

## D2.3 Tender documents

Version 1.0

Author(s) \_ CPS

Contributors \_ FMS, FPS, PERH, WSS, AZM, CHV, ZAS, CGR, CIB,  
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THERESA - Treat HEalthcaRE System wAstewater

### Abstract

Hospital Wastewater (HWW) poses a significant environmental and health risk due to the presence of pharmaceuticals, pathogens, and other hazardous substances that are administered in healthcare institutions. Unfortunately, current urban Wastewater Treatment (WWT) plants are not capable of effectively removing many of the pollutants generated by hospitals. As a result, these contaminants reach and accumulate in natural water bodies, threatening ecosystems and biodiversity, and public health through the contamination of drinking water or food. To reduce the risk associated to these contaminants, it is key to remove them as close to their source as possible, and before they are discharged to the municipal water network. Despite the existence of different technologies that efficiently remove contaminants from HWW, currently, there is no single process that can be used for the comprehensive treatment of HWW regarding the elimination of a mix of pollutants to a high degree. In this context, the main objective of THERESA PCP is to launch a Pre-Commercial Procurement (PCP) process based on the development of environmentally sustainable on-site systems to 1) decontaminate HWW, being capable of effectively removing, among other contaminants, cytostatic drugs, X-ray contrast agents, antibiotics, ARB and ARG, from HWW and/or 2) to prevent that these contaminants enter the HWW.



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## Authors

Author	Company	E-mail
Anabel Peiró, Lucrezia Paglia and Valeriya Bregman,	Corvers Iberia SLU	<a href="mailto:a.baquedano@corvers.com">a.baquedano@corvers.com</a> <a href="mailto:v.bregman@corvers.com">v.bregman@corvers.com</a> <a href="mailto:l.paglia@corvers.com">l.paglia@corvers.com</a>
Azra Atalan	Corvers procurement Services BV	<a href="mailto:a.atalan@corvers.com">a.atalan@corvers.com</a>

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## Document abstract

The Tender Documents draft is based on the Horizon Europe Guidelines and templates to implement Pre-Commercial Procurement (PCP). The Deliverable includes in one compilation the draft of the different Tender Documents (TD), including the Request for Tenders (TD1) and the following TDs:

Tender Document 2 (TD 2): Framework Agreement

Tender Document 3 (TD 3): PCP Specific Contract for Phase 1

Tender Document 4 (TD 4): PCP Specific Contract for Phase 2

Tender Document 5 (TD 5): PCP Specific Contract for Phase 3

Tender Document 6 (TD 6): PCP End of Phase (1, 2, 3) report

Tender Document 7 (TD 7): Contractor details and Project abstracts

Tender Document 8 (TD 8): Technical form

Tender Document 9 (TD 9): Financial form

Tender Document 10 (TD 10): ESPD (European Single Procurement Document)

Tender Document 11 (TD 11): Consortia Statement

Tender Document 12 (TD 12): Generic test plan template

Tender Document 13 (TD 13): Generic test report template

## Keywords

Pre-Commercial Procurement (PCP), Request For Tenders (RFT), Framework Agreement (FA), Specific Phase Contract, Exclusion, Selection, Award and Compliance Criteria, Evaluation, Intellectual Property Rights (IPR).



# Annex 1. Test Sites

## 1. Baseline situation for testing site 1

Testing site 1 is a major public hospital. It serves as a key general and tertiary care centre for the city and surrounding population, offering a wide range of medical and surgical specialties.

Table 1

	Main Characteristics	
	Number of beds	777
	Number of admissions	~42.000
	Outpatient visits	~1.036.900
	Case mix index	N/A

### Effluent characteristics

**Number of final discharge points to municipal sewer: 6**

### Hydraulic parameters

Table 2

Parameter	Range / value	Unit	Notes
Yearly flow rate	97,273	m <sup>3</sup> /year	Calculated from annual water use: 97,273 m <sup>3</sup> /year. (2024), monthly values ranged between 6.688–10.065 m <sup>3</sup> in 2024
Daily flow rate	215–335	m <sup>3</sup> /day	Daily discharge data not available. Daily flow rate calculated on daily water consumption
Seasonal flow variation	No significant reported	–	-

### General physico-chemical parameters:



Table 3

Parameter	Range / value	Unit	Notes
<b>pH</b>	6-9,5	–	
<b>Temperature</b>	≤ 35	°C	
<b>BOD<sub>5</sub></b>	N/A	mg O <sub>2</sub> /L	
<b>COD</b>	N/A	mg O <sub>2</sub> /L	
<b>Suspended solids</b>	N/A	mg/L	
<b>Oil/grease substances</b>	N/A	mg/L	

**Nutrients:** No data available

**Metals and trace elements** No data available

**Other parameters** No data available

#### Target pollutants in effluent

No data available on concentrations of:

- Cytostatic contaminants content
- Representative X-ray contrast agents content
- Priority antibiotic groups content
- Priority antimicrobial-resistant bacteria (ARB) content
- Priority antimicrobial-resistant genes (ARG) content

#### Baseline situation of existing wastewater management at testing site 1

Table 4

Category	Details
<b>Existing Infrastructure</b>	<p><b>Segregation:</b> No separation for lab, kitchen streams(mixed), no laundry wastewater (laundry outsourced). No radioactive wastewater segregation. No separate rainwater drainage system.</p> <p><b>Discharge points:</b> 6.</p> <p><b>Pre-treatment:</b> grease separator</p> <p><b>Other:</b> sampling manhole, siphon manhole.</p>

<b>Monitoring &amp; Control</b>	<b>Monitoring:</b> water inlet via supplier billing <b>Sensors:</b> none reported. <b>Effluent quality monitoring:</b> not reported <b>Integration:</b> no BMS data indicated. <b>Remote access need:</b> not reported
<b>Capacity, Barriers &amp; Constraints</b>	<b>Staffing:</b> unspecified.
<b>Capacity, Barriers &amp; Constraints</b>	<b>Barriers:</b> limited information; outdoor access may constrain installation.
<b>Wastewater &amp; Public Health</b>	All streams mixed. Infection risks from wipes, biological waste, pharmaceuticals.
<b>Space &amp; Integration</b>	Outdoor installation possible via existing manholes. Modularity useful. Utilities accessible.
<b>Water reuse practices and potential</b>	Reuse is not yet practiced.

### Specific regulatory compliance requirements for THERESA PCP solutions testing site 1

Table 5

Category	Requirement / Parameter	Threshold / Obligation
<b>Effluent discharge Limits – Physical/Chemical Parameters</b>	pH	6–9,5
	Temperature	≤ 40°C
	Suspended solids (SS)	1000 mg/L
	Conductivity at 25 °C	5000 µS/cm
	Settleable solids (1 h)	10 mL/L
	BOD <sub>5</sub>	1000 mg/L
	COD	1750 mg/L
	Total P	15 mg/L



	Total N	90 mg/L
	Oils & greases	200 mg/L
<b>Gaseous compounds</b>	Ammonia (NH <sub>3</sub> )	25 cm <sup>3</sup> gas/m <sup>3</sup> air
	Hydrogen cyanide (HCN)	2 cm <sup>3</sup> gas/m <sup>3</sup> air
	Chlorine (Cl <sub>2</sub> )	0,5 cm <sup>3</sup> gas/m <sup>3</sup> air
	Sulphur dioxide (SO <sub>2</sub> )	2 cm <sup>3</sup> gas/m <sup>3</sup> air
	Carbon monoxide (CO)	15 cm <sup>3</sup> gas/m <sup>3</sup> air
	Hydrogen sulphide (H <sub>2</sub> S)	10 cm <sup>3</sup> gas/m <sup>3</sup> air
	Prohibited discharges	No toxic, corrosive, radioactive, or flammable substances; no dilution to meet limits is permitted
<b>Infrastructure Requirements</b>	Connection to sewer	Required
	Discharge point access	Must maintain clean, accessible points for inspection & sampling
	Pre-treatment infrastructure	Required
	Noise emission	
<b>Waste and hazardous streams</b>	Segregation of hazardous streams	Required for sanitary, cytotoxic and chemical waste
	Storage and containment	Proper containment for chemicals, pharmaceuticals, cytotoxics
	Waste segregation	Mandatory segregation of sanitary waste & dangerous substances
<b>Monitoring and Sampling Requirements</b>	Monitoring frequency	Defined in the discharge permit; periodic selfmonitoring required compliant to the list of parameters included
<b>Monitoring and Sampling Requirements</b>	Monitoring regulation.	The scope, parameters and frequency of analyses are determined based on the type of activity, the pollution category of the discharge, and previous compliance history.

	Monitoring scope (parameters)	regulated parameters (pH, T°, COD, BOD <sub>5</sub> , SS, oils/grease, prohibited substances, other substance incl. metals)
	Analytical methods	Must follow accredited / legally recognised methods



## 2. Baseline situation for testing site 2

Testing site 2 is a general hospital

Table 6

	Main Characteristics (data for 2024)	
	Number of installed beds	198
	Number of admissions	~12900
	Outpatient visits	~182.590
	Case mix index	N/A

### Effluent characteristics

**Number of final discharge points to municipal sewer 1 main discharge point.**

### Hydraulic parameters

Table 7

Parameter	Range/ value	Unit	Notes
<b>Yearly flow rate</b>	29.786	m <sup>3</sup> /year	Calculated from annual water use.
<b>Daily flow rate</b>	82	m <sup>3</sup> /day	Daily discharge data not available. Daily flow rate calculated on daily water consumption
<b>Seasonal flow variation</b>	No significant seasonal variation reported	–	

### General physico-chemical parameters

Table 8

Parameter	Range / value	Unit	Notes
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<b>pH</b>	7,8	–	
<b>Temperature</b>	18,8	°C	
<b>BOD<sub>5</sub></b>	91	mg O <sub>2</sub> /L	
<b>COD</b>	242	mg O <sub>2</sub> /L	
<b>Suspended solids</b>	64	mg/L	
<b>Oil/grease substances</b>	20	mg/L	

## Nutrients

Table 9

Parameter	Range / value	Unit
<b>Total nitrogen (Kjeldahl)</b>	38,4	mg/L
<b>Total phosphorus</b>	4,5	mg/L

## Metals and trace elements

Table 10

Parameter	Range / value	Unit	Notes
<b>Arsenic (As)</b>	0,006	mg/L	test data as of 08/07/2020, external analyses
<b>Chromium (Cr)</b>	0,003	mg/L	test data as of 08/07/2020, external analyses
<b>Copper (Cu)</b>	0,022	mg/L	test data as of 08/07/2020, external analyses
<b>Lead (Pb)</b>	0,008	mg/L	test data as of 08/07/2020, external analyses
<b>Nickel (Ni)</b>	0,005	mg/L	test data as of 08/07/2020, external analyses
<b>Zinc (Zn)</b>	0,094	mg/L	test data as of 08/07/2020

## Other parameters (test data as of 08/07/2020)

Table 11

Parameter	Result	Units	Note
<b>BTEX</b>	< 0.001	mg/L	External analyses
<b>1,1-Dichloroethane</b>	< 0.1	µg/L	External analyses
<b>1,2-Dichloroethene</b>	< 0.1	µg/L	External analyses
<b>Aluminium</b>	0.23	mg/L	Limit 20 mg/L , External analyses
<b>Barium</b>	0.017	mg/L	External analyses
<b>Benzene</b>	< 0.2	µg/L	External analyses
<b>Iron</b>	0.15	mg/L	Limit 10 mg/L, External analyses
<b>Formaldehyde</b>	< 0.5	mg/L	External analyses
<b>Selenium</b>	< 0.01	mg/L	External analyses
<b>Tetrachloromethane</b>	< 0.13	µg/L	External analyses
<b>Trichloroethene</b>	< 0.1	µg/L	External analyses
<b>Trichloromethane (Chloroform)</b>	12	µg/L	External analyses

### Target contaminants in the effluent

Data is not available on:

- Cytostatic contaminants content
- Representative X-ray contrast agents content
- Priority antibiotic groups content
- Priority antimicrobial-resistant bacteria (ARB) content
- Priority antimicrobial-resistant genes (ARG) content

### Baseline situation of existing wastewater management at testing site 2

Table 12

Category	Details
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<b>Existing Infrastructure</b>	<p><b>Segregation:</b> lab wastewater streams separated; no streams laundry (outsourced service), kitchen wastewater not separated, no separate drainage for rainwater; radioactive wastewater not segregated (no tanks or holding systems).</p> <p><b>Discharge points:</b> 1 main outlet with pre-screening.</p> <p><b>Pre-treatment:</b> mechanical coarse screen for larger solid fractions</p>
<b>Monitoring &amp; Control</b>	<p><b>Devices:</b> 3 inlet flowmeters,</p> <p><b>Sensors:</b> temperature &amp; pH sensors.</p> <p><b>Effluent quality monitoring:</b> full annual + quarterly analyses; Legionella &amp; metals.</p>
	<p><b>BMS:</b> compatible.</p> <p><b>Remote access need:</b> not specified</p> <p><b>Alarm /notifications need:</b> All preventing controls are manual</p>
<b>Capacity, Barriers &amp; Constraints</b>	<p><b>Staff:</b> 10 technical workers; some tasks outsourced.</p> <p><b>Capacity:</b> site for a new installation after a former WWTP area available</p> <p><b>Administrative constraints:</b> The hospital operates under strict EMAS/ISO 14001 compliance, meaning any new installation requires risk evaluation, environmental impact review, formal authorisation.</p>
<b>Wastewater &amp; Public Health</b>	Improved segregation vs other hospitals; some risk from mixed general wastewater.
<b>Space &amp; Integration</b>	Sufficient space in allocated zone. Modularity optional. Utilities fully available. No ventilation or drainage requirement.
<b>Water reuse practices and potential</b>	There's a recirculation system for the reject water from hemodialysis water treatment system. Regulatory drivers and infrastructure (separate rainwater, advanced monitoring) make it a promising candidate additionally stimulated by strong regional policy on water scarcity management, reuse obligations under current regulatory and EMAS/ISO 14001 compliance.

## Specific regulatory compliance requirements for testing site 2

Table 13

Category	Requirement / Parameter	Threshold / Obligation
<b>Discharge Limits – Physical/Chemical Parameters</b>	pH	6–10
	Temperature	≤ 40°C
	Suspended solids (SS)	750 mg/L
	BOD <sub>5</sub>	750 mg/L
	COD	1500 mg/L
	Oils & greases	250 mg/L
	Total P	50 mg/L
	Nitrates	100 mg/L (as NO <sub>3</sub> <sup>-</sup> )
	Ammonium	60 mg/L (as NH <sub>4</sub> <sup>+</sup> )
	Organic + ammoniacal nitrogen (Kjeldahl)	90 mg/L (as N)
	Prohibited discharges	No toxic, corrosive, radioactive, or flammable substances; no dilution to meet limits is permitted
<b>Infrastructure Requirements</b>	Connection to sewer	If no sewer exists within 100 m, the property owner must construct a sewer extension to connect to the network under municipal/regional guidance
	Discharge point access	Must maintain clean, accessible points for inspection & sampling
	Pre-treatment infrastructure	Not mandatory when the discharge does not comply with the applicable limits or conditions set by the authority.
	Noise emission	No information
<b>Waste and hazardous streams</b>	Segregation of hazardous streams	Required for sanitary, cytotoxic and chemical waste
	Storage and containment	Proper containment for chemicals, pharmaceuticals, cytotoxics

	Waste segregation	Mandatory segregation of sanitary waste & dangerous substances
Monitoring and Sampling Requirements	Monitoring frequency	Defined in the discharge permit; periodic selfmonitoring required
	Monitoring scope (parameters)	The discharger must ensure that wastewater continuously complies with the authorised discharge conditions and numerical limits.
	Analytical methods	Must follow accredited / legally recognised methods

### 3. Baseline situation for testing site 3

Testing site 3 is a highly specialized facility with fast diagnostics and access to consultations with high-class specialists. The hospital provides multispecialty acute care for the patients from the whole province (and beyond).

Table 14

Main Characteristics (2023 data)	
	Number of beds 458
	Number of admissions 25,000
	Outpatient visits 140,000
	Case mix index N/A

#### Effluent characteristics

**Number of final discharge points: 4**

**Hydraulic parameters**

Table 15

Parameter	Range / value	Unit	Notes
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<b>Yearly flow rate</b>	54.000	m <sup>3</sup> /year	Calculated from annual water use
<b>Daily flow rate</b>	~150	m <sup>3</sup> /day	Daily discharge data not available. Daily flow rate calculated on daily water consumption
<b>Seasonal variation</b> <b>flow</b>	Not reported	–	

## General physico-chemical parameters

Table 16

Parameter	Range / value	Unit	Notes
<b>pH</b>	7,5	–	
<b>Temperature</b>	18-20	°C	
<b>BOD<sub>5</sub></b>	1000	mg O <sub>2</sub> /L	
<b>COD</b>	1830	mg O <sub>2</sub> /L	
<b>Suspended solids</b>	700	mg/L	
<b>Oil/grease substances</b>	-	–	

## Nutrients

Table 17

Parameter	Range / value	Unit
<b>Total nitrogen</b>	118	mg/L
<b>Total phosphorus</b>	9,9	mg/L

## Metals and trace elements\*)

Table 18

Parameter	Range / value	Unit	Notes
<b>Zinc (Zn)</b>	0,3	mg/L	

## Other parameters (specify)

Table 19

Parameter	Range / value	Unit	Notes
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<b>Chloride concentration</b>	4173	mg/l	Data for the dialysis station effluent only
<b>Total iron concentration</b>	0,02	mg/l	Data for the dialysis station effluent only

### Target contaminants in the effluent

No data available on:

- Cytostatic contaminants content
- Representative X-ray contrast agents' content
- Priority antibiotic groups content
- Priority antimicrobial-resistant bacteria (ARB) content
- Priority antimicrobial-resistant genes (ARG) content

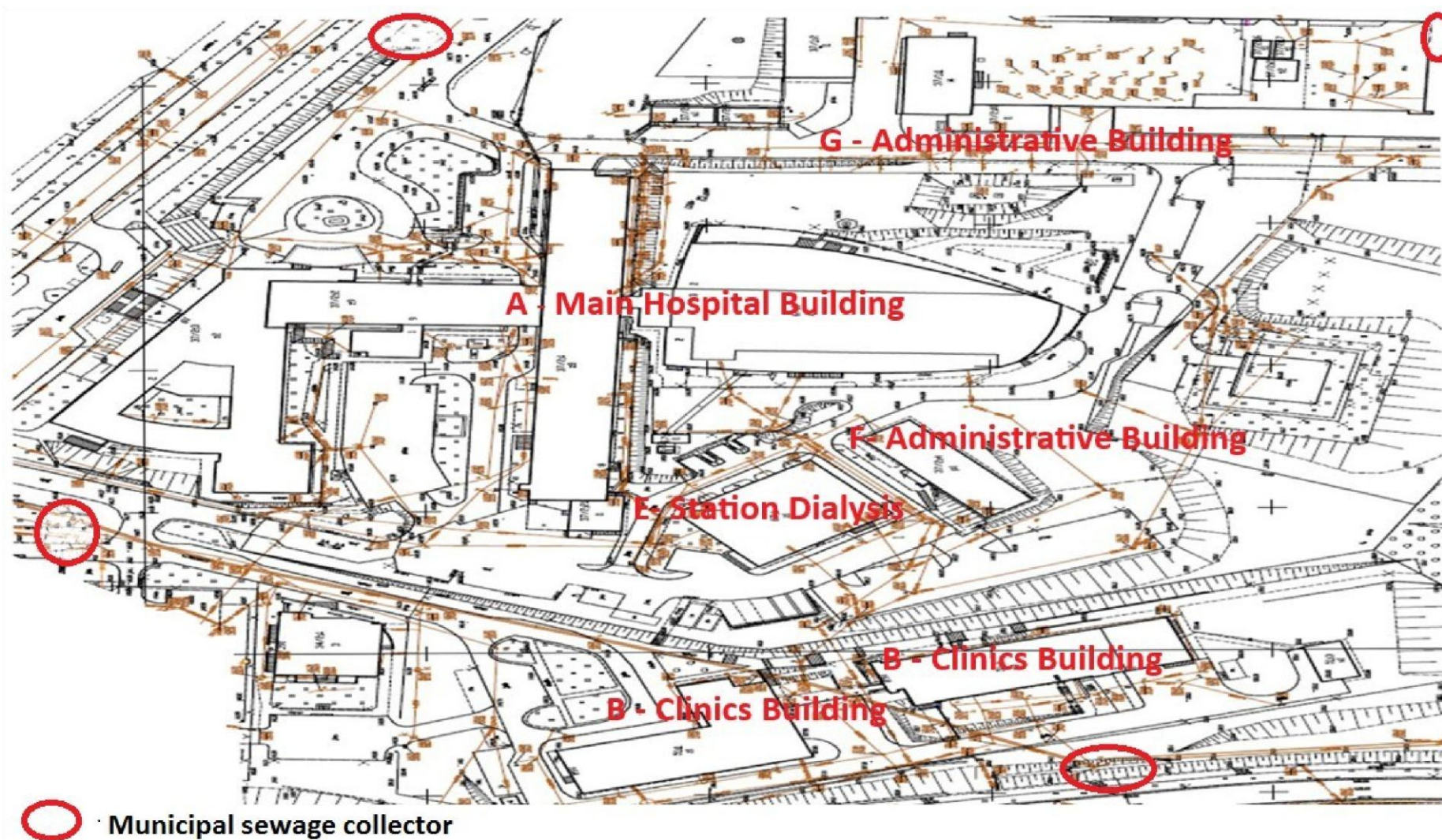
### Baseline situation of existing wastewater management at testing site 3

