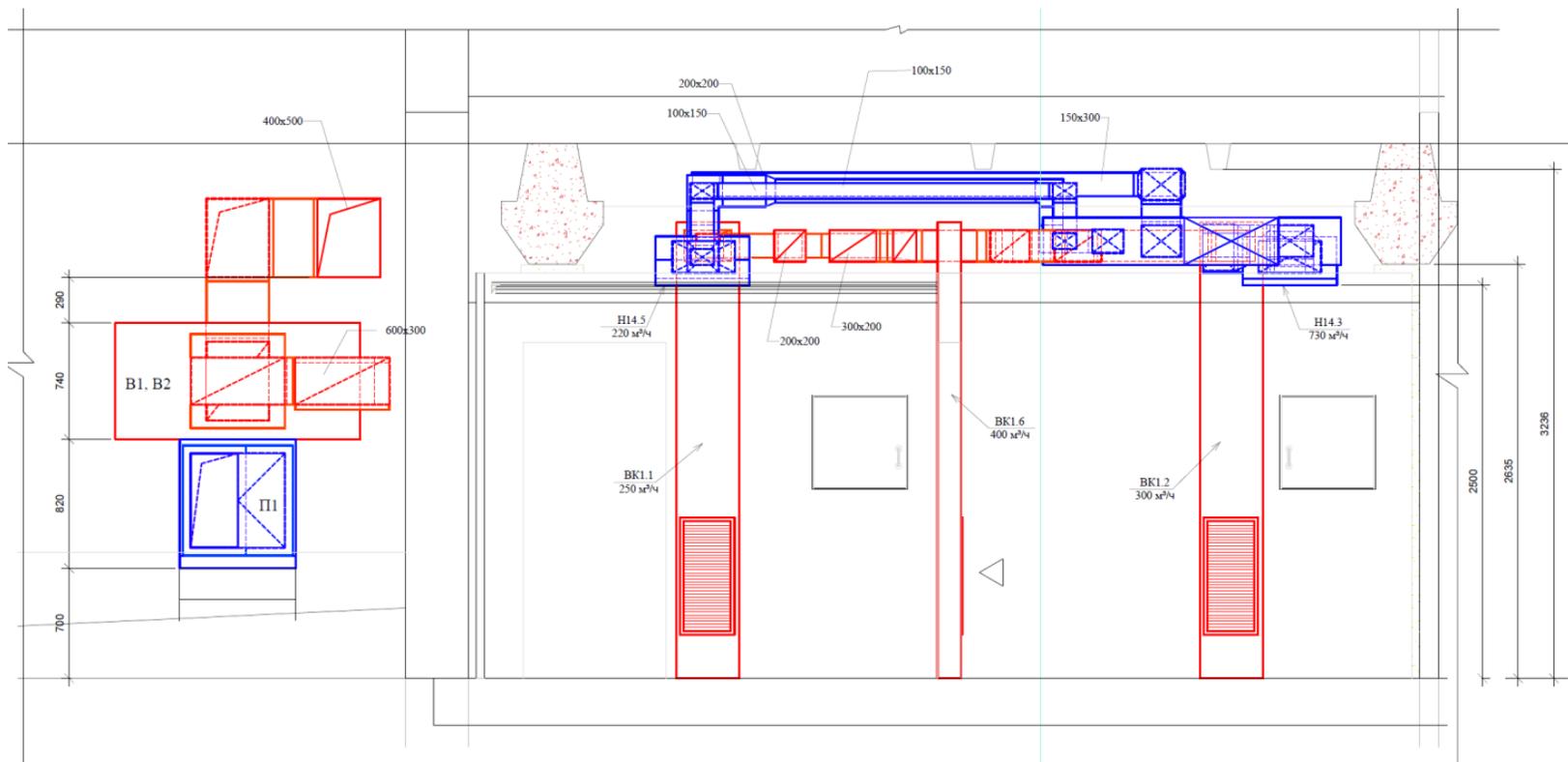
«HK» - uncontrolled zone

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|--|---|
| 1. Washbasin (WxDxH: 600x500x900) - 1 p. | 6. Thermostat (WxD: 600x600) - 2 ps. |
| 2. Wardrobe (WxDxH: 755x500x1800) - 3 ps. | 7. Lighting switch IP54 (h 900) - 5 ps. |
| 3. Lateral bench (WxDxH: 1165x400x500) - 3 ps. | 8. Power outlet x2 IP54 (h 300) - 4 ps. |
| 4. Material transfer sluice (WxDxH: 400x600x400) - 2 ps. | 9. Power outlet x2 IP54 (h 1500) - 1 p. |
| 5. Laminar box (WxDxH: 1800x815x2300) - 2 ps. | 10. Door (WxH: 900x2100) |

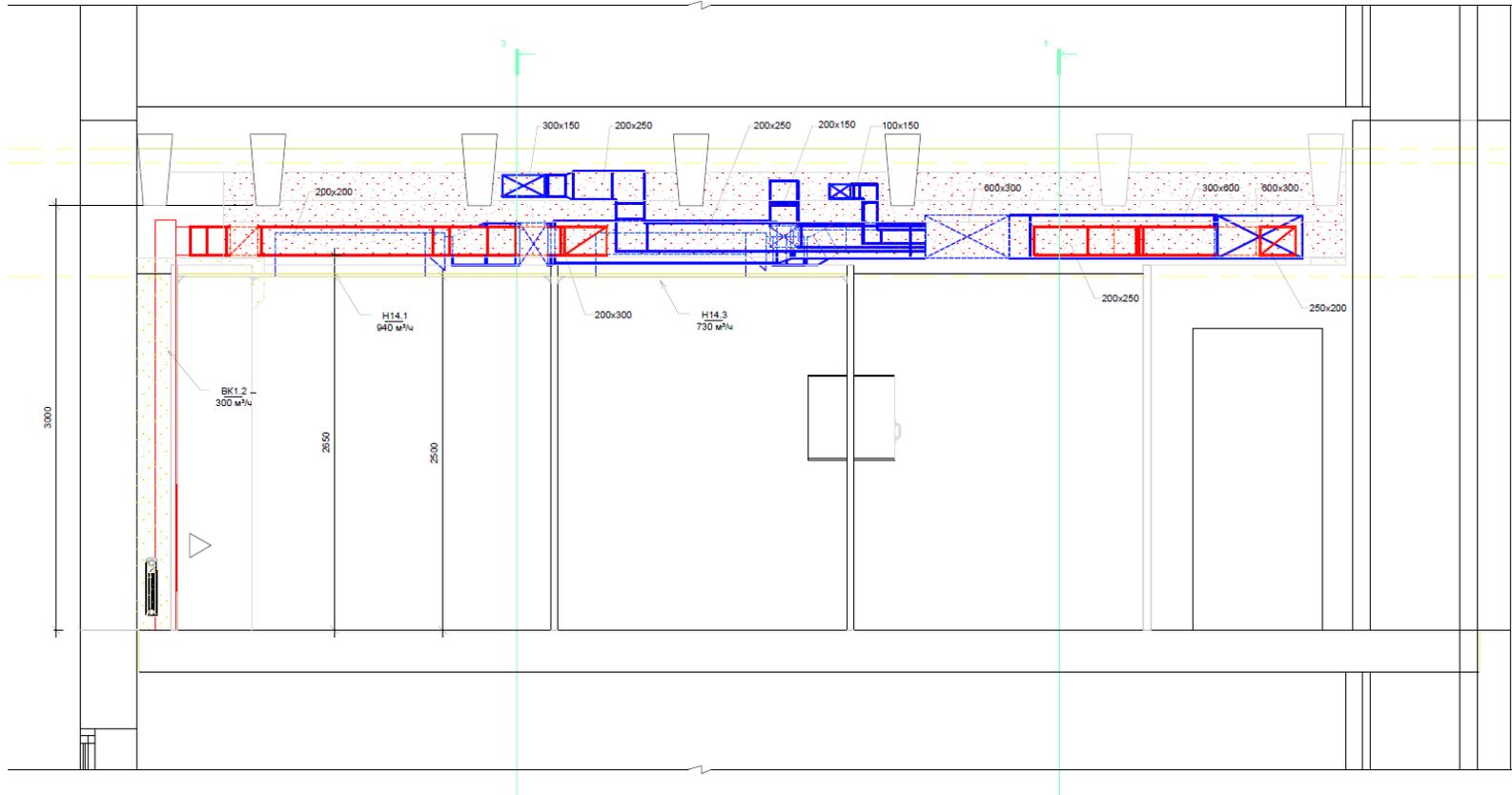
Щит управління вентиляцією – Ventilation control panel

Щит управління освітленням – Lighting control panel

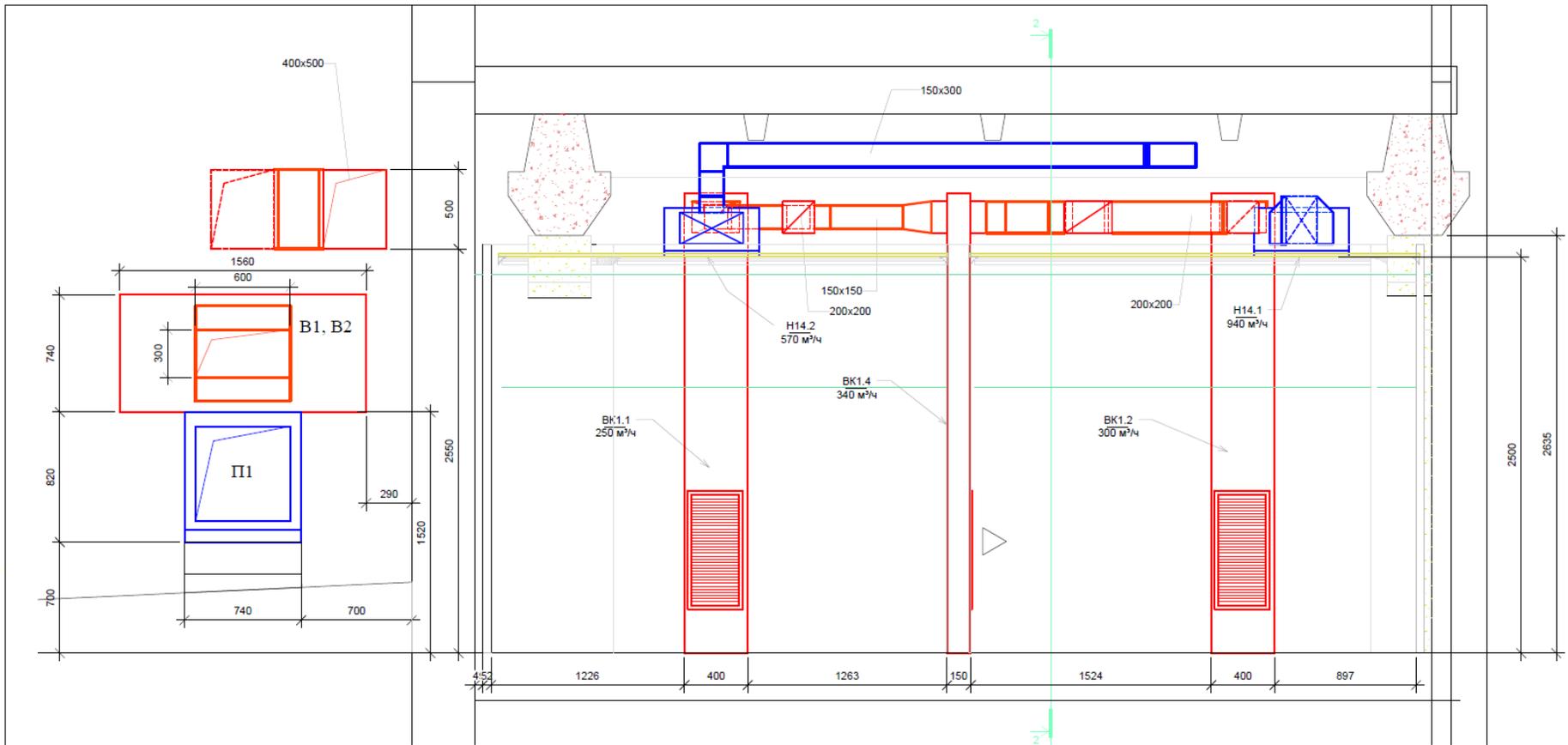
Місце відведення води і каналізації – Place of water and sewage discharge



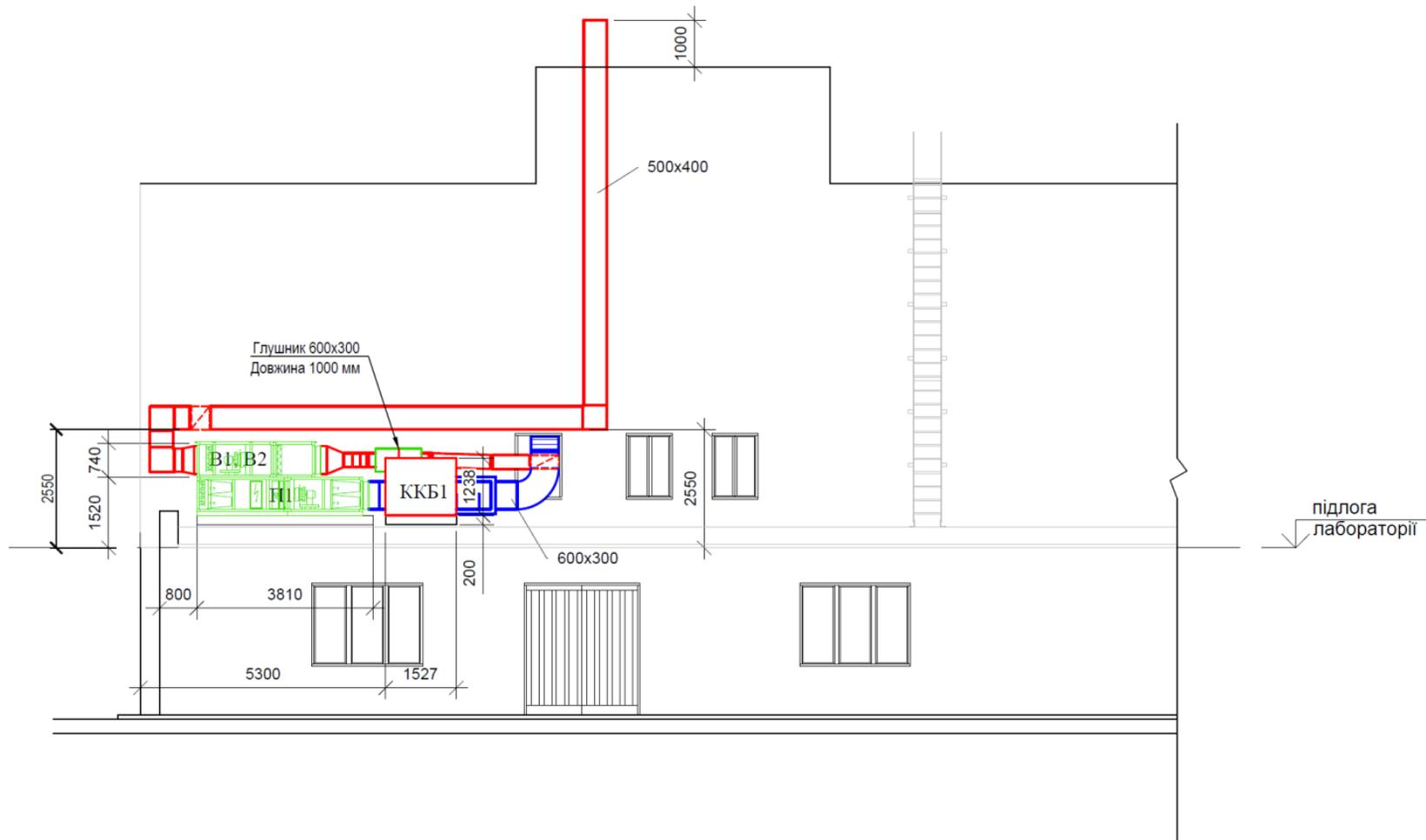
						0407/МН -ЧП.ОБ				
						Repair of the laboratory for microbiological control of the production conditions and quality of radiopharmaceuticals pr.Nauki,47 in Kiev				
Зм	№уч	Арк	№док	Підпис	Дата					
ГП			Погорелова			Laboratory for microbiological control of the production conditions and quality of radiopharmaceuticals		Стадія	Аркуш	Аркушів