Table 20

Category	Details
<b>Existing Infrastructure</b>	<p><b>Segregation:</b> separate drainage system for rainwater, mixed system for lab, kitchen and laundry wastewater. Both sewage and rainwater system are gravity systems. No separation of radioactive</p>
	<p>stream. No septic tanks or retention tanks for laboratory / radioactive wastewater streams.</p> <p><b>Discharge points:</b> 4.</p> <p><b>Pre-treatment:</b> none.</p>
<b>Monitoring &amp; Control</b>	<p><b>Devices:</b> water inlet flowmeter.</p> <p><b>Sensors:</b> none reported.</p> <p><b>Effluent quality monitoring:</b> none reported.</p> <p><b>BMS:</b> none.</p> <p><b>Remote access need:</b> not reported.</p> <p><b>Alarms/notification need:</b> not reported</p>

<b>Capacity, Barriers &amp; Constraints</b>	<p><b>Staff:</b> all maintenance outsourced (external contractors for technical systems) limited operator availability, no maintenance skills, no monitoring capabilities</p> <p><b>Barriers:</b> space/technical limitations: power supply, noise, vibration, safety, access)</p> <p><b>Constraints:</b> ·Access restrictions to delivery/installation (doors, corridors, basement, roof access), time constraints related to operation (night shift, quiet hours)/noise constraints, odour constraints.</p> <p>Supply and exhaust ventilation required for a container system.</p> <p>Lack of segregation and four separate discharge points, making centralised treatment difficult.</p>
<b>Wastewater &amp; Public Health</b>	<p>No High-risk from mixed streams reported; physical waste (wipes, solids) may be problematic.</p> <p>No separate tanks or storage systems for radioactive wastewater</p>
<b>Space &amp; Integration</b>	<p>General constraints likely; modularity beneficial. Weather resistance requested. System must be secured against unauthorized access.</p> <p>Utilities available: ·electrical power (available power, voltage) – 7.5 kW, connection to the water supply network possible at a distance of 50 m, water supply connection possible at a distance of 50 m.</p>
<b>Water reuse practices and potential</b>	<p>Reuse is not yet practiced</p>

## Overview of testing site 3 sewage system



### Specific regulatory compliance requirements for PCP THERESA at testing site 3

Table 21

Category	Requirement / Parameter	Threshold / Obligation
Discharge Limits – Physical/Chemical Parameters	pH	6–9.5
	Temperature	≤ 35°C
	Suspended solids (SS)	Information not available
	BOD <sub>5</sub>	Information not available
	COD	Information not available
	Oils & greases	Information not available
	Prohibited discharges	No toxic, corrosive, radioactive, or flammable substances; no dilution to meet limits is permitted
Infrastructure Requirements	Connection to sewer	Obligatory
	Discharge point access	Must maintain clean, accessible points for inspection & sampling
	Pre-treatment infrastructure	Where wastewater exceeds permissible levels, the utility may require pre-treatment or corrective action as specified in the detailed regulation or contractual conditions
	Noise emission	Information not available
Waste and hazardous streams	Segregation of hazardous streams	Required for sanitary, cytotoxic and chemical waste
	Storage and containment	Proper containment for chemicals, pharmaceuticals, cytotoxics
	Waste segregation	Mandatory segregation of sanitary waste & dangerous substances

Monitoring and Sampling Requirements	Monitoring frequency	Periodic sampling and analysis of wastewater quality (e.g., physical and chemical parameters), but specific parameters and frequencies are set by detailed conditions in the service agreement.
	Monitoring scope (parameters)	regulated parameters defined in permit
	Analytical methods	Must follow accredited / legally recognised methods

## 4. Baseline situation for testing site 4

Testing site 4 is a centre committed to sustainability, having signed the National Green Deal (3.0) to implement actions that reduce the emission of medicines into surface waters, reduce CO<sub>2</sub> emissions from buildings, energy and transport, promote use of renewable raw materials (bio-based) and resource efficiency.

Table 22

	Main Characteristics (2023 data)	
	Number of beds	546
	Number of admissions	163.681
	Outpatient visits	24.715 >393.200 polyclinic consultations
	Case mix index	

### Effluent characteristics

**Number of final discharge points: 1 main discharge point +2 auxiliary points**

**Hydraulic parameters**



Table 23

Parameter	Range/ value	Unit	Notes
<b>Yearly flow rate</b>	120.000	m <sup>3</sup> /year	Calculated from annual water use: 160.000 m <sup>3</sup> / year about 40.000 for cooling (evaporates) thus 120.000 m <sup>3</sup> in sewage
<b>Daily flow rate</b>	300-450	m <sup>3</sup> /day	Daily discharge data not available. Daily flow rate calculated on daily water consumption
<b>Seasonal flow variation</b>		–	In summer extra water used for cooling. Rainwater is not separated and may influence the hospital sewage flow considerably.)

## General physico-chemical parameters

Table 24

Parameter	Range / value	Unit	Notes
<b>pH</b>	N/A	–	
<b>Temperature</b>	20-30	°C	
<b>BOD<sub>5</sub></b>	N/A	mg O <sub>2</sub> /L	
<b>COD</b>	N/A	mg O <sub>2</sub> /L	
<b>Suspended solids</b>	N/A	mg/L	
<b>Oil/grease substances</b>	N/A	–	

**Nutrients:** No data available

**Metals and trace elements:** No data available as there is no regulatory requirement to measure them

**Other parameters (specify):** No data available

Target contaminants in effluent

Cytostatic contaminants content

Table 25

ATC Code	Active substance	Pharmacological group/mode of action	Content in effluent	Data source (measurement, estimation provided based on use data*) µg/L
L01AA06	Ifosfamide	Alkylating agent		5,4
L01AX03	Temozolomide	Alkylating agent		4,3
L01AA01	Cyclophosphamide	Alkylating agent		18,6
L02BB04	Enzalutamide	Androgen receptor antagonist		13,3
L01BC02	Fluorouracil	Antimetabolite		28,5
L01BA01	Methotrexate	Antimetabolite		2,9
L02BX03	Abiraterone	Steroid hormone synthesis inhibitor		229,2
L04AA06	Mycophenolate	Immunosuppressant, anti-proliferative		246,1
L01XA01	Cisplatin	Platinum-containing agent		0,7
L01XA02	Carboplatin	Platinum-containing agent		3,3
L01XA03	Oxaliplatin	Platinum-containing agent		0,7
L01BC01	Cytarabine	Antimetabolite		6,3
L01BC05	Gemcitabine	Antimetabolite		11,5
L01XX05	Hydroxycarbamide	Antimetabolite		266,3
L01BC06	Capecitabine	Antimetabolite (prodrug of fluorouracil)		262,4



L01EX02	Sorafenib	Kinase inhibitor (BRAF-VEGFR)		0,7
L01EM03	Alpelisib	PI3-kinase inhibitor		14,5
L01ED03	Alectinib	Tyrosine kinase inhibitor (ALK)		90,6

\*) NOTE: the estimate in micrograms/Liter is a maximum number assuming that

- 1) all dispensed agents are administered to patients
- 2) all patients are hospitalized and do not go home
- 3) there is no metabolism of parent compounds in the patient or sewage system
- 4) the administration is gradual over time

The data should be corrected for non-compliance, number of ambulant patients, fractional absorption (oral availability / iv administration) of parent compound. Metabolism of parent compound (in human body) or occurrence of transformation products in sewage. Most drugs enter the sewage during the hours the clinics are active. At night medicines from hospitalized patients enter via the urine (the flow is much lower then).

Note that time corrected samples of the sewage of the testing site 4 over 4 working are available for chemical analysis to determine the real concentration of the active substances. The same applies to testing site 7.

### Representative X-ray contrast agents content

Table 26

Modality	Active substance	Description / note	Content in effluent µg/L	Data source
V08AB05	Iopromide (CT)	Iodinated X-ray contrast agent	14509	<b>Estimation provided based on use data.</b>
V08AB02	Iohexol (CT)	Iodinated X-ray contrast agent	45	
V08CA09	Gadobutrol (MRI)	Gadolinium-based MRI contrast agent	541	

### Priority antibiotic groups content

Table 27

ATC Code	Sub-group description	Content in effluent Micrograms / Liter	Data source
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J01CA	Penicillins with extended spectrum	72,8	<b>Estimation provided based on use data: totalled values for antibiotic groups</b>
J01CE	Beta-lactamase-sensitive penicillins	6,4	
J01CF	Beta-lactamase-resistant penicillins	206,7	
J01CR	Combinations incl. beta-lactamase inhibitors	N/A	
J01DD	3rd-generation cephalosporins	261,1	
J01DH	Carbapenems	86,7	
J01FA	Macrolides	4,0	
J01MA	Fluoroquinolones	62,5	
J01XA	Glycopeptide antibacterials	65,9	

### Priority antimicrobial-resistant bacteria (ARB) content

Data not available

### Priority antimicrobial-resistant genes (ARG) content

Data not available

### Baseline situation of existing wastewater management testing site 4

Testing site 4 operates as a single hospital with multiple *functional zones*, but wastewater infrastructure is mainly centralised. There are two buildings where most hospitalized patients are bedded. The sewage pipes of these building converge at one point. There is another building where all MRI imaging takes place and this has sewage that enters the municipal system at another location.

It is important to mention that the wastewater of testing site 4 flows to a small WasteWater Treatment Plant, about 2.5 km away. This is a small WWTP that on dry weather conditions processes 13.000 m<sup>3</sup> water/day. Testing site 5 has a major contribution to the emission of medicines in that WWTP. The WWTP allows flow-dependent 24-h sampling of influent to verify the magnitude of effect (e.g. reduction of emissions of targeted medicines) induced by solutions/interventions taken at the hospital.

Table 28

Category	Details
<b>Existing Infrastructure</b>	<p><b>Segregation:</b> some radioactive wastewater separated into dedicated holding tanks. Some radioactive tracers with short half-life that are used for diagnostics such as <sup>18</sup>F-fluorodeoxyglucose are allowed to enter the sewage. No separate drainage system for rainwater. Other wastewater (lab, kitchen) mixed.</p> <p><b>Discharge points:</b> 1 main + 2 auxiliary outlets.</p> <p><b>Pre-treatment:</b> grease interceptors, plaster trap (at plaster room and the Emergency Department / First Aid) amalgam separator / Oral and Maxillofacial Surgery Outpatient Clinic), oil and grease separator is situated near the waste park, grease filter in sewage pipe from kitchen discharge</p>
<b>Monitoring &amp; Control</b>	<p><b>Devices:</b> inlet water flowmeters,</p> <p><b>Sensors:</b> No sensors in the sewage system. Temperature sensors installed only for inlet water (legionella control).</p> <p>Reports on these measurements (flow and drinking water temperature) are available from the so-called energy control system on request. <b>Monitoring:</b> Legionella monitoring in drinking water systems.</p> <p><b>BMS:</b> full integration, 24/7 preferably real time, but for normal control, daily readouts suffice.</p> <p><b>Remote access need:</b> not reported</p> <p><b>Alarm/notification needs:</b> daily</p> <p><b>Other:</b> In some buildings automated flush systems are installed to reduce the temperature of drinking water to 20°C if it gets higher than 25°C</p>

<b>Capacity, Barriers &amp; Constraints</b>	<p><b>Staff:</b> 50 FTE facility team; maintenance outsourced.</p> <p><b>Space constraints:</b> Severe outdoor space limitation: only 6×8m near the main sewage pit outside the hospital for a centralised solution.</p> <p><b>Barriers:</b> High cooling-water flows may influence wastewater hydraulics. Evaporation-related losses of water due to cooling (~60% of water input) complicate flow prediction and treatment sizing.</p> <p>If solution is outside: no water supply connection, No electricity connection</p>
	<p>If solution is inside on department level, connections to water / electricity are possible.</p> <p>All new constructions on the outside require permission regarding noise, vibration, safety, odour, access for ambulance etc. Also, permission of municipality is required.</p>
<b>Wastewater &amp; Public Health</b>	Radioactive wastewater separately collected if radioactivity above permissible limits for discharge; mixed only if below the limits, general HWW mixed.
<b>Space &amp; Integration</b>	<p>Installation must not obstruct emergency routes, patient transport corridors, medical logistics pathways. Compact modular units strongly preferred.</p> <p>Indoors (small rooms) are available for decentralized systems</p> <p>Main sewer connection points: 6 meters away from the building, 4 meters deep, partly on the emergency route</p>
<b>Water reuse practices and potential</b>	Reuse is not yet practiced, no extra greywater reuse system installed.

## Specific regulatory compliance requirements for THERESA PCP solutions for Testing site 4

Table 29

Category	Requirement / Parameter	Threshold / Obligation
Discharge Limits – Physical/Chemical	pH	Not required
	Temperature	Not required

<b>Parameters</b>	Suspended solids (SS)	Not required
	BOD <sub>5</sub>	Not required
	COD	Not required
	Oils & greases	Grease filter installed
	Prohibited discharges	No radioactive, or flammable substances in discharge; no dilution to meet limits is permitted
<b>Infrastructure Requirements</b>	Connection to sewer	Required
	Discharge point access	Must maintain clean, accessible points for inspection & sampling
	Pre-treatment infrastructure	Must remove toilet paper / tissue and all large organic content
	Noise emission	Should not exceed normal requirements
<b>Waste and hazardous streams</b>	Segregation of hazardous streams	If the materials are solids, they should be collected in special bins (to be incinerated)
	Storage and containment	Proper containment for chemicals, pharmaceuticals, cytotoxics
	Waste segregation	Mandatory segregation of sanitary waste & dangerous substances
<b>Monitoring and Sampling Requirements</b>	Monitoring frequency	There are no discharge requirements, monitoring performed on a yearly basis for calculation of discharge fees
	Monitoring scope (parameters)	The installed solutions should work simple and be more or less sustainable and need little maintenance
	Analytical methods	Must follow accredited / legally recognised methods

## 5. Baseline situation for testing site 5

Testing site 5 provides comprehensive general and highly specialized care, including complex medical and surgical services, advanced diagnostics, emergency care, and intensive care. Testing site 5 operates across three centres

Table 30

Main Characteristics	
Number of beds	1077 520 HUN-A / 450 HVC-B / 107 CU-C
Number of admissions	~42.000
Outpatient visits	~780.000
Case mix index	

### Effluent characteristics

**Number of discharge points:** Several discharge connections depending on building.

**Main center:** 3 main collectors, but the discharge point to the municipal network is **a single one**.

There is no flow or discharge volume monitoring. The discharge rate is estimated based on the water consumed.

### Hydraulic parameters

Table 31

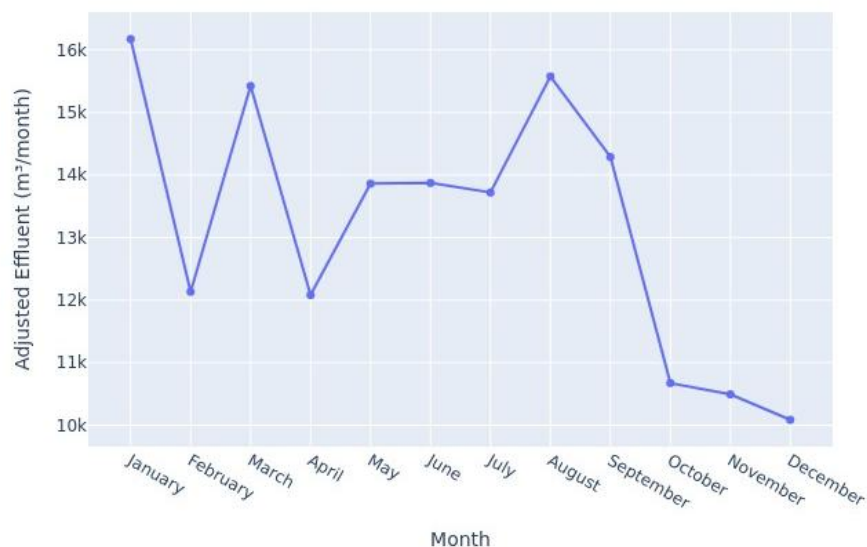
Parameter	Range/ value	Unit	Notes
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<b>Yearly flow rate</b>	163.982	m <sup>3</sup> /year	Calculated from annual water use. The annual effluent was calculated by multiplying the hospital's annual water consumption by the estimated percentage that becomes wastewater (87% after adjusting for losses and climate)
<b>Daily flow rate</b>	449	m <sup>3</sup> /day	Daily discharge data not available. Daily flow rate calculated on daily water consumption
<b>Seasonal flow variation</b>	Reported, see table below	–	

This table shows the seasonal variation of effluent for main center, calculated from monthly water consumption and adjusted for precipitation. It includes monthly effluent (m<sup>3</sup>) and its daily equivalent (m<sup>3</sup>/day):

Table 32

Month	Water Consumption (m <sup>3</sup> )	Adjusted Effluent (m <sup>3</sup> )	Daily Effluent (m <sup>3</sup> /day)
January	19.220	16.172,26	539,08
February	14.470	12.134,13	404,47
March	18.360	15.422,40	514,08
April	14.310	12.081,73	402,72
May	16.390	13.861,26	462,04
June	16.600	13.872,86	462,43
July	16.530	13.719,90	457,33
August	18.700	15.574,43	519,15
September	16.980	14.287,46	476,25
October	12.560	10.676,00	355,87
November	12.390	10.496,10	349,87
December	11.970	10.089,00	336,30



### General physico-chemical parameters

Key parameters that are typically measured but they are not subject to mandatory monitoring include: pH, temperature, COD, suspended solids, oil and grease substances content.

Data for other parameters is not available. Although the information is not available yet, water analysis is expected to be performed in the following months. The table below presents data from another hospital under testing site 5. The data provided in the table is for indicative purposes only.

**Nutrients:** ammoniacal nitrogen, data for other parameters is not available.

**Metals and trace elements:** mercury (Hg), data for other parameters is not available.

**Other parameters:** formaldehyde, toxicity by inhibition of V.Fischeri, conductivity.

Table 33

Parameter	Range / value	Unit	Notes
<b>pH</b>	8,4	–	
<b>Temperature</b>	No information currently available	°C	
<b>BOD<sub>5</sub></b>	No information currently available	mg O <sub>2</sub> /L	
<b>COD</b>	1060	mg O <sub>2</sub> /L	
<b>Suspended solids</b>	203	mg/L	
<b>Oil/grease substances</b>	49	–	



**Nutrients:** Ammoniacal nitrogen: 0,62 mg/L **Metals and trace elements:** Mercury: <0,10 µg/L

**Other parameters (specify):**

Conductivity at 20C: 554 uS/cm

Formaldehyde: <0,50 mg/L

Toxicity by inhibition of V.Fischeri: 3,7 U.T.

### Target contaminants in effluent

Only approximate estimations available, although with significant limitations. Estimation provided is based on the approach/assumptions:

1. **Drug consumption** (amount administered in the hospital over a given period). This figure corresponds to testing site 5 as a whole, therefore these numbers are approximate and should be revised in future to refine them accurately.
2. **Apply the percentage of the active ingredient excreted unchanged** (pharmacokinetic data, usually found in the drug's technical sheet or scientific literature).
3. **Consider the fraction that reaches the sewer system** (almost all excreted material, except what is retained in solid waste).
4. **Dilute in the estimated effluent volume** (m<sup>3</sup>/day) to calculate a theoretical concentration.