Розробив			Томчук					К	3	
Перевірив			Сергійчук							
						Ventilation and air conditioning. Section 1 - 1		ТОВ "СТЕРІЛС"		
Н.контр.			Сергійчук							



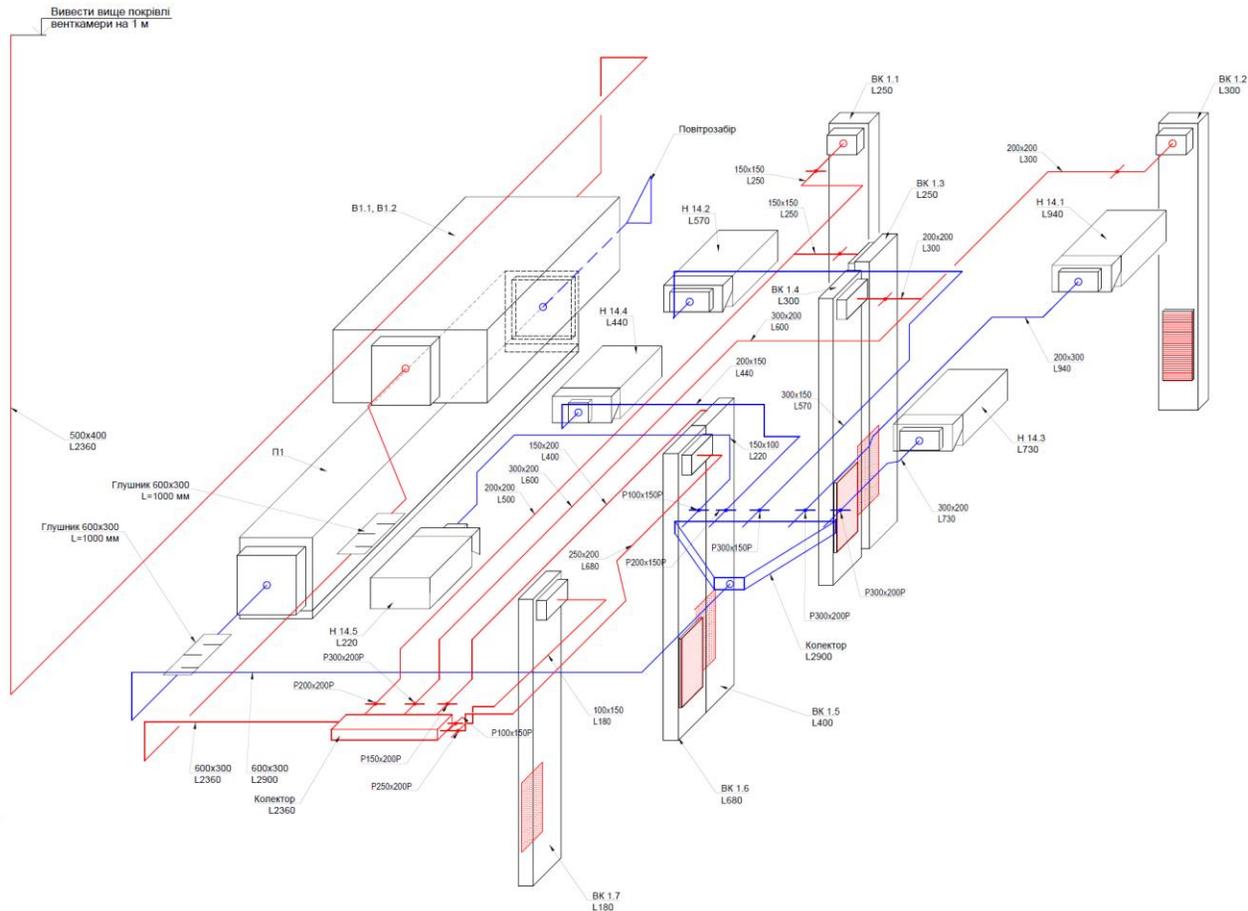
						0407/МН -ЧП.ОВ			
						Repair of the laboratory for microbiological control of the production conditions and quality of radiopharmaceuticals pr.Nauki,47 in Kiev			
Зм	№зуч	Арк	№док	Підпис	Дата	Laboratory for microbiological control of the production conditions and quality of radiopharmaceuticals	Стадія	Аркуш	Аркушів