The basic formula is:

$$\text{Estimated concentration (mg/L)} = \frac{\text{Consumption (mg/day)} \times \text{Excreted fraction}}{\text{Effluent volume (L/day)}}$$

### Limitations:

- Does not account for active metabolites, degradation, or removal in internal processes.
- Ignores variability among patients, incomplete treatments, and retention in sludge.
- It is only a theoretical approximation

### Cytostatic contaminants content

Table 34

ATC Code	Active substance	Pharmacological group/mode of action	Content in effluent	Estimated concentration (mg/L)	Consumption in 2024 (g/year)
L01AA06	Ifosfamide	Alkylating agent	N/A	0.0009	978,00
L01AX03	Temozolomide	Alkylating agent	N/A	0.0002	546,04



L01AA01	Cyclophosphamide	Alkylating agent	N/A	0.0011	1.231,80
L02BB04	Enzalutamide	Androgen receptor antagonist	N/A	0.0008	2.682,04
L01BC02	Fluorouracil	Antimetabolite	N/A	0.0039	5.843,05
L01BA01	Methotrexate	Antimetabolite	N/A	0.0024	495,00
L02BX03	Abiraterone	Steroid hormone synthesis inhibitor	N/A	0.0106	34.854,00
L04AA06	Mycophenolate	Immunosuppressant, anti-proliferative	N/A	0.0011	3.488,28
L01XA01	Cisplatin	Platinumcontaining agent	N/A	0.0000	69,25
L01XA02	Carboplatin	Platinumcontaining agent	N/A	0.0003	912.51
L01XA03	Oxaliplatin	Platinumcontaining agent	N/A	0.0001	264.93
L01BC01	Cytarabine	Antimetabolite	N/A	0.0007	731.59
L01BC05	Gemcitabine	Antimetabolite	N/A	0.0009	2,990.20
L01XX05	Hydroxycarbamide	Antimetabolite	N/A	0.0003	846.00
L01BC06	Capecitabine	Antimetabolite (prodrug of fluorouracil)	N/A	0.0195	64,016.55
L01EX02	Sorafenib	Kinase inhibitor (BRAF-VEGFR)	N/A	0.0002	660.20
L01EM03	Alpelisib	PI3-kinase inhibitor	N/A	0.0000	121.80
L01ED03	Alectinib	Tyrosine kinase inhibitor (ALK)	N/A	0.0009	3,083.40

### Representative X-ray contrast agents content



Table 35

Modality	Active substance	Description / note	Content in effluent	Estimated concentration (mg/L)	Consumption in 2024 (g/year)
V08AB05	Iopromide	Iodinated X-ray contrast agent	N/A	2,40	393,976.00
V08AB02	Iohexol	Iodinated X-ray contrast agent	N/A	0,11	20,400.00
V08CA09	Gadobutrol	Gadolinium-based MRI contrast agent	N/A	0,23	38,264.38

### Priority antibiotic groups content

Table 36

ATC Code	Sub-group description	Content in effluent	Estimated concentration (mg/L)	Consumption in 2024 (g/year)
J01CA	Penicillins with extended spectrum	N/A	0.0695	18.975,25
J01CE	Beta-lactamase-sensitive penicillins	N/A	0.0103	3.361,32
J01CF	Beta-lactamase-resistant penicillins	N/A	0.0198	10.820,50
J01CR	Combinations incl. betalactamase inhibitors	N/A	1.6242	532.374,45
J01DD	3rd-generation cephalosporins	N/A	0.1799	89.343,63
J01DH	Carbapenems	N/A	0.1863	50.894,09
J01FA	Macrolides	N/A	0.0047	5.080,48
J01MA	Fluoroquinolones	N/A	0.0540	17.698,45
J01XA	Glycopeptide antibacterials	N/A	0.0288	5.909,35

**Priority antimicrobial-resistant bacteria (ARB) content:** data not available



**Priority antimicrobial-resistant genes (ARG) content:** data not available

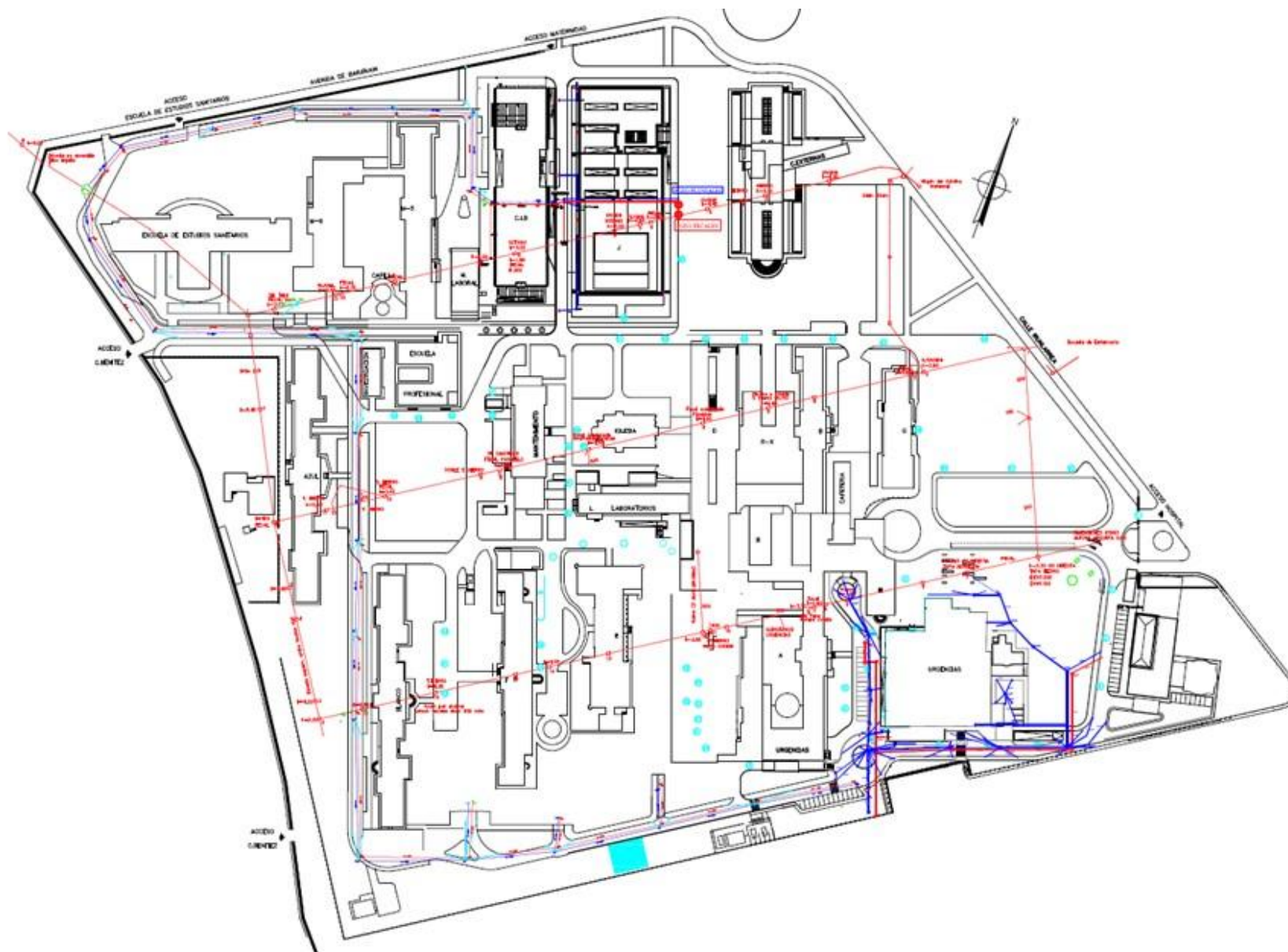
## Baseline situation of existing wastewater management in testing site 5

Table 37

Category	Details
<b>Existing Infrastructure</b>	<p><b>Segregation:</b> separate drainage system for rainwater; however, typically both wastewater and rainwater systems merge at the discharge points to the municipal sewage network.</p>
	<p>Infrastructure outdated, separation of rainwater and wastewater flows is limited.</p> <p>Radioactive wastewater collected separately in dedicated holding tanks to lose radioactivity, then discharged to wastewater system. Dedicated contaminated water collection tank for emergency situations (patient decontamination) at Emergency Department, handled if needed to an authorized handler. separate drums for subsequent management of lab wastewater available but used only if required. Otherwise, streams mixed except for. kitchen wastewater with a separate discharge directly to municipal sewer. No laundry wastewater (service outsourced).</p> <p><b>Discharge points:</b> multiple building-specific connections.</p> <p><b>Pre-treatment:</b> none except isolated hazard systems for radioactive wastewater</p>
<b>Monitoring &amp; Control</b>	<p><b>Devices:</b> water inlet flowmeters</p> <p><b>Sensors:</b> chlorine sensors for inlet water (at the softening station)</p> <p><b>Effluent monitoring:</b> no monitoring reported.</p> <p><b>BMS:</b> not integrated.</p> <p><b>Remote access need:</b> remote integration to enable operational control from the Maintenance department without requiring onsite access.</p> <p><b>Alarms and notification needs:</b> daily but no real-time required.</p>

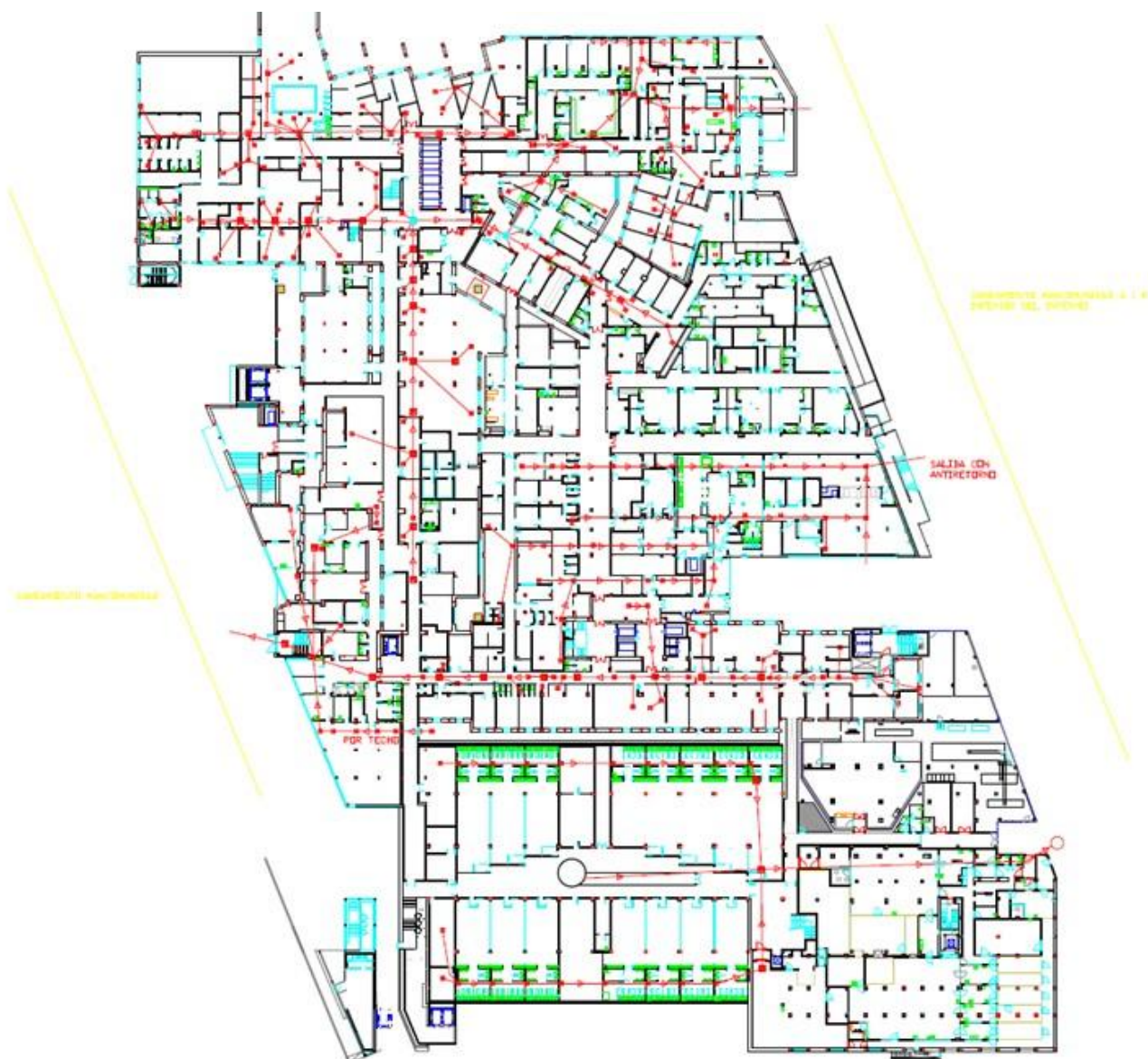
<b>Capacity, Barriers &amp; Constraints</b>	<p><b>Staff:</b> large in-house team (12 plumbers/mechanical + other specialists).</p> <p><b>Construction barriers:</b> Collector depth at 6 meters, making connection of decentralised treatment modules technically difficult. Multiple discharge points across 3 centres makes complex hydraulics.</p> <p>Noise and odour constraints.</p> <p><b>Administrative barriers:</b> any outdoor installation requires Navarra municipal approval.</p> <p>Other: Noise limit.</p>
<b>Wastewater &amp; Public Health</b>	<p>Need for watertight and odour-tight installations to prevent the proliferation of insects, rodents, or other types of pests. Physical waste may be a recurrent challenge.</p>
<b>Space &amp; Integration</b>	<p>Outdoor installation preferred. Outdoor space available although limited; depth of collectors problematic ( 6 m). Modularity advantageous due to distributed campuses. Utilities present but may require long cabling.</p> <p>The future installation should include solar panels or another renewable energy source to operate autonomously, with the hospital's grid supply used as backup or during nighttime hours.</p>
<b>Water reuse practices and potential</b>	<p>Currently no reuse practices, potential due to irrigation of green areas for which potable water is currently used.</p>

## Sanitary Sewer System - center 1





## Sanitary Sewer System Layout – center 2



Specific regulatory compliance requirements for PCP THERESA solution for testing site 5



Table 38

Category	Requirement / Parameter	Threshold / Obligation
<b>Discharge Limits – Physical/Chemical Parameters</b>	pH	5.5-9.5
	Temperature	Máx. 40°C
	Suspended solids (SS)	
	BOD <sub>5</sub>	BOD5/COD Relation : 0,3
	COD	
	Oils & greases	40
	Prohibited discharges	No toxic, corrosive, radioactive, or flammable substances; no dilution to meet limits is permitted
<b>Infrastructure Requirements</b>	Connection to sewer	Obligatory
	Discharge point access	Must maintain clean, accessible points for inspection & sampling
	Pre-treatment infrastructure	No information provided
	Noise emission	
<b>Waste and hazardous streams</b>	Segregation of hazardous streams	Required for sanitary, cytotoxic and chemical waste
	Storage and containment	Proper containment for chemicals, pharmaceuticals, cytotoxics
	Waste segregation	Mandatory segregation of sanitary waste & dangerous substances
<b>Monitoring and Sampling Requirements</b>	Monitoring frequency	Defined in the discharge permit; periodic selfmonitoring required
	Monitoring scope (parameters)	No information provided



	Analytical methods	Must follow accredited / legally recognised methods
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## 6. Baseline situation for testing site 6

Testing site 6 was established in 2001. And is a teaching hospital and an eager user of latest technology and new solutions Hospital is located in **Northern climatic conditions**. Winter wastewater temperatures drop to **10–15°C**, affecting biological and chemical reaction kinetics. Systems must maintain performance despite seasonal temperature fluctuations.

Table 39

Main Characteristics	
Number of beds	1259
Number of admissions	38 205
Outpatient visits	~690 000
Case mix index	1,73

### Effluent characteristics

**Number of final discharge points: 14**

### Hydraulic parameters

Table 40

Parameter	Range/ value	Unit	Notes
<b>Yearly flow rate</b>	86.970	m <sup>3</sup> /year	Calculated from annual water use.
<b>Daily flow rate</b>	~238	m <sup>3</sup> /day	Daily discharge data not available. Daily flow rate calculated on daily water consumption
<b>Seasonal flow variation</b>	Some peaks in Jan-August	–	Peaks due to higher water consumption in this period

### General physico-chemical parameters

Table 41

Parameter	Range / value	Unit	Notes
<b>pH</b>	8-8.5	–	Norm: 6,5-8,5
<b>Temperature</b>	20	°C	May drop to 10–15°C in wintertime
<b>BOD<sub>7</sub></b>	130-270	mg O <sub>2</sub> /L	Norm: 375
<b>COD</b>	N/A	mg O <sub>2</sub> /L	
<b>Suspended solids</b>	140-180	mg/L	Norm 500
<b>Oil/grease substances</b>	18-230	–	Norm 50

## Nutrients

Table 42

Parameter	Range / value	Unit	Notes
<b>Total nitrogen</b>	111-114	mg/L	Norm:125
<b>Total phosphorus</b>	10,6-11,2	mg/L	Norm 15

**Metals and trace elements** No data available

**Other parameters:** No data available

## Target contaminants in effluent

The effluent has moderate pharmaceutical load, including cytostatics (oncology department), antibiotics (ICU, surgery), and contrast agents (diagnostic imaging).

**No data is however available for:**

- Cytostatic contaminants content
- Representative X-ray contrast agents content
- Priority antibiotic groups content
- Priority antimicrobial-resistant bacteria (ARB) content
- Priority antimicrobial-resistant genes (ARG) content

## Baseline situation of existing wastewater management

Table 43

Category	Details
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<b>Existing Infrastructure</b>	<p><b>Segregation:</b> rainwater separated. The hospital currently does not segregate wastewater streams meaning all pharmaceutical, laboratory, kitchen, and patient care</p>
	<p>wastewater is mixed before discharge. No laundry effluent (service outsourced). No separate collection of radioactive wastewater</p> <p><b>Discharge points:</b> The hospital's internal sewerage system consists of <b>14 separate channels</b> that converge and discharge into the municipal sewer collector. All wastewater generated by the hospital ultimately passes through a single main sewerage outlet located adjacent to the hospital premises on land owned by the municipality.</p> <p><b>Pre-treatment:</b> minimal basic pre-treatment 3 grease traps for kitchen wastewater</p>
<b>Monitoring &amp; Control</b>	<p><b>Devices:</b> Water inlet flowmeters</p> <p><b>Sensors:</b> temperature &amp; pressure of inlet water only.</p> <p><b>Effluent Monitoring:</b> No direct wastewater monitoring, volumes, flows rely on water consumption data, quarterly wastewater tests by municipal operator for basic parameters .</p> <p><b>BMS:</b> integration with the existing BMS system is needed; the solution must be compatible with BAcnetIP or ModbusRTU network protocols</p> <p><b>Cybersecurity:</b> All external remote access connections must comply with the controls and measures defined in the ISO/IEC 27000 series or the E-ITS standards.</p> <p><b>Alarm/notifications need:</b> Real-time</p>



<b>Capacity, Barriers&amp; Constraints</b>	<p><b>Staff:</b> 6 specialists available during working-hours. 6 technical specialists with expertise in facility management, but limited on-site intervention capacity for complex wastewater systems. Routine maintenance must be simple and infrequent (weekly or monthly tasks, not daily). Hospital staff can perform basic checks (refill chemicals, clean sensors), but complex troubleshooting requires external contractors</p> <p><b>Barriers:</b> very restricted indoor space (1.5–4 m<sup>2</sup> toilet rooms); outdoor installations require Tallin City and Municipal Wastewater Utility's permits.</p> <p>Administrative: hospital implements EITS, therefore if any software is used, the software solution must comply with the ISO 27 000 or EITS standard. Vibration is not allowed.</p> <p>Indoor noise level must be between 35-40 dB.</p> <p>Only standard toilet exhaust ventilation is available.</p>
<b>Wastewater &amp; Public Health</b>	<p>Kitchen wastewater is not separated, but outlets have it's own pipes leading to certain discharge points which have grease traps</p> <p>High-risk streams mixed</p>
<b>Space &amp; Integration</b>	<p>Indoor installation has to fit to very limited space.</p> <p>Outdoor installation requires city permit. Strong requirement for modular, compact units.</p>
<b>Water reuse practices and potential</b>	<p>No current reuse systems</p>

### Specific regulatory compliance requirements for PCP THERESA solutions at testing site 6

Table 44

Category	Requirement / Parameter	Threshold / Obligation
Discharge Limits – Physical/Chemical Parameters	pH	6,5–8.5
	Temperature	No information
	Suspended solids (SS)	500 mg/L

	BOD <sub>5</sub>	375 mg/L
	COD	750 mg/L
	Petrochemicals	5,5 mg/L
	Total N	125 mg/L
	Total P	15 mg/L
	Polar hydrocarbons	50 mg/L
	Monohydric phenols	2,9 mg/L
	Surfactants	44 mg/L
	Prohibited discharges	No toxic, corrosive, radioactive, or flammable substances; no dilution to meet limits is permitted
<b>Infrastructure Requirements</b>	Connection to sewer	Obligatory
	Discharge point access	Must maintain clean, accessible points for inspection & sampling
	Pre-treatment infrastructure	Required only if limits exceeded.
	Noise emission	No information available
<b>Waste and hazardous streams</b>	Segregation of hazardous streams	Required for sanitary, cytotoxic and chemical waste
	Storage and containment	Proper containment for chemicals, pharmaceuticals, cytotoxics
	Waste segregation	Mandatory segregation of sanitary waste & dangerous substances
<b>Monitoring and Sampling Requirements</b>	Monitoring frequency	Primary responsibility lies with the sewer operator, Monitoring is based on periodic sampling and laboratory analysis, no frequency specified.

	Monitoring scope (parameters)	Parameters covered: pH, TSS, BOD <sub>7</sub> / COD, oils and petroleum products, Total N, Total P, surfactants and phenols (where relevant)
	Analytical methods	Must follow accredited / legally recognised methods

## 7. Baseline situation for testing site 7

Testing site 7 is a network of 11 Campus Hospitals. With 3,200 beds and 10,000 employees, testing site 7 is one of the largest hospital in Europe.

Table 45

Main Characteristics		
	Number of beds	3.200
	Number of admissions	79.000
	Outpatient visits	120.000 > 1 million consultations
	Case mix index	N/A

The most detailed characteristics of the effluent is available for center 6 (discharge points to sewer: suppliers, driveway car park and main entrance), center 2 (discharge points to sewer: main sewer, discharge to sewer from laboratory building, discharge to sewer from outpatient clinic) and center 4 (discharge points 4,5,6).

### Effluent characteristics

**Number of discharge points: 16+ distributed across campuses**

**Hydraulic parameters**

Table 46

Parameter	Overall range	Unit	Notes
<b>Yearly flow rate</b>	~3.066 ~291.467	– m <sup>3</sup> /year	Lowest: Center 4 discharge point 5 psych Y; Highest: Center 2 main sewer
<b>Daily flow rate</b>	8,40 – 798,54	m <sup>3</sup> /day	
<b>Seasonal flow variation</b>	Not quantified	–	

### General physico-chemical parameters

Table 47

Parameter	Overall range	Unit	Notes
<b>pH</b>	~7 (stable)	–	No measurable variation reported
<b>Temperature</b>	1,40 – 6,6	°C	
<b>BOD<sub>5</sub></b>	3,5 – 1000	mg O <sub>2</sub> /L	Lowest: Center 1; Highest: Center 4 - discharge point 4 psych h
<b>COD</b>	26 – 1520	mg O <sub>2</sub> /L	Strong inter-site variability
<b>Suspended solids</b>	5,2 – 300	mg/L	Highest at Center 4 - discharge point 4 psych h
<b>Oil/grease substances</b>	Not measured	–	No data

### Nutrients

Table 48

Parameter	Overall range	Unit	Notes
<b>Total nitrogen</b>	13,20– 130	mg/L	Broad range across sites
<b>Total phosphorus</b>	2,2 – 18,9	mg/L	Highest at Center 4 - discharge point 6 psych h

### Metals and trace elements

Table 49

Parameter	Overall range	Unit	Notes
<b>Arsenic (As)</b>	<0,00060 – 0,00235	mg/L	Highest at Center 6 - discharge point 2 Car park
<b>Cadmium (Cd)</b>	<0,00040	mg/L	Always below detection limit
<b>Chromium (Cr)</b>	<0,0050 – 0,0208	mg/L	
<b>Copper (Cu)</b>	0,0127 – 0,312	mg/L	Max at Center 4 - discharge point 5 psych Y
<b>Lead (Pb)</b>	0,00120 – 0,0171	mg/L	Highest at laboratory building
<b>Nickel (Ni)</b>	<0,0040 – 0,0138	mg/L	Highest at Center 4 - discharge point 6 psych h
<b>Zinc (Zn)</b>	0,0211 – 0,61	mg/L	Large variability, Center 4 - discharge point 4 psych h peak
<b>Mercury (Hg)</b>	<0,000100 – 0,000272	mg/L	Two elevated values: Center 2 – main sewer Center 2 – laboratory
<b>Silver (Ag)</b>	<0,00040 – 0,033	mg/L	Highest at Center 4 - discharge point 6 psych h





## Consolidated comparison table of selected testing site 7 wastewater discharge points

### Hydraulic parameters

Table 50

Parameter	Unit	Center 1 – discharge point 2 fysio DATA 2024	Center 2 – main sewer DATA 2025	Center 2 – laboratory DATA 2025	Center 2 – outpatient DATA 2025
Yearly flow rate	m <sup>3</sup> /year	No data	~291.467	~8.249	~19.411
Daily flow rate	m <sup>3</sup> /day	No data	798,54	22,6	53,18
Seasonal flow variation	–	Not reported	Not reported	Not reported	Not reported

Table 51

Parameter	Unit	Center 3 - discharge point number 2030108 DATA 2024	Center 4 - discharge point 4 psych h DATA 2025	Center 4 - discharge point 5 psych Y DATA 2025	Center 4 - discharge point 6 psych h Data 2025
Yearly flow rate	m <sup>3</sup> /year	~54.720	~3.358	~3.066	No data
Daily flow rate	m <sup>3</sup> /day	149,92	9,2	8,4	No data
Seasonal flow variation	–	Not reported	Not reported	Not reported	Not reported

Table 52

Parameter	Unit	Center 6 - discharge point 1 suppliers <b>DATA 2024</b>	Data Center 6 - discharge point 2 Car park <b>DATA 2024</b>	Center 6 - discharge point 3 main entrance <b>DATA 2024</b>	Center 7 Discharge point 1 <b>DATA 2025</b>
Yearly flow rate	m <sup>3</sup> /year	~27.886	~8.796	~9.818	No data
Daily flow rate	m <sup>3</sup> /day	76,4	24,1	26,9	No data
Seasonal flow variation	–	Not reported	Not reported	Not reported	Not reported
Parameter	Unit	Center 7 Discharge point 2 ambulances <b>DATA 2025</b>	Center 8 Discharge point 1 <b>DATA 2025</b>		
Yearly flow rate	m <sup>3</sup> /year	No data	~5.548		
Daily flow rate	m <sup>3</sup> /day	No data	15,2		
Seasonal flow variation	–	Not reported	Not reported		

### General physico-chemical parameters

Table 53

Parameter	Unit	Center 1 discharge point 2 fysio	Center 2 – main sewer <b>DATA 2025</b>	Center 2 – laboratory <b>DATA 2025</b>	Center 2 – outpatient <b>DATA 2025</b>
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DATA 2024					
pH	–	~7	~7	~7	~7
Temperature	°C	~20	~20	~20	~20
BOD <sub>5</sub>	mg O <sub>2</sub> /L	3,5 – 7,4	29 - 61	21 - 220	150 - 310
COD	mg O <sub>2</sub> /L	26 - 44	105 - 155	93 - 440	300 - 560
Suspended solids	mg/L	5, 2 – 7,2	66 - 74	17,3 - 40	37 - 97
Oil / grease substances	–	Not measured	Not measured	Not measured	Not measured

Table 54

Parameter	Unit	Center 3 - discharge point number 2030108 DATA 2024	Center 4 - discharge point 4 psych h DATA 2025	Center 4 - discharge point 5 psych Y DATA 2025	Center 4 - discharge point 6 psych h DATA 2025
pH	–	~7	~7	~7	~7
Temperature	°C	~20	~20	~20	~20
BOD <sub>5</sub>	mg O <sub>2</sub> /L	300 - 370	430 – 1000	121 - 360	240 - 350
COD	mg O <sub>2</sub> /L	640 - 710	720 – 1520	270 - 610	480 - 670
Suspended solids	mg/L	92 - 120	80 – 300	39 - 77	62 - 123
Oil / grease substances	–	Not measured	Not measured	Not measured	Not measured

Table 55

Parameter	Unit	Center 6 - discharge point 1 suppliers <b>DATA 2024</b>	Center 6 - discharge point 2 Car park <b>DATA 2024</b>	Center 6 - discharge point 3 main entrance <b>DATA 2024</b>	Center 7 Discharge point 1 <b>DATA 2025</b>
pH	–	~7	~7	~7	No data
Temperature	°C	~20	~20	~20	No data
BOD <sub>5</sub>	mg O <sub>2</sub> /L	125 - 210	240 – 370	75 - 210	340 - 470
COD	mg O <sub>2</sub> /L	270 - 330	440 – 530	290 - 350	630 - 770
Suspended solids	mg/L	26 - 34	55 – 66	28 - 48	55 - 78
Oil / grease substances	–	Not measured	Not measured	Not measured	Not measured

Table 56

Parameter	Unit	Center 7 Discharge point 2 ambulances <b>DATA 2025</b>	Center 8 Discharge point 1 <b>DATA 2025</b>
pH	–	No data	~7
Temperature	°C	No data	~20
BOD <sub>5</sub>	mg O <sub>2</sub> /L	190 - 260	95 – 104
COD	mg O <sub>2</sub> /L	380 - 480	250 – 260



Suspended solids	mg/L	37 - 54	40 – 43
Oil / grease substances	–	Not measured	Not measured

## Nutrients

Table 57

Parameter	Unit	Center 1 – discharge point 2 fysio DATA 2024	Center 2 – main sewer DATA 2025	Center 2 laboratory DATA 2025	Center 2 – outpatient DATA 2025
Total nitrogen	mg/L	22,4 - 54	13,2 - 17	16,5 - 49	27 - 49
Total phosphorus	mg/L	2,52 – 6,2	2,20 - 2,8	5,4-13,1	2,42 – 3,7

Table 58

Parameter	Unit	Center 3 - discharge point number 2030108 DATA 2024	Center 4 - discharge point 4 psych h DATA 2025	Center 4 - discharge point 5 psych Y DATA 2025	Center 4 - discharge point 6 psych h DATA 2025
Total nitrogen	mg/L	93 - 122	45 - 85	45 - 92	88 - 104
Total phosphorus	mg/L	13,6 – 16,2	5,3 – 15,5	5,5 – 17,5	13,8 – 18,9



Table 59

Parameter	Unit	Center 6 - discharge point 1 suppliers <b>DATA 2024</b>	Center 6 - discharge point 2 Car park <b>DATA 2024</b>	Center 6 - discharge point 3 main entrance <b>DATA 2024</b>	Center 7 - Discharge point 1 <b>DATA 2025</b>
Total nitrogen	mg/L	39 - 43	46 - 52	57 - 63	17,9 - 61
Total phosphorus	mg/L	5,5 – 6,5	8,4 – 11,2	6,5 – 7,8	17,3 – 17,9

Table 60

Parameter	Unit	Center 7 - Discharge point 2 ambulances <b>DATA 2025</b>	Center 8 - Discharge point 1 <b>DATA 2025</b>
Total nitrogen	mg/L	122 - 130	70 - 76
Total phosphorus	mg/L	15,2 – 15,8	9,3 – 10,2

### Metals and trace elements

Table 61

Parameter	Unit	Center 1 – discharge point 2 fysio <b>DATA 2024</b>	Center 2 – main sewer <b>DATA 2025</b>	Center 2 – laboratory <b>DATA 2025</b>	Center 2 – outpatient <b>DATA 2025</b>
Arsenic (As)	mg/L	0,00095 – 0,00115	0,00111 – 0,00141	<0,00060 – 0,00131	0,00093 – 0,00127
Cadmium (Cd)	mg/L	<0,00040	<0,00040	<0,00040	<0,00040

<b>Chromium (Cr)</b>	mg/L	<0,0050	<0,0050	<0,0050	<0,0050
<b>Copper (Cu)</b>	mg/L	0,0202 – 0,0242	0,0127 – 0,0309	0,0150 – 0,060	0,0166 – 0,0242
<b>Lead (Pb)</b>	mg/L	0,00158 – 0,00275	<0,00120	<0,00120 – 0,0171	<0,00120 – 0,0063
<b>Nickel (Ni)</b>	mg/L	<0,0040	<0,0040 – 0,0049	<0,004	<0,0040
<b>Zinc (Zn)</b>	mg/L	0,0264 – 0,044	0,033 – 0,044	0,0211 – 0,162	0,031 – 0,095
<b>Mercury (Hg)</b>	mg/L	<0,000100	<0,000100 – 0,000272	<0,000100 – 0,000155	<0,000100
<b>Silver (Ag)</b>	mg/L	0,00043 – 0,00155	<0,00040 – 0,00055	<0,00040 – 0,0029	<0,00040

Table 62

Parameter	Unit	Center 3- discharge point number 2030108	Center 4 - discharge point 4 psych h	Center 4 - discharge point 5 psych Y	Center 4 - discharge point 6 psych h
		DATA 2024	DATA 2025	DATA 2025	DATA 2025
<b>Arsenic (As)</b>	mg/L	0,00107 – 0,00144	0,00088 – 0,00155	0,00086 – 0,00135	0,00098 – 0,00121
<b>Cadmium (Cd)</b>	mg/L	<0,00040	<0,00040	<0,00040	<0,00040
<b>Chromium (Cr)</b>	mg/L	<0,0050	<0,0050	<0,0050 – 0,0208	<0,0050
<b>Copper (Cu)</b>	mg/L	0,091 – 0,106	0,112 – 0,284	0,129 – 0,312	0,201 – 0,236
<b>Lead (Pb)</b>	mg/L	<0,00120 – 0,00177	0,0073 – 0,0142	0,0049 – 0,00274	<0,00120 – 0,00242
<b>Nickel (Ni)</b>	mg/L	<0,0040	<0,0040 – 0,0053	0,0043 – 0,0062	<0,0040 – 0,0138
<b>Zinc (Zn)</b>	mg/L	0,058 – 0,094	0,100 – 0,61	0,81 – 0,133	0,060 – 0,103



Mercury (Hg)	mg/L	<0,000100	<0,000100	<0,000100	<0,000100
Silver (Ag)	mg/L	0,0169 – 0,0205	0,0084 – 0,029	0,0119 – 0,028	0,031 – 0,033
Parameter	Unit	Center 7 - discharge point 1 suppliers <b>DATA 2024</b>	Center 7 - discharge point 2 Car park <b>DATA 2024</b>	Center 7 - discharge point 3 main entrance <b>DATA</b> <b>2024</b>	Center 8 - Discharge point 1 <b>DATA 2025</b>
Arsenic (As)	mg/L	0,00124 – 0,00143	0,0028 – 0,00235	0,00147 – 0,00200	<0,00060
Cadmium (Cd)	mg/L	<0,00040	<0,00040	<0,00040	<0,00040
Chromium (Cr)	mg/L	<0,0050	<0,0050	<0,0050	<0,0050
Copper (Cu)	mg/L	0,054 – 0,063	0,055 – 0,067	0,0444 – 0,050	0,156 – 0,253
Lead (Pb)	mg/L	0,00126 – 0,00145	0,00146 – 0,00174	0,00205 – 0,00268	0,00351 – 0,0055
Nickel (Ni)	mg/L	<0,0040 – 0,0057	<0,0040	<0,0040	<0,0040 – 0,0046
Zinc (Zn)	mg/L	0,034 – 0,037	0,041 – 0,086	0,036- 0,069	0,062 – 0,091
Mercury (Hg)	mg/L	<0,000100	<0,000100	<0,000100	<0,000100
Silver (Ag)	mg/L	<0,00040	0,0029 – 0,0035	0,00058 – 0,00082	<0,00040



Table 63

Parameter	Unit	Center 7 - Discharge point 2 ambulances DATA 2025	Center 8 - Discharge point 1 DATA 2025	
Arsenic (As)	mg/L	0,00109 – 0,00113	0,00098 – 0,00136	• Center 1: data from 3-day campaign (25–27 March 2024)
Cadmium (Cd)	mg/L	<0,00040	<0,00040	• Center 2 main sewer: 5-day campaign (09–15 July 2025)
Chromium (Cr)	mg/L	<0,0050	<0,0050	• Center 2 laboratory: 6-day campaign (07–12 July 2025)
Copper (Cu)	mg/L	0,0485 – 0,077	0,193 – 0,218	• Center 2 outpatient: 5-day campaigns (07 – 11 July 2025)
Lead (Pb)	mg/L	0,00204 – 0,0068	0,0043 – 0,0051	• Center 3: data from 5-day campaign (10 – 16 Dec 2024)
Nickel (Ni)	mg/L	<0,0040	<0,0040	• Center 4 discharge point 4 psych h: data from 3-day campaign (24 –26 June 2025)
Zinc (Zn)	mg/L	0,046 – 0,076	0,0270 – 0,056	• Center 4 discharge point 5 psych Y: data from 3-day campaign (24 –26 June 2025)
Mercury (Hg)	mg/L	<0,000100	<0,000100	• Center 4 discharge point 6 psych h: 3-day campaign (01 – 3 July 2025)
Silver (Ag)	mg/L	<0,00040	0,0205 – 0,027	• Center 6 discharge point 1 suppliers: 3-day campaign (22 –24 April 2024)
				• Center 6 discharge point 2 Car park: 3-day campaign (22 –24 April 2024)
				• Center 6 - discharge point 3 main entrance: 5-day campaign (22 –26 April 2024)
				• Center 7 Discharge point 1 Leopoldstraat driveway car park: 3 – day campaign (10 – 12 June 2025)
				• Center 7 Discharge point 2 ambulances: 3 – day campaign (10 – 12 June 2025)
				• Center 8 Discharge point 1 Garden wall railway: 3 – day campaign (1 – 3 July 2025) •
				• “<” indicates below detection limit

## Target contaminants content in effluent

### No data available for

- Cytostatic contaminants content
- Representative X-ray contrast agents content
- Priority antibiotic groups content
- Priority antimicrobial-resistant bacteria (ARB) content
- Priority antimicrobial-resistant genes (ARG) content

## Baseline situation of existing wastewater management at testing site 7

Table 64

Category	Details
<b>Existing Infrastructure</b>	<p><b>Segregation:</b> rainwater separated partially and used in multiple campuses; reused for toilet flushing at centers 3, 4 and 6. Lab wastewater separated in most campuses except center 2. Radioactive wastewater segregated at center 2 via holding systems.</p> <p>Rainwater separation is partial: most campuses discharge rainwater together with mixed wastewater, but at centers 3, 4 and 6 collect rainwater for toilet flushing.</p> <p>Laboratory wastewater separated, particularly in RRL laboratories and collected in dedicated drums or containers for proper disposal. The central laboratory building is equipped with a separate wastewater pit, ensuring controlled handling of potentially hazardous laboratory effluents. No laundry wastewater (service outsourced). Radioactive wastewater, segregated partially: the medical imaging department operates a dedicated decay tank, ensuring radioactive liquids are safely stored until isotopes decay to permissible levels before disposal.</p> <p>Kitchen wastewater is not separated (not required by national regulations).</p> <p>Additionally, across several campuses septic or collection tanks are present, providing localized containment for specific wastewater streams that require controlled handling.</p> <p><b>Discharge points:</b> 16+ across campus network.</p> <p><b>Pre-treatment:</b> amalgam separators, hydrocarbon separators, grease separators, coarse screens, septic tanks.</p>



<b>Monitoring &amp; Control</b>	<b>Devices:</b> inlet & outlet flowmeters, Sensors: temperature & pH sensors.
<b>Monitoring &amp; Control</b>	<b>Effluent monitoring:</b> Periodic water quality checks for parameters include Temp, pH, BOD, COD, N, P, SS, metals (As, Cd, Cr, Cu, Pb, Ni, Zn, Hg, Ag). <b>BMS:</b> not required.
<b>Capacity , Barriers &amp; Constraints</b>	<b>Staff:</b> limited full-time equivalents; extensive outsourcing. <b>Barriers:</b> old buildings, highly heterogeneous infrastructure of the campuses,
<b>Wastewater &amp; Public Health</b>	Mixed high-risk streams; campus variability increases operational risks.
<b>Space &amp; Integration</b>	Many campuses with serious space limitations; differing sewer depths and access conditions. Strong need for modularity and flexible installation design applicable to different campuses, as well as old and new buildings.
<b>Water reuse practices and potential</b>	Already implemented water reuse system (rainwater) for toilets flushing at at centers 3, 4 and 6.