ГП		Погорелова					К	3	
Розробив		Томчук				Ventilation and air conditioning. Section 2 - 2	ТОВ "СТЕРИЛС"		
Перевірив		Сергійчук							
Н.контр.		Сергійчук							



						0407/МН - ЧП.ОВ				
						Repair of the laboratory for microbiological control of the production conditions and quality of radiopharmaceuticals pr.Nauki,47 in Kiev				
Зм	№уч	Арк	№док	Підпис	Дата	Laboratory for microbiological control of the production conditions and quality of radiopharmaceuticals		Стадія	Аркуш	Аркушів
		Погорелова				Laboratory for microbiological control of the production conditions and quality of radiopharmaceuticals		К	3	
		Томчук				Ventilation and air conditioning. Section 3 - 3		ТОВ "СТЕРІЛС"		
		Сергійчук								
Н.контр.		Сергійчук								



							0407/МН -ЧП.ОБ			
							Repair of the laboratory for microbiological control of the production conditions and quality of radiopharmaceuticals pr.Nauki,47 in Kiev			
Зм	№вчч	Арк	№док	Підпис	Дата		Лабораторія для мікробіологічного контролю ум виробництва та якості радіофармацевтичних препаратів	Стадія	Аркуш	Аркушів
Розробив		Томчук					Лабораторія для мікробіологічного контролю ум виробництва та якості радіофармацевтичних препаратів	К	3	
Перевірив		Сергійчук					Вентиляція та кондиціонування повітря. Фасад	ТОВ "СТЕРІЛС"		
Н.контр.		Сергійчук								



						0407/МН -ЧП.ОВ		
Repair of the laboratory for microbiological control of the production conditions and quality of radiopharmaceuticals pr.Nauki,47 in Kiev						Стадія	Аркуш	Аркушів
Зм	Нач	Арк	Модок	Підпис	Дата	К	3	
ГП		Погорелова				Ventilation and air conditioning. Schemes П1, В1, В2		
Розробив		Томчук						
Перевірив		Сергійчук				ТОВ "СТЕРІЛІС"		
Н.контр.		Сергійчук						



3-D images of the clean rooms of the MBC RFP laboratory