### Specific regulatory compliance requirements for PCP THERESA solutions for testing site 7

Table 65

Category	Requirement / Parameter	Threshold / Obligation	Source Regulation / Compliance System
Discharge Limits – Physical/Chemical Parameters	pH	Discharge norms/conditions for business (nonhousehold) wastewater are set in the permit and depend on the wastewater type	
	Temperature		
	Suspended solids (SS)		
	BOD <sub>5</sub>		
	COD		

	Oils & greases	
	Prohibited discharges	
<b>Infrastructure Requirements</b>	Connection to sewer	Obligatory
	Discharge point access	Must maintain clean, accessible points for inspection & sampling
	Pre-treatment infrastructure	
	Noise emission	No information
<b>Waste and hazardous streams</b>	Segregation of hazardous streams	Required for sanitary, cytotoxic and chemical waste
	Storage and containment	Proper containment for radioactive wastewater (storage tanks for curation to reduce radioactivity before discharge)
	Waste segregation	Mandatory segregation of sanitary waste & dangerous substances
<b>Monitoring and Sampling Requirements</b>	Monitoring frequency	Discharge permit based
	Monitoring scope (parameters)	Discharge permit based. parameters, sampling frequency, and reporting duties are set in the permit depending on discharge characteristics
	Analytical methods	Must follow accredited / legally recognised methods

## 8. Regulatory and compliance framework SPAIN

### Key National Regulations (Spain)

In Spain there is **no national numeric limit** (mg/L or µg/L) for pharmaceuticals in hospital wastewater. However, HUVM operates under a regulatory and compliance framework combining national, regional, municipal/local-level requirements. Core obligations include compliance with EMASESA discharge thresholds, and fulfilling monitoring, reporting, and risk-management duties mandated by SAS/SSPA. The hospital must prevent hazardous, pharmaceutical, cytotoxic, or otherwise prohibited substances from entering the sewer system and must implement appropriate pre-treatment if limits are exceeded. Regular monitoring, proper infrastructure (inspection chambers, secure chemical storage, pre-treatment where needed), emergency reporting, and strict waste segregation are mandatory. For water reuse for non-potable purposes, compliance to water quality requirements specified in Royal Spanish Decree 1085/2024 applies.

National Spanish regulations relevant for THERESA PCP solutions compliance in terms of hospital wastewater management and installations include:

- Ley de Aguas (Spanish Water Law) establishes the national framework for water planning, water resource protection, wastewater discharge permitting, and pollution prevention and prohibits discharges harmful to sewer systems or WWTPs.
- Decree 606/2003 regulates discharges into sewer networks, including industrial and non-domestic wastewater, defines obligations for pollutant control, prohibited substances including pharmaceuticals, and pretreatment.
- Law 22/2011 on Waste and Contaminated Soil: regulates hazardous waste generation, segregation, collection, storage, and traceability, including pharmaceutical, cytotoxic, and chemical waste streams. It defines cytostatic drugs as hazardous waste and prohibits sewer discharge.
- Royal Decree 487/2022, covers Legionella prevention and control in various facilities.

### ANDALUCIA

#### Regional Legislation (Andalusia)

- Andalusian Water Law 9/2010<sup>6</sup> sets monitoring and reporting duties.
- Environmental Protection Laws 7/2007 and 3/2015<sup>7</sup> require pollution control and environmental impact prevention.
- Decrees 73/2012 and 18/2015<sup>8</sup> regulate healthcare waste and hazardous substances.
- Drinking water surveillance (Decree 70/2009)<sup>9</sup> requires control of systems linked to wastewater.

#### Local Regulations (Seville / EMASESA)

Empresa Metropolitana de Abastecimiento y Saneamiento de Aguas de Sevilla, S.A. (EMASESA) water & sanitation regulations (2016-2018)<sup>10</sup> define the fees, responsibilities and technical requirements for potable water supply, sewage,



discharge and treatment services. The [EMASESA Ordinance and Sanitation Service Regulation](#)<sup>1</sup> establishes in particular the conditions under which wastewater may be discharged into the municipal sewer system operated by EMASESA. It applies to non-domestic discharges, including those from industrial, commercial, and institutional facilities. Hospitals effluent falls under **non-domestic dischargers** and therefore must comply with Table 2 limits when discharged to the municipal sewer including gaseous compounds.

Public Cleaning and Urban Waste Management Ordinance, the Energy, Climate Change and Sustainability Ordinance, and the [Noise and Vibration Ordinance \(2014\)](#)<sup>2</sup>—establish environmental and operational rules that indirectly impact hospital water management by regulating waste, sustainability and environmental quality in the city.

### SAS Environmental Management Framework

HUVM operates under UNE-EN ISO 14001 integrated with Andalusian Health Service (SAS). Since 2015 HUVM has been registered under European EcoManagement and Audit Scheme EMAS (Reg. No. ES-AN-000107). Additionally, the hospital is included within the Environmental Management System of the Andalusian Public Health System (SIGA-SSPA) and publicly publishes an annual Environmental Statement under EMAS requirements

## CATALONIA

### Regional Regulations (Catalonia / Generalitat de Catalunya)

The regional regulations define CHV's obligations for water supply, wastewater discharge (obligatory discharge permit specifying the discharge limits of pollutants, environmental monitoring, and emergency management and include:

- Catalan Water Agency (ACA) Regulations o [Text Refós de la Llei d'Aigües de Catalunya \(TRLAC\)](#) – Catalan Water Law.
  - o [Decret 152/2017 – regulation of the water use and pollution declaration \(DUCA\)](#). o Decret 130/2003 – establishes the Water Canon (Cànon de l'Aigua) and discharge control fees.
  - o [ACA Monitoring & Reporting Requirements](#) – includes quarterly water consumption declarations and DUCA updates every 4 years.
- Wastewater Discharge & Sewer Network Rules o [Reglament d'Abocaments d'Aigües Residuals a les Xarxes de Sanejament](#) (Catalonia) – overarching regional rules for wastewater discharge to sewer systems.
- Health & Safety / Public Health o [Decret 95/2000](#) – prevention & control of Legionella. o [Decret 153/2019](#) – management of biosanitary waste in hospitals.

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<sup>1</sup> Normativa Reguladora De Las Contraprestaciones Económicas Que Debe Percibir Emasesa Por Los Servicios De Abastecimiento Domiciliario De Agua Potable, Saneamiento (Vertido Y Depuración) Y Otras Actividades Conexas A Los Mismos.

<sup>2</sup> Ordenanza Municipal contra la Contaminación Acústica, Ruidos y Vibraciones of the City of Sevilla



## Local / Municipal Regulations (Vic, Osona Region)

- Osona County Wastewater Discharge Regulation ([Reglament d'Abocaments d'Aigües Residuals de la Comarca d'Osona](#)) – the central local regulation governing: discharge permits, prohibited substances, thresholds, required pre-treatment, inspection chambers, emergency notification, penalties & sanctions.
- Vic Municipal Ordinances o [Ordenança Municipal de Sanejament – defines local sewer access rules and discharge conditions.](#)
  - o Ordenança Municipal de Gestió de Residus – waste handling affecting wastewater pathways.
  - o Ordenances Ambientals – noise, pollution, environmental quality conditions impacting hospital operations.

## Local Agency Requirements

- [Consell Comarcal d'Osona](#) – oversight on sanitation obligations, emergency reporting, and enforcement. Dischargers must obtain authorisation for their wastewater discharge from the Consell Comarcal d'Osona. As part of the authorisation process, the Consell may establish specific discharge limits for parameters considered relevant based on the pollution characteristics of the activity. These are determined in accordance with the objectives of protecting the sanitation system and public health.
- Aigües Vic / local water operator rules – supply, sewer connection requirements, and sampling obligations.

## NAVARRA

### Regional Regulations (Navarra)

[Royal Decree 1620/2007](#), of December 7, establishing the legal regime for the reuse of treated wastewater.

The regulation **allows** the reuse of water for different purposes.

The regulation **prohibits** the use of reclaimed water:

- For human consumption, except in disaster situations where the health authority will specify the required quality levels and uses.
- For uses within the food industry, except as provided in the Annex for process and cleaning water in the food industry.
- **For use in hospital facilities and similar uses.**
- For the cultivation of filter-feeding mollusks in aquaculture.
- For recreational use as bathing water.
- For any other use that the health or environmental authority considers a risk to human health or harmful to the environment, at any time such risk or harm is identified.





[\*\*Royal Decree-Law 4/2007\*\*](#), of April 13, amending the consolidated text of the Water Law, approved by Royal Legislative Decree 1/2001 of July 20, which consolidates Law 29/1985 on Water.

It adapts existing water legislation based on the development of Law 6/2001, of May 8, and the Second Final Provision of Law 46/1999, of August 13, which authorized the Government to issue this consolidated text within two years.

The main objectives are:

- Achieve and maintain an adequate level of water quality.
- Prevent toxic or hazardous compounds from contaminating groundwater.
- Avoid factors that degrade water quality.
- Consolidates Law 29/1985 on Water, of August 2.

[\*\*Order MAM 985/2006\*\*](#), of March 23, developing the legal regime for collaborating entities of the hydraulic administration in matters of water quality control and monitoring and management of discharges into the public hydraulic domain.

#### Regional regulatory and compliance framework

Specific regional/local regulatory and compliance framework for the Hospital Universitario de Navarra includes:

- [\*\*REGIONAL NAVARRE WASTE PLAN 2017-2027\*\*](#)
- [\*\*FORAL LAW 10/1988\*\*](#) and its implementing regulations establish the framework for sanitation, including the Master Sanitation Plan to protect rivers.
- [\*\*FORAL LAW 34/2013\*\*](#): Amends the 1988 law, updating aspects of the regulations.
- [\*\*FORAL DECREE 12/2006\*\*](#): Sets technical conditions for activities discharging into public collectors, limiting pollutant load and flow to avoid overloading treatment plants.

At local level, HUN's effluents are discharged as an indirect discharge to the public sewer network managed in the Pamplona metropolitan area by the Mancomunidad de la Comarca de Pamplona (MCP), which is responsible for the integrated water cycle (water and wastewater services) in the comarca. At local/regional operational level, [\*\*MCP's Ordenanza de Redes de Saneamiento\*\*](#) sets binding technical conditions for sewer infrastructure and connections applicable to networks carrying domestic, stormwater, unitary or industrial flows.

The ordinance does not itself list numeric discharge quality limits like those in industrial discharge tables; instead it sets design, connection and infrastructure requirements that must be met before a discharge can be accepted onto the network.

Any specific conditions for discharge quality (e.g., pollutant concentrations, pretreatment requirements) are typically established by the sewerage service under the MCP's regulatory framework and/or through individual connection permits or authorisations reviewed prior to approval by MCP.



## 9. Regulatory and compliance framework POLAND

### Regional regulatory and compliance framework

Poland does not have numeric thresholds for pharmaceuticals in hospital wastewater.

In Poland, hospital wastewater discharge is regulated through a combination of national laws, executive regulations, and local/utility permits.

There is no single “hospital wastewater law”, but hospitals must comply with all regulations governing wastewater, hazardous substances, infectious agents, chemical pollutants, and discharge to municipal sewers. Hospital wastewater is considered as “industrial effluent”.

Key legal regulations that apply to hospital wastewater management and effluent discharge are summarised below.

### National regulations requirements

- [Water Law Act \(Prawo wodne\) of 20 July 2017](#) –the overarching act regulating all wastewater discharges (domestic and industrial) in Poland. According to the provisions of the act discharge of wastewater to the sewer system requires compliance with utility operator regulations and a discharge permit. The act prohibits the discharge flammable and explosive substances (gasoline, kerosene), corrosive, toxic substances (strong acids, bases, cyanides, formalin) and defines dangerous substances lists consistent with the EU Water Framework Directive. Wastewater must be free of solid waste (sand, gravel, glass, fibers) before entering the sewer. The law also requires monitoring and documentation of discharges.
- Polish water and sewerage law : [Ustawa z dnia 7 czerwca 2001 r. o zbiorowym zaopatrzeniu w wodę i zbiorowym odprowadzaniu ścieków. \(Dz.U. 2001 nr 72 poz. 747\)](#)
- Environmental Protection Law ([Prawo ochrony środowiska](#)) of 27 April 2001 is relevant for hospital wastewater because it regulates restrictions on hazardous substances:
- Regulation of the Minister of Construction on the Method of Fulfilling the Obligations of Industrial Wastewater Suppliers and the Conditions for Introducing Wastewater into Sewerage Systems of 14 July 2006 ([Rozporządzenie Ministra Budownictwa w sprawie sposobu realizacji obowiązków dostawców ścieków przemysłowych oraz warunków wprowadzania ścieków do urządzeń kanalizacyjnych z dnia 14 lipca 2006](#))
- Waste Act (Ustawa o odpadach) of 14 December 2012, the Regulation of Minister of Health on Medical Waste of 17 October 2017 ([Rozporządzenie Ministra Zdrowia o odpadach medycznych z dnia 17 października 2017r](#)) define cytotoxic and cytostatic drugs as hazardous waste that must not be discharged into sewer similarly as infectious waste and pharmaceutical waste and the requirement for segregating medical waste.



### Local water agency requirements

- Regulations issued by the local water and sewage company (Olsztyn Water and Wastewater Enterprise- PWIK Olsztyn) govern acceptance criteria for wastewater entering municipal sewers. The regulation applies to collective sewerage services and defines rights and obligations of the utility and customers (including wastewater discharge) under Polish water and sewerage law (Ustawa o zbiorowym zaopatrzeniu w wodę i zbiorowym odprowadzaniu ścieków). While the *Regulamin* itself does not list numerical discharge limits specifically in the publicly available excerpt, it includes general references to technical environmental regulations that govern discharge quality. They specify maximum accepted numerical values for physico-chemical parameters and pollutant concentrations in the discharge permit based on. o requirements for pre-treatment o requirements for flow equalisation o obligations for sampling and monitoring.

## 10. Regulatory and compliance framework the NETHERLANDS

### Regulatory framework

[The Water Act \(Waterwet\)](#) provided the national framework for water quality and wastewater management and, although largely integrated into the Omgevingswet, its principles persist: water authorities regulate wastewater treatment plants, sewer systems and quality objectives, and often set local discharge limits via regional by-laws and water board permits.

Water authorities (Waterschappen) therefore play a key role in setting operational conditions for discharges into sewer systems and receiving waters, including quality conditions that may apply indirectly to wastewater discharged to municipal sewer networks. For Maastricht this is Waterschap Limburg.

Specific requirements for discharge require submission of annual declarations to calculate wastewater treatment charges and measurements of pollution metrics to determine pollution units for charging purpose.

## 11. Regulatory and compliance framework ESTONIA

### Regulatory and compliance framework

Estonia aligns with the EU Water Framework Directive and has emerging national priorities for reducing nutrient (N, P) pollution in the Baltic Sea ecosystem. Pharmaceutical contamination is an increasing concern, hospital wastewater discharge is regulated through a combination of national laws, executive regulations, and local/utility permits. Pharmaceuticals are not specifically addressed by the regulatory requirements but are addressed indirectly in local regulations under toxic, harmful, or dangerous substances, substances that disrupt wastewater treatment, substances classified as hazardous waste, any discharges that create environmental or health risks.



The key requirements are defined in the following framework:

#### National regulatory requirements

- Water Act ([Veeseadus-Riigi Teataja](#)) defines requirements for wastewater treatment and discharge of effluent including, among others stormwater water, into water bodies, provides measures for assessing compliance with requirements, and limit values for pollutant content. It also defines the main wastewater treatment methods (mechanical, biological, and advanced/tertiary) and establishes the maximum allowable pollutant limits that the treated wastewater must meet before being discharged. Pharmaceuticals are addressed when they have hazard classifications such as: toxic to aquatic life, long-lasting effects, carcinogenic/mutagenic, harmful if released to environment.
- [National AMR Strategy of Estonia](#) (Eesti antimikroobse resistentsuse ohjamise strateegia - One Health approach covering humans, animals and the environment) aimed at, among others, reducing AMR spread in humans, animals and the environment. The document sets goals for systematic, harmonised monitoring, including surveillance of ARB and ARG in wastewater, especially municipal and hospital influent. The strategy recommends better source separation and control of pharmaceuticals and disinfectants and encourages healthcare facilities to adopt pre-treatment measures to reduce AMR load before discharge to the sewer. The strategy also calls for innovations for detecting antimicrobial residues in wastewater, technologies that reduce ARB/ARG emissions and piloting new pretreatment systems in high-risk settings (e.g., hospitals).

#### Local regulatory requirements

- Regulation on connecting to and using the public water supply and sewerage system of the city of Tallinn ([Tallinna linna ühisveevärgi ja https://www.riigiteataja.ee/akt/407022025022?leiaKehtivkanalisatsiooniga liitumise ning ühisveevärgi ja -kanalisatsiooni kasutamise eeskiri-Riigi Teataja](#)) sets the technical, safety and maintenance requirements for water and wastewater systems at the point of consumption. Section 16 defines obligations for preventing contamination, flooding and damage to the public network, including requirements for backflow prevention, ventilation, access for sampling, and proper upkeep of private installations. It prohibits unsafe connections between drinking water, wastewater and stormwater systems. Section 18 specifies which wastewater and stormwater streams may be discharged into the public sewer. Wastewater must meet pollutant limit values, avoid damaging infrastructure, and must not contain hazardous, explosive, toxic, oily or prohibited substances. It restricts of high-temperature effluents, forbids waste dumping and shock loads, and requires immediate incident reporting, on-site pretreatment where necessary, and provision of sampling points for potentially polluted discharges. It also restricts the discharge of pharmaceuticals identified under toxic, harmful, or dangerous substances, substances that disrupt wastewater treatment, substances classified as hazardous waste, any



discharges that create environmental or health risks. This implicitly includes many pharmaceuticals, especially: antibiotics (antimicrobial resistance risk), contrast media (persistent), cytostatics (carcinogenic, mutagenic), endocrine-disrupting pharmaceuticals.

- [Tallinn City Council Regulation No. 1 of 23 January 2025 “Rules for Connecting to and Using the Public Water Supply and Sewerage System of the City of Tallinn”](#) specifies the list Limit Values for Wastewater Pollution Indicators (List 1) including pH, suspended solids, BOD<sub>7</sub>, oils and greasy substances, petroleum products, total nitrogen and total phosphorus. Under systems like Tallinn City Council Regulation No. 1 (2025), wastewater is grouped into pollution groups (e.g. Groups 4–8) according to conventional pollution indicators, not by source (hospital vs. industry). Hospital wastewater is therefore classified according to: pH, suspended solids, BOD<sub>7</sub> / COD, oils and petroleum products, total nitrogen, total phosphorus and other listed parameters such as surfactants, phenols.
- Municipal sewerage company's technical requirements (Tallinna Vee tehnilised nõuded) specify additional requirements concerning systems sewerage systems design and construction including materials and equipment.

## 12. Regulatory and compliance framework BELGIUM

### Regulatory and compliance framework

There is limited Belgian regulation regarding hospital wastewater. There is also no legislation defining upper and lower limits for micropollutants. ZAS pays for the discharged wastewater, and the main regulatory responsibility for wastewater lies with the water treatment companies. The only sub-area that is subject to specific regulation is radioactive wastewater. This must be collected and stored for a certain period until the radioactivity has decreased sufficiently to allow discharge. ZAS complies with Belgian regulations.

Belgium does not generally publish uniform city-level “wastewater discharge limits for sewer” in a single online ordinance that is easily accessible — instead:

Permits and sewer connection conditions are issued on a case-by-case basis by the relevant municipal authority and/or water utility (e.g., the local sewer operator in Antwerp, in cooperation with Aquafin and regional regulators).

These permits/conditions typically include required quality standards for effluent entering public sewer to protect sewer integrity and WWTP performance.

Industrial users (including hospitals) are generally subject to monitoring and reporting requirements specified in their permit or connection agreement with the sewer authority.

## **Annex 2. Pre-existing rights of the PBG**

The PBG does not have relevant pre-existing rights. Additional pre-existing rights might be included during Phase 2 and 3.



## **Annex 3. List of environmental, social and labour law obligations established by EU Law, national legislation, collective agreements which bids must comply with**

<b>ILO Convention 87 on Freedom of Association and the Protection of the Right to Organise</b>
<b>ILO Convention 98 on the Right to Organise and Collective Bargaining</b>
<b>ILO Convention 105 on the Abolition of Forced Labour</b>
<b>ILO Convention 138 on Minimum Age</b>
<b>ILO Convention 111 on Discrimination (Employment and Occupation)</b>
<b>ILO Convention 100 on Equal Remuneration</b>
<b>ILO Convention 182 on Worst Forms of Child Labour</b>
<b>Vienna Convention for the Protection of the Ozone Layer and its Montreal Protocol on substances that deplete the Ozone Layer</b>
<b>Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal (Basel Convention)</b>
<b>Stockholm Convention on Persistent Organic Pollutants (Stockholm POPs Convention)</b>
<b>Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade (UNEP/FAO) (The PIC Convention) Rotterdam, 10 September 1998, and its 3 regional Protocols</b>



## Annex 4. OMC report

Please see here the full report including annexes:

[https://theresa-pcp.eu/wp-content/uploads/2026/05/D2.2-THERESA\\_OMC-Report.pdf](https://theresa-pcp.eu/wp-content/uploads/2026/05/D2.2-THERESA_OMC-Report.pdf)





# Annex 5. Performance Criteria/KPI and evaluation/measurement methods for pass/fail award criteria and weighted award criteria of Phase 1

The tender must comply with all the requirements and their evaluation methods/KPIs listed under *section 3.5 Award criteria of TD1. Request for Tender* and under this *Annex 5*.

Please note that the Performance Criteria/KPI and evaluation/measurement methods for phase 2 and 3 will be finetuned based on the finetuned award criteria for said phases.

## **Alternative Functional Unit Reporting**

Where the proposed technology configuration does not allow performance or resource consumption indicators to be expressed per m<sup>3</sup> of total treated wastewater, for example in decentralised or source-separated systems, the supplier shall justify why the standard functional unit is not applicable and propose a technically appropriate alternative. The alternative unit must be clearly defined, consistently applied across all reported indicators, and accepted by the evaluation team prior to scoring.



<b>Category</b>	<b>CONTAMINANT REMOVAL REQUIREMENTS</b>
<b>Requirement ID</b>	CRR 1.1
<b>Requirement Title</b>	<b>Cytostatics Removal</b>
<b>Short Description</b>	<p>The solution shall demonstrate removal/degradation performance of cytostatic drugs. Suppliers are expected to provide a concise description of how their solution achieves the required removal in these particular contaminants, including the key treatment mechanisms, process steps, removal rates and any supporting evidence from published data, literature, technical specifications of the units processes, validated test results and/or technical documentation. The measurement methodology and calibration data (multiple measurements) should be included, where relevant.</p> <p>The solution shall demonstrate a removal efficiency and an absolute post-treatment concentrations below specific threshold values (to be defined in Phase 1). Both criteria must be met.</p>
<b>Performance Criteria/KPI</b>	The solution must demonstrate that, for each selected targeted cytostatic compound: Removal efficiency is sufficient; and the absolute post-treatment concentration is below the threshold value defined in Phase 1.
<b>Evaluation Method</b>	Compliance must be demonstrated through available test data and technical documentation (Phase 1), experimental results (Phase 2 and Phase 3). For phase 3 the data shall originate from ISO/IEC 17025 accredited labs with relevant measurement methods included in the scope of accreditation.
<b>Requirement ID</b>	CRR 1.2
<b>Requirement Title</b>	<b>Watersoluble, nephrotropic, low osmolar iodinated x-ray contrast media removal</b>
<b>Short Description</b>	Solution shall demonstrate removal/degradation performance of watersoluble, nephrotropic, high osmolar Iodinated CT contrast media (ATC code: V08AB). Suppliers are expected to provide a concise description of how their solution achieves the required removal in these particular contaminants,

	<p>including the key treatment mechanisms, process steps, removal rates and any supporting evidence from published data, literature, technical specifications of the units processes, validated test results and/or technical documentation.</p> <p>The measurement methodology and calibration data (multiple measurements) should be included, where relevant. The solution shall demonstrate a removal efficiency and an absolute post-treatment concentrations below specific threshold values (to be defined in Phase 1). Both criteria must be met.</p>
<b>Performance Criteria/KPI</b>	<p>For each compound: Removal efficiency (%)=<math>((C_{\text{influent}} - C_{\text{effluent}})/C_{\text{influent}}) \times 100</math> And <math>C_{\text{effluent}} \leq \text{Threshold value}</math></p> <p>Where:</p> <p><math>C_{\text{influent}}</math>= measured influent concentration</p> <p><math>C_{\text{effluent}}</math>= measured post-treatment concentration</p> <p>Threshold Value = predefined concentration limit</p> <p>Absolute concentration compliance prevails over percentage removal.</p>
<b>Evaluation Method</b>	<p>Supplier shall provide: Phase 1 : Identification of representative V08CA substances tested, description of removal or degradation mechanisms (e.g., adsorption, membrane separation, advanced oxidation, precipitation, etc.), description of key treatment steps responsible for removal, analytical methods used, including limits of quantification (LOQ) and detection (LOD), Influent and effluent concentration data, supporting evidence such as: Laboratory validation results, published peer-reviewed literature, technical documentation. For Phase 2 and Phase 3: Controlled testing under representative conditions, replicate measurements, Clear reporting of detection limits and analytical uncertainty. For phase 3 the performance data shall originate from ISO/IEC 17025 accredited laboratories with the relevant measurement methods in the scope of accreditation.</p>
<b>Requirement ID</b>	CRR 1.3
<b>Requirement Title</b>	<b>Gadolinium-Based Magnetic resonance imaging contrast media removal</b>
<b>Short Description</b>	<p>Solution shall demonstrate removal/degradation performance of Paramagnetic Gadolinium based contrast media (ATC code: V08CA). Suppliers are expected to provide a concise description of how their</p>

	<p>solution achieves the required removal in these particular contaminants, including the key treatment mechanisms, process steps, removal rates and any supporting evidence from published data, literature, technical specifications of the units processes, validated test results and/or technical documentation. The measurement methodology and calibration data (multiple measurements) should be included, where relevant.</p> <p>The solution shall demonstrate a removal efficiency and an absolute post-treatment concentrations below specific threshold values (to be defined in Phase 1). Both criteria must be met.</p>
<b>Performance Criteria/KPI</b>	<p>For each compound:  Removal efficiency (%) = <math>\frac{(C_{\text{influent}} - C_{\text{effluent}})}{C_{\text{influent}}} \times 100</math> And <math>C_{\text{effluent}} \leq \text{Threshold value}</math>  Where:  C_influent = measured influent concentration  C_effluent = measured post-treatment concentration  Threshold Value = predefined concentration limit  Compliance with the absolute concentration threshold is mandatory, regardless of percentage removal.</p>
<b>Evaluation Method</b>	<p>Phase 1: Phase 1 – Design-Level Assessment  The contractor shall provide:</p> <ul style="list-style-type: none"> <li>- identification of the relevant gadolinium-based contrast media compounds (ATC code V08CA) addressed by the solution;</li> <li>- a concise description of the treatment mechanism(s) and process steps responsible for removal/degradation;</li> <li>- expected removal efficiency for each relevant compound;</li> <li>- available supporting evidence from published literature, prior validated tests, technical specifications of the unit processes, or other technical documentation;</li> <li>- description of the proposed analytical measurement methodology, including calibration approach and data quality provisions, where available.</li> </ul> <p>Evaluation in Phase 1 shall be based on documentation review and shall verify that the proposed solution has a technically credible basis for achieving both:</p> <ul style="list-style-type: none"> <li>- the required removal efficiency; and</li> </ul>

	<p>the absolute post-treatment concentration thresholds to be defined in Phase 1.</p> <p>Phase 2/3:– Performance Validation/ Verification:</p> <p>The contractor shall demonstrate compliance through testing under the applicable test conditions defined for the phase.</p> <p>For each relevant gadolinium-based contrast medium, the contractor shall provide:</p> <ul style="list-style-type: none"> <li>influent and post-treatment concentration data based on multiple measurements;</li> <li>analytical method used for determination;</li> <li>calibration data and quality control information;</li> <li>calculated removal efficiency for each compound;</li> <li>confirmation that post-treatment concentration is below the predefined threshold value.</li> </ul> <p>Compliance shall be verified for each compound using:</p> <p>Removal efficiency (%)= <math>((C_{\text{influent}} - C_{\text{effluent}}) / C_{\text{Influent}}) \times 100</math></p> <p>with mandatory confirmation that:</p> <p><math>C_{\text{effluent}} \leq \text{Threshold value}</math></p> <p>The requirement shall be considered fulfilled only if, for each relevant compound:</p> <ul style="list-style-type: none"> <li>- the required removal efficiency is achieved; and</li> <li>- the post-treatment concentration is at or below the predefined threshold value.</li> </ul> <p>Failure to meet either criterion for any relevant compound shall result in non-compliance for this requirement.</p>
<b>Requirement ID</b>	CRR 1.4
<b>Requirement Title</b>	<b>Antibiotics Removal</b>
<b>Short Description</b>	<p>Solution shall demonstrate the removal/degradation performance of antibiotics. Suppliers are expected to provide a concise description of how their solution achieves the required removal in these particular contaminants, including the key treatment mechanisms, process steps, removal rates and any supporting evidence from published data, literature, technical specifications of the units processes, validated test results and/or technical documentation. The measurement methodology and calibration data (multiple measurements) should be included, where relevant.</p>

	The solution shall demonstrate a removal efficiency and an absolute post-treatment concentrations below specific threshold values (to be defined in Phase 1). Both criteria must be met.
<b>Performance Criteria/KPI</b>	<p>For each antibiotic/family: Removal efficiency (%)=((C_influent -C_effluent)/Cinfluent) x 100 And C_effluent≤Threshold value</p> <p>Where:</p> <p>C_influent= measured influent concentration</p> <p>C_effluent= measured post-treatment concentration</p> <p>Threshold Value = predefined concentration limit</p> <p>Compliance with the absolute concentration threshold is mandatory, regardless of the percentage removal achieved.</p>
<b>Evaluation Method</b>	<p>Suppliers shall provide: Phase 1 identification of representative antibiotics tested (e.g., defined target compounds); description of removal/degradation mechanisms (e.g., adsorption, biodegradation, advanced oxidation, membrane separation, etc.);description of key process steps responsible for removal; Influent and effluent concentration data; analytical methods used, including limits of quantification (LOQ) and detection (LOD), supporting evidence such as: Laboratory validation results; test results (if available);peer-reviewed publications; technical documentation.</p> <p>For Phase 2 and Phase 3: Controlled experimental validation; replicate measurements; reporting of analytical uncertainty and detection limits. For phase 3 the performance data shall originate from ISO/IEC 17025 accredited laboratories with the relevant measurement methods in the scope of accreditation.</p>
<b>Category</b>	<b>OPERATIONAL &amp; TECHNICAL REQUIREMENTS</b>
<b>Requirement ID</b>	OPRI.1
<b>Requirement Title</b>	<b>Wastewater flow capacity and system stability</b>
<b>Short Description</b>	The solution shall be technically adaptable to varying hospital wastewater volumes while maintaining stable operation and consistent treatment performance. The solution shall demonstrate the ability to:

	operate effectively across a range of wastewater flow rates representative of different hospital sizes; the proposed operating range shall be consistent with the proposed solution layout (SSI 1.5)); and maintain stable treatment performance within this operational range. Adaptability may be achieved through modular design, scalable reactor configuration, adjustable hydraulic retention time, variable-speed pumping, parallel treatment lines, or other technical means
<b>Performance Criteria/KPI</b>	Suppliers shall demonstrate: A defined operational flow range (minimum and maximum design flow); stable operation within this range; no significant deterioration of key treatment performance parameters when flow varies within the design limits.
<b>Evaluation Method</b>	Suppliers shall provide: a description of system scalability concept (e.g., modular expansion, adjustable process parameters); Hydraulic design range (Qmin–Qmax); explanation of how performance is maintained under varying flows; supporting evidence (modelling, lab tests, pilot data, technical documentation); Identification of any operational constraints/assumptions/limitations related to flow variation. Performance stability shall be demonstrated through design calculations (Phase 1); controlled testing under variable flow conditions (Phase 2); pilot validation under real flow variability (Phase 3).
<b>Requirement ID</b>	OPR1.2
<b>Requirement Title</b>	<b>Wastewater flow peaks</b>
<b>Short Description</b>	Suppliers shall clearly describe: 1. the defined design peak flow capacity (m <sup>3</sup> /month); 2. stable system operation under short-term peak inflow conditions and daily high/low flow variability; 3. the defined and controlled system behaviour during exceedance conditions, safeguards to prevent uncontrolled discharge or system failure, operational procedures for temporary bypass under exceptional inflow conditions.
<b>Performance Criteria/KPI</b>	The Suppliers shall demonstrate: Defined operational flow range (minimum, average, and peak); maximum peak flow capacity (xx m <sup>3</sup> /month or equivalent rate); No critical process failure under peak conditions; No uncontrolled release of untreated wastewater;

	<p>Clearly described operational response mechanisms, such as equalisation capacity, flow buffering, automated control adjustments, load shedding or staged treatment, safe temporary bypass management.</p> <p>Temporary bypass is permitted only if: trigger conditions are clearly defined; safeguards are implemented; environmental and health risks are minimised.</p>
<b>Evaluation Method</b>	<p>Suppliers shall provide: a description of system scalability concept (e.g., modular expansion, adjustable process parameters); Hydraulic design range (Qmin–Qmax); explanation of how performance is maintained under varying flows; supporting evidence (modelling, lab tests, pilot data, technical documentation); Identification of any operational constraints/assumptions/limitations related to flow variation.</p> <p>Performance stability shall be demonstrated through design calculations (Phase 1); controlled testing under variable flow conditions (Phase 2); pilot validation under real flow variability (Phase 3).</p>
<b>Requirement ID</b>	OPR1.3
<b>Requirement Title</b>	<b>Wastewater temperature tolerance</b>
<b>Short Description</b>	<p>The solution shall be capable of continuous operation within a discharge temperature of the water treated within a range 10°C to 40 °C, without loss of operational integrity or treatment performance. The solution shall demonstrate the ability to operate continuously within an influent temperature range of 10 °C to 40 °C; maintain stable mechanical, hydraulic, and process performance within this range; avoid material degradation, safety risks, or system instability due to temperature variation.</p>
<b>Performance Criteria/KPI</b>	<p>The Suppliers shall demonstrate: defined operational temperature range covering 10–40 °C; no critical failure of system components within this range; no significant deterioration of key treatment performance parameters attributable to temperature variation; suitable materials and component specifications for thermal resistance.</p>
<b>Evaluation Method</b>	<p>Suppliers shall provide: a description of system scalability concept (e.g., modular expansion, adjustable process parameters); Hydraulic design range (Qmin–Qmax); explanation of how performance is</p>



	<p>maintained under varying flows; supporting evidence (modelling, lab tests, pilot data, technical documentation); Identification of any operational constraints/assumptions/limitations related to flow variation.</p> <p>Performance stability shall be demonstrated through design calculations (Phase 1); controlled testing under variable flow conditions (Phase 2); pilot validation under real flow variability (Phase 3).</p>
<b>Requirement ID</b>	OPR1.4
<b>Requirement Title</b>	<b>pH tolerance and variability</b>
<b>Short Description</b>	<p>The solution shall be capable of operating within a discharge wastewater average pH variability and fluctuations (6.0-9.0) expected during routine hospital operation, without loss of treatment performance or system integrity. The solution shall demonstrate: a supported operational average pH range 6.0-9.0; stable mechanical, hydraulic, and process operation within this range; no significant deterioration of key treatment performance parameters due to pH fluctuations within this interval; no material degradation, corrosion risk, or structural instability within this range.</p> <p>The Contractors shall specify: the full supported average pH operating range; the acceptable short-term pH variability tolerance; whether pH adjustment is required for stable operation; the impact (if any) of pH variation on removal performance.</p>
<b>Performance Criteria/KPI</b>	The Suppliers shall demonstrate continuous operability within pH 6.0-9.0; no critical system failure; no significant performance decline attributable solely to pH variation within this range.
<b>Evaluation Method</b>	<p>Suppliers shall provide: a description of system scalability concept (e.g., modular expansion, adjustable process parameters); Hydraulic design range (Qmin-Qmax); explanation of how performance is maintained under varying flows; supporting evidence (modelling, lab tests, pilot data, technical documentation); Identification of any operational constraints/assumptions/limitations related to flow variation.</p> <p>Performance stability shall be demonstrated through design calculations (Phase 1); controlled testing under variable flow conditions (Phase 2); pilot validation under real flow variability (Phase 3).</p>

<b>Requirement ID</b>	OPR1.5
<b>Requirement Title</b>	<b>Baseline organic load compatibility</b>
<b>Short Description</b>	The solution shall be technically compatible with hospital wastewater organic load characteristics. Its operational envelope with respect to COD (Chemical Oxygen Demand) and/or BOD <sub>5</sub> (Biochemical Oxygen Demand) shall be clearly defined and justified. Where relevant, the solution shall demonstrate: a clearly defined applicable operating range for COD and/or BOD <sub>5</sub> ; technical coherence between the selected treatment processes and the expected organic load characteristics; explicit identification of operational constraints or performance dependencies related to organic load variability.
<b>Performance Criteria/KPI</b>	<p>The Suppliers shall specify the supported COD and/or BOD<sub>5</sub> operating range; Indicate whether the system is:</p> <ul style="list-style-type: none"> <li>- Load-independent (e.g., primarily physicochemical), or</li> <li>- Load-dependent (e.g., biological processes);</li> </ul> <p>Describe minimum and maximum organic load conditions required for stable operation; Clearly state any constraints (e.g., minimum biodegradable fraction required); explain how the system adapts to load variability (if applicable). The solution must not rely on unrealistic or undefined organic load assumptions.</p>
<b>Evaluation Method</b>	<p>Suppliers shall provide: a description of system scalability concept (e.g., modular expansion, adjustable process parameters); Hydraulic design range (Q<sub>min</sub>–Q<sub>max</sub>); explanation of how performance is maintained under varying flows; supporting evidence (modelling, lab tests, pilot data, technical documentation); Identification of any operational constraints/assumptions/limitations related to flow variation.</p> <p>Performance stability shall be demonstrated through design calculations (Phase 1); controlled testing under variable flow conditions (Phase 2); pilot validation under real flow variability (Phase 3).</p>
<b>Requirement ID</b>	OPR1.6

<b>Requirement Title</b>	<b>Operational autonomy, staffing, and maintenance</b>
<b>Short Description</b>	The solution shall be designed for operational autonomy and low maintenance burden, minimising manual intervention by hospital staff during normal operation. Suppliers shall provide a clear description of operational and maintenance requirements, such as: Standard Operating Procedures (SOPs), fail safe behaviours and recovery mechanisms, expected frequency and type of routine and corrective interventions; easy access for inspection, replacement of parts and repair; required number of personnel for operation and maintenance; whether continuous on-site supervision is required or remote monitoring and automated operation; required training effort, expressed as training hours per operator; required skill level of operators (e.g. technician, engineer, basic operator).
<b>Performance Criteria/KPI</b>	KPI OPR1.6.1 – Operational autonomy and supervision requirements KPI OPR1.6.2 – Routine and corrective intervention frequency KPI OPR1.6.3 – Staffing requirements for operation and maintenance KPI OPR1.6.4 – Operator training effort and skill requirements
<b>Evaluation Method</b>	Suppliers shall provide: a description of system scalability concept (e.g., modular expansion, adjustable process parameters); Hydraulic design range (Qmin–Qmax); explanation of how performance is maintained under varying flows; supporting evidence (modelling, lab tests, pilot data, technical documentation); Identification of any operational constraints/assumptions/limitations related to flow variation. Performance stability shall be demonstrated through design calculations (Phase 1); controlled testing under variable flow conditions (Phase 2); pilot validation under real flow variability (Phase 3).
<b>Requirement ID</b>	OPR1.7
<b>Requirement Title</b>	<b>Performance</b>

<b>Short Description</b>	The solution shall work 24/7 without unplanned downtime and without interruption of treatment performance. The solution shall demonstrate the capability to operate continuously (24 hours per day, 7 days per week) under normal operating conditions, ensuring: no unplanned treatment interruption; no uncontrolled discharge of untreated wastewater; no system shutdown required for routine operation. Temporary interruptions are only permitted if: they are planned, they do not interrupt treatment (e.g., redundancy, parallel lines); they do not result in untreated discharge.
<b>Performance Criteria/KPI</b>	The solution shall demonstrate: design provisions for continuous operation (e.g., redundancy, buffering, modularity); backup systems for critical components (where applicable); defined procedures for maintenance without full system shutdown; system resilience during power or operational disturbances (if applicable).
<b>Evaluation Method</b>	Suppliers shall provide: a description of system scalability concept (e.g., modular expansion, adjustable process parameters); Hydraulic design range (Qmin–Qmax); explanation of how performance is maintained under varying flows; supporting evidence (modelling, lab tests, pilot data, technical documentation); Identification of any operational constraints/assumptions/limitations related to flow variation. Performance stability shall be demonstrated through design calculations (Phase 1); controlled testing under variable flow conditions (Phase 2); pilot validation under real flow variability (Phase 3).
<b>Requirement ID</b>	OPR1.8
<b>Requirement Title</b>	<b>Cybersecurity</b>
<b>Short Description</b>	The solution architecture shall be capable of incorporating structured cybersecurity controls aligned with recognised standards (e.g., ISO/IEC 27001/27002 principles or equivalent frameworks (e.g E-ITS) for systems deployed in hospital environments), including secure operation/communication when integrated/interoperable with other legacy systems.

## Performance Criteria/KPI

Verification that cybersecurity considerations are incorporated at the system architecture and design level. Assessment of the proposed cybersecurity approach, including identification of relevant control domains (e.g., access control, data protection, secure communication, logging and monitoring) and alignment with recognised cybersecurity frameworks (e.g., ISO/IEC 27001/27002 principles or equivalent). Suppliers shall provide: cybersecurity architecture overview, description of implemented or planned controls covering at least:

- access control
- data protection (e.g. encryption in transit where applicable)
- secure configuration
- logging or traceability
- secure integration interfaces
- identification of risks related to hospital IT integration.

KPI phase 1 Cybersecurity Consideration in System Architecture

PASS: The solution architecture is compatible with the integration of cybersecurity controls aligned with recognised standards (e.g. ISO/IEC 27001/27002 principles or E-ITS).

A high-level cybersecurity architecture or concept is described. The supplier identifies key cybersecurity domains relevant for hospital deployment (e.g. access control, data protection, logging, secure interfaces).

Potential risks related to integration with hospital IT systems are identified. The proposal explains how cybersecurity controls could be implemented or integrated in later development stages.

FAIL: Cybersecurity considerations are not addressed at all in the system architecture. The proposal does not demonstrate that the solution could support secure integration with hospital IT systems. No cybersecurity risks or integration considerations are identified.

KPI Phase 2/3 Prototype Architecture Compatibility with Cybersecurity Controls

PASS: The prototype architecture remains compatible with the integration of cybersecurity controls foreseen in Phase 1; Interfaces for data exchange, monitoring, or remote access (if present) are described with basic security considerations; The supplier confirms that no architectural limitations exist that would prevent the implementation of cybersecurity controls in later stages (e.g. in Phase 3



	<p>deployment); Any cybersecurity-related risks identified during prototype testing are documented, together with mitigation approaches. Implementation of cybersecurity systems in the prototype at Phase 2/3 is not required.</p> <p>FAIL: The prototype architecture introduces design constraints preventing integration of cybersecurity controls in later stages; Communication interfaces are designed in a way that would prevent secure integration with hospital IT systems; Cybersecurity considerations are not addressed in the prototype documentation.</p>
<b>Evaluation Method</b>	<p>Suppliers shall provide: a description of system scalability concept (e.g., modular expansion, adjustable process parameters); Hydraulic design range (Qmin–Qmax); explanation of how performance is maintained under varying flows; supporting evidence (modelling, lab tests, pilot data, technical documentation); Identification of any operational constraints/assumptions/limitations related to flow variation.</p> <p>Performance stability shall be demonstrated through design calculations (Phase 1); controlled testing under variable flow conditions (Phase 2); pilot validation under real flow variability (Phase 3).</p>
<b>Requirement ID</b>	OPR1.9
<b>Requirement Title</b>	<b>Suspended Solids and solid fractions handling capability</b>
<b>Short Description</b>	<p>The solution shall be capable of handling suspended solids (Total Suspended Solids, TSS) and typical solid fractions (e.g. Uricacid crystals) present in hospital wastewater without loss of treatment performance, hydraulic blockage, fouling, or mechanical damage. Suppliers shall specify:</p> <ul style="list-style-type: none"> <li>- Maximum allowable influent suspended solids concentration (expressed in mg/L TSS);</li> <li>- Maximum allowable particle size (if applicable to the technology);</li> <li>- Required pre-treatment measures, where applicable (e.g., screening, coarse filtration, grit removal, equalisation);</li> <li>- Design and operational measures implemented to prevent clogging, fouling, scaling, or hydraulic disruption, including: hydraulic design features; anti-fouling mechanisms; backwashing or cleaning procedures; protective barriers or filters; operational safeguards under variable solids load. The supplier</li> </ul>

	shall clearly define the applicable operating envelope for suspended solids and indicate any operational constraints or performance dependencies related to solids loading.
<b>Performance Criteria/KPI</b>	<p>Phase 1: The contractors shall provide: supported TSS operating range (minimum–maximum), maximum allowable particle size (if relevant to the technology); identification of required pre-treatment (e.g., screening, grit removal); description of clogging/fouling prevention mechanisms; operational limits beyond which performance or integrity may be compromised. The solution must not rely on undefined influent solids assumptions.</p> <p>Phase 2: Validate under controlled prototype testing conditions, that the solution can operate reliably within its declared suspended solids (TSS) operating range without experiencing significant clogging, hydraulic instability, excessive fouling, or mechanical damage. The objective is to confirm short-term operational robustness and consistency with the solids tolerance declared in Phase 1, without requiring long-term durability validation</p> <p>Phase 3: The solution shall demonstrate: stable operation under real influent TSS variability; no recurrent clogging causing operational interruption; no structural or mechanical damage attributable to solids loading; maintenance frequency related to solids handling consistent with declared expectations/maintenance and servicing procedures; no significant deterioration of treatment performance due to solids.</p>
<b>Evaluation Method</b>	<p>Suppliers shall provide: a description of system scalability concept (e.g., modular expansion, adjustable process parameters); Hydraulic design range (<math>Q_{min}</math>–<math>Q_{max}</math>); explanation of how performance is maintained under varying flows; supporting evidence (modelling, lab tests, pilot data, technical documentation); Identification of any operational constraints/assumptions/limitations related to flow variation.</p> <p>Performance stability shall be demonstrated through design calculations (Phase 1); controlled testing under variable flow conditions (Phase 2); pilot validation under real flow variability (Phase 3).</p>
<b>Requirement ID</b>	OPR1.10
<b>Requirement Title</b>	<b>Monitoring System/Dashboard</b>

<b>Short Description</b>	The solution shall provide a monitoring system depicting the process parameters (technology specific) responsible for the proper operation of the system (connected with alarms indicating that the system is not working properly, maintenance logs and O&M instructions)
<b>Performance Criteria/KPI</b>	<p>KPI Phase 1 Monitoring System Design Completeness</p> <p>The proposed solution shall include a clearly defined monitoring concept covering critical process parameters, alarm logic, maintenance logging, and O&amp;M documentation necessary for safe and proper operation.</p> <p>KPI Phase 2/3: Prototype Monitoring Functionality Verification</p> <p>The monitoring system described in Phase 1 is implemented at prototype level and supports proper system operation through parameter display, alarm activation, and maintenance logging functionality.</p>
<b>Evaluation Method</b>	<p>Suppliers shall provide: a description of system scalability concept (e.g., modular expansion, adjustable process parameters); Hydraulic design range (<math>Q_{min}</math>–<math>Q_{max}</math>); explanation of how performance is maintained under varying flows; supporting evidence (modelling, lab tests, pilot data, technical documentation); Identification of any operational constraints/assumptions/limitations related to flow variation.</p> <p>Performance stability shall be demonstrated through design calculations (Phase 1); controlled testing under variable flow conditions (Phase 2); pilot validation under real flow variability (Phase 3).</p>
<b>Requirement ID</b>	OPR1.11
<b>Requirement Title</b>	<b>Fault Handling mechanisms</b>
<b>Short Description</b>	The solution shall be robust and include appropriate automatic mechanisms to detect, isolate, and manage operational faults (e.g., blockages, pump failure, sensor malfunction) with minimal manual intervention. The system shall incorporate fail-safe behaviour and, where applicable, automatic protective responses to prevent performance degradation or equipment damage.



<b>Performance Criteria/KPI</b>	<p>KPI Phase 1: Fault Management Design Adequacy The proposed solution shall include a coherent fault detection and automatic response concept ensuring operational robustness with minimal manual intervention.</p> <p>Phase 2/3 KPI: Prototype Fault Handling Verification The prototype shall implement the declared fault detection and automatic response mechanisms and be able to manage common fault scenarios without requiring excessive manual intervention.</p>
<b>Evaluation Method</b>	<p>Suppliers shall provide: a description of system scalability concept (e.g., modular expansion, adjustable process parameters); Hydraulic design range (Qmin–Qmax); explanation of how performance is maintained under varying flows; supporting evidence (modelling, lab tests, pilot data, technical documentation); Identification of any operational constraints/assumptions/limitations related to flow variation.</p> <p>Performance stability shall be demonstrated through design calculations (Phase 1); controlled testing under variable flow conditions (Phase 2); pilot validation under real flow variability (Phase 3).</p>
<b>Requirement ID</b>	OPRI.12
<b>Requirement Title</b>	<b>Interoperability and Communication Compliance with existing systems</b>
<b>Short Description</b>	The solution shall be interoperable and capable of communication with hospital IT systems through standardised and documented interfaces (e.g., APIs or equivalent mechanisms), enabling integration into existing digital infrastructures and avoiding stand-alone operation.
<b>Performance Criteria/KPI</b>	<p>KPI Phase 1: Interoperability Design Readiness The proposed solution shall include a clearly defined interoperability concept enabling secure communication with hospital IT systems via standardised interfaces.</p> <p>KPI Phase 2/3: Prototype Communication Capability Verification</p>

	The prototype shall implement the declared communication interface and is technically capable of data exchange via standardised mechanisms, even if not connected to a hospital IT system.
<b>Evaluation Method</b>	Suppliers shall provide: a description of system scalability concept (e.g., modular expansion, adjustable process parameters); Hydraulic design range (Qmin–Qmax); explanation of how performance is maintained under varying flows; supporting evidence (modelling, lab tests, pilot data, technical documentation); Identification of any operational constraints/assumptions/limitations related to flow variation. Performance stability shall be demonstrated through design calculations (Phase 1); controlled testing under variable flow conditions (Phase 2); pilot validation under real flow variability (Phase 3).
<b>Category</b>	<b>SPACE &amp; SITE INTEGRATION REQUIREMENTS</b>
<b>Requirement ID</b>	SSI1.1
<b>Requirement Title</b>	<b>Site Compatibility and Installation</b>
<b>Short Description</b>	The solution shall be compatible with hospital site constraints as defined in Annex 1. Test sites, and shall be installable either indoors or outdoors, or as a combination of both, as appropriate for the proposed deployment scenario. The supplier shall clearly specify installation requirements, including: Required infrastructure (e.g., electrical supply, drainage, ventilation, access needs); Environmental installation conditions (e.g., temperature range, weather exposure, ventilation requirements); Water loss prevention measures (e.g., sealed piping, containment, leak detection); Any required site adaptations or structural provisions. The solution shall demonstrate practical feasibility for installation within hospital environments without imposing extensive infrastructure modifications. The supplier may perform site visits at the start of Phase 1 or propose the collection techniques for the detailed information on the site layout.
<b>Performance Criteria/KPI</b>	KPI Phase 1: Site Adaptability Design Assessment The proposed solution shall be adaptable to Annex 1. Test sites site constraints and related installation requirements shall be clearly defined.

	<p>KPI Phase 2/3: Prototype Installation Feasibility</p> <p>The prototype shall remain consistent with declared installation requirements and does not introduce additional site constraints.</p>
<b>Evaluation Method</b>	<p>Phase 1:</p> <p>Measurement method_ design based assessment Contractor shall provide: Installation scenario (indoor/outdoor/hybrid); infrastructure requirements (power, drainage, ventilation); environmental installation conditions; water loss prevention measures; required site adaptations;</p> <p>PASS: Installation requirements clearly defined; infrastructure needs are realistic; environmental conditions addressed; water loss prevention described; no evident incompatibility with Annex 1. Test sites</p> <p>FAIL : Installation requirements unclear; infrastructure unrealistic or undefined; water containment not addressed; environmental installation conditions omitted; incompatibility with Annex 1. Test sites evident.</p> <p>Phase 2/3: Measurement method based</p> <p>Even if the prototype is lab-based: actual footprint matches declared installation requirement shall be confirmed based on prototype testing together with confirmation of infrastructure needs (required power supply, drainage etc); demonstrate water loss prevention measures implemented; confirmation that no additional site requirements emerged; updated installation documentation shall be provided.</p> <p>PASS: Prototype is consistent with declared installation logic; infrastructure requirements remain realistic including water containment measures, no new incompatibility with Annex 1. Test sites occurs.</p> <p>FAIL : Prototype testing shows significant footprint deviation (increase), Infrastructure needs increase unjustifiably including water containment measures; new constraints contradict Phase 1 feasibility.</p>

<b>Requirement ID</b>	SSI1.2
<b>Requirement Title</b>	<b>Space Efficiency &amp; Scalability</b>
<b>Short Description</b>	<p>The solution shall be suitable for deployment in hospitals with limited available space and complex built environments (e.g., multiple buildings, urban hospitals), as described in Annex 1. Test sites.</p> <p>The contractor shall demonstrate that the solution: Is space-efficient, with clearly defined physical footprint and height requirements relative to treatment capacity; is modular in design, enabling installation as independent or interconnected units; can be adapted to different installation scenarios, including: indoor technical rooms, toilets , outdoor areas, distributed configurations across multiple buildings, while maintaining the required treatment performance parameters.</p> <p>The solution shall include a clear upscaling and downscaling strategy, describing: the achievable treatment capacity range without fundamental redesign; the method of capacity expansion (e.g., parallel modules, staged expansion, containerised units); the impact of scaling on space requirements; preservation of treatment performance when scaling, and demonstrate that the solution maintains technical coherence between space efficiency and performance (i.e., performance shall not depend on disproportionate spatial expansion).</p>
<b>Performance Criteria/KPI</b>	<p>KPI Phase 1: KPI: Design-Level Space and Scalability Verification</p> <p>The proposed solution shall be space-efficient, modular, and scalable, and adaptable to hospitals with limited space and complex built environments without requiring fundamental redesign.</p> <p>KPI Phase 2/3: KPI: Prototype Modularity and Adaptability Confirmation</p> <p>The prototype configuration shall remain consistent with declared space efficiency, modularity, and scalability and does not introduce constraints limiting adaptability to complex hospital layouts.</p>
<b>Evaluation Method</b>	<p>Measurement Method Phase 1</p> <p>Assessment based on Concept Design -Evaluation shall be based on submitted design documentation.</p> <p>The contractor shall provide: Physical footprint (m<sup>2</sup>) and height requirements relative to treatment capacity (e.g., m<sup>2</sup> per m<sup>3</sup>/day); description of modular architecture, including: independent or</p>

	<p>repeatable treatment units; interconnection logic between modules; possibility of partial deployment; defined treatment capacity range achievable without redesign; clear upscaling and downscaling strategy (e.g., parallel modules); description of adaptability to different installation configurations, including: indoor technical rooms; outdoor installations; possible distributed configurations across multiple buildings; confirmation that treatment performance is preserved when scaling or modularly configuring the system.</p> <p>PASS : Footprint and capacity relationship clearly defined; modular design concept clearly described; scalability method technically coherent; adaptability to multiple installation configurations demonstrated;</p> <p>no architectural lock-in to a single layout; performance preservation under scaling addressed.</p> <p>FAIL: No defined footprint or capacity relationship; no modular structure described; no scaling strategy; adaptability to different configurations not demonstrated; system is inherently rigid or site-specific; performance under scaling not addressed.</p> <p>Measurement Method Phase 2</p> <p>Even if installed in a laboratory setting, evaluation shall focus on architectural adaptability. The contractor shall demonstrate: Prototype footprint consistent with Phase 1 declaration; clearly identifiable modular units or modular logic in construction; defined inlet/outlet interfaces enabling distributed or multi-building configurations; confirmation that scaling remains achievable without redesign of the core treatment process; confirmation that no new architectural constraints emerged during prototype development.</p> <p>Physical upscaling is not required (Phase 3)</p>
<b>Requirement ID</b>	SSI1.3
<b>Requirement Title</b>	<b>Climate Adaptability</b>
<b>Short Description</b>	The solution shall be capable of continuous and stable operation under representative European climatic conditions, including temperature, humidity, and precipitation extremes relevant for both

	northern and southern European regions. For outdoor installations, the solution shall be designed to withstand environmental exposure without loss of performance, structural integrity, or operational stability. The contractors shall define the environmental operating envelope (including minimum and maximum ambient temperature, relative humidity, and weather exposure conditions) and demonstrate that treatment performance and system integrity are preserved within this range.
<b>Performance Criteria/KPI</b>	<p>Phase 1: Verify, at design level, that the solution defines and supports an environmental operating envelope suitable for representative European climatic conditions and outdoor deployment where applicable.</p> <p>Phase 2/3: Confirm that the prototype design remains consistent with the environmental operating envelope declared in Phase 1 and does not introduce technical constraints that would prevent future deployment under representative European climatic conditions.</p>
<b>Evaluation Method</b>	<p>Phase 1. Evaluation shall be based on analysis of submitted technical documentation. Contractors shall provide a defined environmental operating envelope including: minimum and maximum ambient temperature (°C); relative humidity range (%); weather exposure tolerance (rain, snow, solar radiation, dust – where relevant); identification of critical components ( e.g. electronic) sensitive to environmental conditions; description of protection measures, including e.g. insulation; fading or frost protection; ventilation or cooling; weatherproof enclosures; corrosion protection, etc.; confirmation that treatment performance is preserved within the declared environmental range; specification of any operational limitations or boundary conditions related to climatic conditions.</p> <p>Phase 2/3: Evaluation shall be based on documentation review and basic prototype inspection. The contractor shall: Confirm the declared environmental operating range (temperature and humidity); provide manufacturer specifications for key components demonstrating compatibility with the declared range; confirm that no prototype modifications contradict the environmental robustness claims made in Phase 1. No environmental stress testing, outdoor deployment, or climate simulation is required at this stage. An environmental stress test or the availability of data will be highly appreciated.</p>
<b>Requirement ID</b>	SSI1.4
<b>Requirement Title</b>	<b>Solution Layout</b>

<b>Short Description</b>	<p>The solution shall be adaptable to different hospital wastewater discharge configurations, including hospitals with single or multiple discharge networks, decentralised plumbing layouts, or distributed wastewater streams.</p> <p>The Supplier shall propose and justify the most suitable collection and treatment configuration (e.g., centralised (all hospital waste water), decentralised (e.g. hospital department), or hybrid), taking into account: existing discharge infrastructure; potential multiple collection points; hydraulic constraints; space limitations.</p> <p>The proposed configuration shall demonstrate technical feasibility and operational coherence within the hospital environment as described in Annex 1. Test sites.</p>
<b>Performance Criteria/KPI</b>	<p>KPI Phase 1. Design-Level Solution Adaptability to Different Hospital Wastewater Discharge Configurations Verification The proposed solution should feature the most appropriate configuration for wastewater collection and treatment, taking into account the characteristics of the test site described in Annex 1. The choice of a centralised, decentralised, or hybrid system must be clearly justified. KPI Phase 2/3. Prototype Adaptability to Different Hospital Wastewater Discharge Configurations Confirmation The prototype configuration shall remain consistent with the declared adaptability to different hospital wastewater discharge configurations and shall not introduce constraints that limit adaptability to complex hospital layouts.</p>
<b>Evaluation Method</b>	<p>Phase 1: Measurement Method – design-based assessment.</p> <p>Evaluation shall be based on the submitted concept documentation. Contractor shall provide a description of the proposed configuration for wastewater collection and treatment e.g., centralised (for all hospital wastewater), decentralised (e.g. hospital department), or hybrid systems. The solution should take into account the real conditions at the test site, including the existing wastewater disposal infrastructure; potential multiple collection points (where applicable); hydraulic constraints; and spatial constraints. Evaluation PASS: configuration for wastewater collection and treatment clearly demonstrated, a comprehensive justification for the choice of configuration, real test site conditions addressed, no evident incompatibility with Annex 1. Test sites</p> <p>FAIL: proposed configuration for wastewater collection and treatment unclear, no justification for the configuration choice, real test site conditions omitted, incompatibility with Annex 1. Test sites are evident. Phase 2: Measurement Method During prototype testing, the supplier must demonstrate that</p>

	<p>its design and performance comply with the documentation submitted in Phase 1. The prototype must include all technical components necessary for its connection to the previously declared centralised, decentralised, or hybrid system.</p> <p>Evaluation</p> <p>PASS: The design and performance of the prototype comply with the documentation submitted in Phase 1 and enable the collection and treatment of wastewater in accordance with the declared technology purpose</p> <p>FAIL: The design and performance do not comply with the documentation submitted in Phase 1. It is not possible to collect and treat wastewater in accordance with the declared technology purpose</p> <p>Phase 3: Measurement Method</p> <p>During Phase 3, the pilot shall be installed at the designated test site in accordance with the specifications of Phase 1.</p> <p>Evaluation</p> <p>PASS: Installation complete; the configuration for wastewater collection and treatment complies with the Phase 1 design, real test site conditions addressed, no evident incompatibility with Annex 1. Test sites</p> <p>FAIL: no pilot installed, the system does not comply with the Phase 1 design, real test site conditions omitted, incompatibility with Annex 1. Test sites are evident.</p>
<b>Category</b>	<b>Water reuse &amp; Water efficiency</b>
<b>Requirement ID</b>	WR1.1
<b>Requirement Title</b>	<b>Water Reusability</b>
<b>Short Description</b>	<p>The quality of the treated water is sufficient to allow reuse for at least one practical reuse application like e.g. irrigation, cleaning, toilet flushing, cooling water for energy, etc. The suppliers are expected to:</p> <ol style="list-style-type: none"> <li>1. Identify the applicable regulatory or technical quality requirements;</li> <li>2. Provide measured (or projected) effluent quality values;</li> <li>3. Demonstrate compliance with the minimum thresholds for that reuse application.</li> </ol>





<b>Performance Criteria/KPI</b>	<p>Verify that the treated effluent quality is sufficient to enable reuse for at least one realistic and legally permitted non-potable application.</p> <p>The treated effluent shall meet the minimum quality requirements applicable to at least one reuse application under the relevant regulatory framework.</p> <p>Compliance must be demonstrated based on measured effluent parameters (Phase 2 / Phase 3) or justified design projections (Phase 1).</p>
<b>Evaluation Method</b>	<p>The contractors shall: identify at least one specific reuse application; identify the applicable regulatory or technical quality requirements; provide measured (or projected for Phase 1) effluent quality values; demonstrate compliance with the minimum thresholds for that use (Phase 2/3). Please refer to A4.4 for additional information.</p>
<b>Category</b>	<b>Sustainability aspects</b>
<b>Requirement ID</b>	SCA1.1
<b>Requirement Title</b>	<b>Energy efficiency</b>
<b>Short Description</b>	<p>The proposed solution shall demonstrate and report energy efficiency per unit of treated wastewater. Energy consumption data will be assessed in relation to the achieved treatment performance (volume, efficiency).</p> <p>Suppliers shall report: Energy intensity (kWh/m<sup>3</sup> treated);</p> <p>The solution shall also be compatible with integration into hospital electrical infrastructure (renewable energy supply, where feasible).</p>
<b>Performance Criteria/KPI</b>	<p>KPI SCA1.1-KPI1: Energy intensity reporting</p> <p>KPI SCA1.1-KPI2: Energy compatibility and integration</p> <p>KPI SCA1.1-KPI3: Energy efficiency performance</p>



## Evaluation Method

In Phase 1, suppliers are expected to provide descriptive and indicative information based on design specifications, prior experience, reference installations, or comparable systems. Measured data is not required at this stage.

In Phases 2 and 3, energy consumption should be measured directly under testing and operational conditions

KPI SCA1.1-KPI1: Energy intensity reporting

Phase 1 Pass criteria: Estimated energy consumption (kWh/m<sup>3</sup>) reported with supporting assumptions.

Evaluation method: Document review of technical proposal

Phase 2 Pass criteria

Measured or prototype-based energy consumption (kWh/m<sup>3</sup>) reported based on testing of the developed prototype under controlled operating conditions. Suppliers shall document measurement methods, operating conditions, and assumptions used to calculate energy intensity.

Evaluation method: Review of prototype testing documentation and energy measurement records.

Phase 3 Pass criteria

Measured energy consumption (kWh/m<sup>3</sup>) reported during pilot operation under representative hospital wastewater conditions.

Evaluation method: Operational monitoring data and performance records review.

KPI SCA1.1-KPI2: Energy compatibility and integration

Suppliers shall describe compatibility with hospital electrical infrastructure and potential for integration with renewable electricity sources where feasible.

Phase 1 Pass criteria: Basic electrical specifications provided (voltage, frequency, power demand, connection requirements), demonstrating compatibility with standard hospital electrical infrastructure.

Phase 2 Pass criteria Updated compatibility with hospital electrical infrastructure demonstrated through prototype testing or engineering validation. Suppliers shall confirm system integration



	<p>requirements and identify any additional infrastructure needed.</p> <p>Evaluation method: Review of prototype testing documentation and updated technical specifications.</p> <p>Phase 3 Pass criteria Stable operation under hospital electrical infrastructure confirmed throughout pilot period.</p> <p>Evaluation method: Operational verification during pilot deployment.</p> <p>KPI SCA1.1-KPI3: Energy efficiency performance The solution shall demonstrate energy-efficient operation relative to achieved treatment performance, assessed in relation to contaminant removal performance and operational effectiveness. Phase 1 Pass criteria: Supplier provides a brief justification of expected energy efficiency, explaining how reported energy consumption corresponds to claimed removal performance and identifying the main energy-consuming components of the system. Justification may draw on calculations, modelling, laboratory testing, pilot studies, comparable technologies, reference installations, or relevant literature. Evaluation method: Document review.</p> <p>Phase 2 Pass criteria Preliminary energy efficiency demonstrated based on prototype testing results, including measured energy consumption and corresponding contaminant removal performance under controlled testing conditions.</p> <p>Evaluation method: Review of prototype test results and supporting documentation.</p> <p>Phase 3 Pass criteria Energy efficiency performance verified during pilot operation based on measured energy consumption and achieved contaminant removal performance under real operating conditions.</p> <p>Evaluation method: Operational performance data review.</p>
<b>Requirement ID</b>	SCA1.2

<b>Requirement Title</b>	<b>Cost Efficiency</b>
<b>Short Description</b>	The proposed solution shall include cost efficiency as a design consideration and provide transparent cost information across all procurement phases to enable assessment of economic sustainability. Suppliers shall provide a structured cost breakdown including CAPEX and OPEX.
<b>Performance Criteria/KPI</b>	KPI SCA1.2-KPI4: CAPEX reporting KPI SCA1.2-KPI5: OPEX reporting
<b>Evaluation Method</b>	<p>Suppliers shall provide:</p> <p>CAPEX: total upfront cost of the proposed system (€ or €/m<sup>3</sup> treated), including equipment, installation, engineering, design, and system integration  OPEX: estimated operational cost (€/m<sup>3</sup> or €/year), including, but not limited to, energy, chemicals, consumables, maintenance, replacement of parts, and waste management</p> <p>Phase 1 Pass criteria: Estimated CAPEX and OPEX provided, covering main cost components. Ranges and assumptions are accepted at this stage. Evaluation method: Financial documentation review.</p> <p>Phase 2 Pass criteria: Updated CAPEX and OPEX estimates reflecting refined system design and prototype development. Suppliers shall update cost assumptions and provide a more detailed breakdown of major cost components where available. Evaluation method: Technical and financial documentation review of updated cost estimates and supporting assumptions.</p> <p>Phase 3 Pass criteria: Final CAPEX and OPEX reported based on pilot deployment and operational records. CAPEX shall reflect actual procurement, installation, and integration costs. OPEX shall be based on measured operational parameters where available. Where a cost component could not be directly measured within the testing period, a justified estimate with clearly stated assumptions is accepted. Evaluation method: Review of financial records, procurement documentation, and operational cost records.</p>

<b>Requirement ID</b>	SCA1.3
<b>Requirement Title</b>	<b>Health &amp; safety</b>
<b>Short Description</b>	The solution shall be designed to minimise exposure risks for hospital staff during installation, operation, maintenance, and handling of consumables, residues, or treatment by-products (if present). Suppliers shall disclose any potential occupational health and safety risks associated with the solution; the technical and organisational measures implemented to minimise exposure to wastewater, chemicals, and treatment processes; safe procedures for operation, maintenance, and handling of consumables and waste.
<b>Performance Criteria/KPI</b>	KPI SCA1.3-KPI7: Risk identification and safety documentation
<b>Evaluation Method</b>	<p>KPI SCA1.3-KPI1: Risk identification and safety documentation</p> <p>Phase 1 Pass criteria: Identification and description of possible occupational risks and a proposal of mitigation measures</p> <p>Evaluation Method: Safety documentation review</p> <p>Phase 2 Pass criteria Safety procedures updated. Suppliers shall report any safety incidents or operational risks observed during testing and demonstrate implementation of mitigation measures.</p> <p>Evaluation Method: Review of safety documentation, testing reports, and risk management procedures.</p> <p>Phase 3 Pass criteria</p> <p>Safety procedures implemented and maintained during pilot deployment under hospital operating conditions. No uncontrolled safety incidents reported during the pilot operation.</p> <p>Where relevant, suppliers shall also indicate whether the proposed technology could lead to the accumulation or concentration of radioactive substances (e.g., from radiopharmaceutical residues) within treatment components, and how such risks are safely managed.</p>

	Evaluation method: Reporting from supplier & hospital. Where the solution involves the use of high voltage systems or reactive chemicals (e.g., ozone (O <sub>3</sub> ), hydrogen peroxide (H <sub>2</sub> O <sub>2</sub> ), or other treatment chemicals), suppliers shall demonstrate that appropriate operational procedures, safety instructions, and trained personnel requirements are in place to ensure safe operation and maintenance.
<b>Requirement ID</b>	SCA1.4
<b>Requirement Title</b>	<b>Supply-chain sustainability and responsible sourcing</b>
<b>Short Description</b>	Suppliers shall confirm compliance with Regulation (EU) 2017/821 on supply chain due diligence for conflict minerals, and where applicable, provide any available supporting documentation demonstrating or committing to supply chain due diligence and responsible sourcing principles.
<b>Performance Criteria/KPI</b>	KPI SCA1.4-KPI9: Supply chain due diligence
<b>Evaluation Method</b>	KPI SCA1.4-KPI8: Supply chain due diligence Phase 1/2/3: Supplier confirms compliance with Regulation (EU) 2017/821 and provides supporting documentation demonstrating or committing to responsible sourcing and supply chain due diligence practices. Evaluation method: Document review of supplier declaration and any supporting documentation.
<b>Requirement ID</b>	SCA1.5
<b>Requirement Title</b>	<b>Environmental added value</b>
<b>Short Description</b>	Suppliers shall identify an appropriate relevant alternative technology and clearly describe the major differences in environmental impacts, whether positive or negative, associated with the proposed technology in comparison with that alternative. The comparison shall focus primarily on the operation phase, considering where relevant: energy consumption and energy source; emissions to water

	<p>(including residual pollutants and by-products); emissions to air (including greenhouse gases where applicable); consumption of chemicals or consumables; water consumption; generation of hazardous and non-hazardous waste; other operational environmental trade-offs, such as noise or odour emissions.</p> <p>The information provided shall allow verification that the proposed solution does not introduce disproportionate environmental impacts compared to the identified relevant alternative(s). Where an aspect is not relevant, a brief justification shall be provided.</p>
<b>Performance Criteria/KPI</b>	<p>Phase 1: Verify, based on the information provided, that the proposed solution does not cause overall greater negative environmental impacts than environmental benefits compared to the identified relevant alternative(s), primarily during the operation phase.</p> <p>Phase 2/3: Verify, based on prototype testing and updated technical information, that the environmental added value claims made in Phase 1 remain valid and that the solution does not introduce disproportionate negative environmental impacts during operation compared to the identified relevant alternative(s).</p>
<b>Evaluation Method</b>	<p>Phase 1: Concept design screening check/assessment, qualitative. The supplier shall provide: Identification of a relevant alternative technology; a structured qualitative comparison of the proposed solution with the alternative(s); clear identification of major environmental benefits and potential adverse impacts during operation, addressing: energy consumption and energy source; emissions to water (including residual pollutants and by-products); emissions to air (including odours, greenhouse gases, where applicable); consumption of chemicals and/or consumables and their potential for recycling if applicable; water consumption; generation of hazardous and non-hazardous waste. Justification where an aspect is not relevant should be provided. Indication of the basis of the information (estimates, modelling, literature, prior experience). Quantitative data are encouraged but not mandatory at Phase 1.</p> <p>Phase 2/3: Evaluation shall be based on prototype test results and updated documentation. The contractor shall: Confirm or update the relevant alternative used for comparison; provide available prototype-level data or updated estimates concerning operation phase impacts, including where applicable: measured or estimated energy consumption; energy source (if relevant at this stage); operational chemical/consumable use; residual emissions to water; waste generation (hazardous and</p>

	non-hazardous); confirm whether Phase 1 environmental assumptions remain valid. The contractor shall also identify any newly observed environmental trade-offs arising from prototype testing. The contractor shall indicate clearly whether data are measured, calculated, or estimated.
<b>Category</b>	<b>General Requirements</b>
<b>Requirement ID</b>	GER1.1
<b>Requirement Title</b>	<b>Phase 2 Prototype Testing</b>
<b>Short Description</b>	<p>In Phase 2, the solution shall undergo a minimum of three (3) months of controlled testing following prototype development in order to ensure the technical performance, relevance, applicability, and suitability of the solution to users' needs. Testing shall be conducted under controlled laboratory or simulated conditions reflecting, to the extent feasible at prototype stage, the operational characteristics of the solution relevant for its intended application (matrix and purpose) and its compatibility with the operational environment including constraints and limitations as described in Annex 1. Test sites</p> <p>The supplier shall provide also information to the staff supervising the testing on the standard operating procedures of the prototype, its maintenance and servicing requirements , the development plan during the testing activities ,safety and hazard aspects related to the testing and operation of the installation, and ensure adequate training of the staff responsible for the tests supervision.</p> <p>Testing may take place either at the premises of SAS or at the supplier's premises, provided that it is conducted under defined and supervised conditions. The supplier shall remain fully responsible for prototype installation, operation, optimisation, utilities, consumables, waste handling, and safe discharge management throughout the testing period. Testing shall be performed in accordance with the Phase 2 testing requirements as specified in Annex 6. Phase 1 testing strategy &amp; requirements.</p> <p>Contractor shall be responsible for the development of a Test Plan according to the template provided in Tender Document 12 (TD 12): Generic test plan template. At the end of Phase 2, the contractor shall submit a comprehensive Test Report developed according to the template provided in Tender Document 13 (TD 13): Generic test report template. The Test Report shall include full performance data, results against the defined KPIs, and documentation of testing conditions and methodologies. The</p>



	report shall also include information about any deviations from the test plan and description of their impact on the test results, The Test Report shall form part of the End of Phase 2 Report.
<b>Performance Criteria/KPI</b>	KPI: Phase 2 Testing Compliance Verification Contractor has conducted Phase 2 prototype testing in full compliance with the defined duration, capacity, operational mode, supervision, documentation, test planning and reporting requirements.
<b>Evaluation Method</b>	Please refer to Annex 6. Phase 2 testing strategy & requirements& Annex 5. Performance Criteria/KPI and evaluation/measurement methods for pass/fail award criteria and weighted award criteria of Phase 1
<b>Requirement ID</b>	GER1.2
<b>Requirement Title</b>	<b>Phase 3 Pilot deployment</b>
<b>Short Description</b>	<p>In Phase 3, the solution shall be deployed, installed, and operationally demonstrated in hospital environments located in Estonia, Poland, Spain, and the Netherlands (see Annex X – Baseline). Piloting shall be performed in accordance with the Phase 3 pilot requirements as specified in Annex 7. Phase 3 verification strategy &amp; requirements. The supplier shall implement the solution at a minimum of two hospital sites (to be defined during Phase 2), in close coordination with the procurers and relevant end users. Prior to installation, the supplier shall conduct site visits to verify technical feasibility, infrastructure compatibility, spatial constraints, safety conditions, and integration requirements. The procurers shall provide reasonable access to relevant technical documentation and applicable hospital procedures. The supplier shall document the site assessment and confirm installation feasibility before deployment. The supplier shall be fully responsible for delivery, installation, commissioning, integration with utilities and hospital infrastructure, and safe operation of the solution at each site. Installation shall comply with applicable regulatory and safety requirements and shall not disrupt critical hospital functions.</p> <p>Before formal pilot performance verification begins, the supplier shall complete commissioning and pre-testing activities to ensure stable and safe operation under real-site conditions. All necessary documentation for installation, operation, maintenance, safety, and troubleshooting shall be provided.</p>

	<p>Structured on site training shall be delivered to designated hospital staff and adapted to the user profile. The supplier shall ensure that the pilot installation complies with site-specific safety requirements proportionate to the scale and nature of the system, including risk assessment, operational safeguards, emergency procedures, and required protective measures. During Phase 3, the supplier shall ensure stable and predictable operation of the pilot under real operational conditions. Performance shall be monitored against Phase 3 KPIs, operational data shall be documented, deviations recorded, and structured user feedback collected. Any optimisation affecting performance shall be completed and documented prior to formal performance data generation for verification purposes. Suppliers shall also describe their multi-site deployment strategy, including logistics, site adaptation, technical support, and operational continuity across pilot locations. The installed solutions shall remain at the participating hospital premises after completion of the PCP process provided that Phase 3 results demonstrate compliance with defined performance thresholds and KPI requirements, stable operation under real hospital conditions, fulfilment of procurer and user needs (including regulatory requirements), and absence of unresolved safety or integration concerns.</p> <p>Final determination shall be based on documented performance results verified through an independent third-party verification process conducted in accordance with ISO 14034 (Environmental Technology Verification) and GER 1.3, and formal acceptance by the procurers in accordance with the contractual framework.</p>
<b>Performance Criteria/KPI</b>	<p>KPI: Pilot Deployment and Performance Verification Readiness Compliance</p> <p>The solution shall be successfully deployed and operated under real hospital conditions in a manner that ensures stable operation, complete documentation and full readiness for independent performance verification under GER 1.3.</p>
<b>Evaluation Method</b>	<p>Please refer to Annex 7. Phase 3 verification strategy &amp; requirements &amp; Annex 5. Performance Criteria/KPI and evaluation/measurement methods for pass/fail award criteria and weighted award criteria of Phase 1</p>
<b>Requirement ID</b>	GER1.3

<b>Requirement Title</b>	<b>Phase 3 Verification (ETV)</b>
<b>Short Description</b>	Suppliers shall commit to undergoing an independent Environmental Technology Verification (ETV) process in accordance with ISO 14034 requirements, as specified in Annex X – Guide for ETV Applicants. The ETV shall be applied to the solution deployed in Phase 3 and shall aim to demonstrate compliance with user needs through third-party validation of pharmaceutical removal efficiency and the sustainability performance of the technology under real hospital operating conditions.
<b>Performance Criteria/KPI</b>	KPI: Pilot Deployment and Performance Verification Readiness Compliance The solution shall be successfully deployed and operated under real hospital conditions in a manner that ensures stable operation, complete documentation and full readiness for independent performance verification under GER 1.3.
<b>Evaluation Method</b>	Please refer to Annex 7. Phase 3 verification strategy & requirements & Annex 5. Performance Criteria/KPI and evaluation/measurement methods for pass/fail award criteria and weighted award criteria of Phase 1
<b>Requirement ID</b>	GER1.4
<b>Requirement Title</b>	<b>Testing compliance</b>
<b>Short Description</b>	The suppliers should demonstrate in Phase 2 & 3 compliance with the testing requirements listed in the current Tender Requirements, the evaluation methodology defined in Annex 5. Performance Criteria/KPI and evaluation/measurement methods for pass/fail award criteria and weighted award criteria of Phase 1 and the ISO 14034 ETV scheme Annex 8. Guide for ETV applicants
<b>Requirement ID</b>	GER1.5
<b>Requirement Title</b>	<b>Pilot (Phase 3) user feedback collection</b>



<b>Short Description</b>	During Phase 3 pilot testing, the supplier shall ensure the systematic collection of feedback from end users through structured evaluation questionnaires. Questionnaires shall be designed to capture user experience, usability, operational performance, and perceived effectiveness of the solution. The supplier shall ensure that feedback is collected from relevant user groups, including non-technical end users where applicable, and that responses are sufficiently addressed in the technical developments of Phase 3 and documented to support evaluation of the pilot results.
<b>Requirement ID</b>	GER1.6
<b>Requirement Title</b>	<b>Bug reporting, helpdesk, and feedback management</b>
<b>Short Description</b>	The supplier shall establish and operate a helpdesk and maintenance support function for the duration of the pilot phase (Phase 3) The supplier shall provide a simple, intuitive, and easily accessible mechanism for error reporting, bug reporting, and general user feedback submission by end users. The feedback and bug reporting mechanism shall allow users to report issues related to functionality, performance, usability, and operational reliability. The supplier shall document all reported issues and feedback and demonstrate how these inputs have been addressed, mitigated, or incorporated into the solution in the Phase 3 final deliverable.
<b>Requirement ID</b>	GER1.7
<b>Requirement Title</b>	<b>Pilot operation and maintenance support</b>
<b>Short Description</b>	The supplier shall ensure continuous operation and maintenance of all deployed systems at each pilot site for the full duration of Phase 3. Systems shall be maintained at full operational quality and performance in accordance with the agreed specifications. The supplier shall provide qualified personnel and resources capable of responding to incidents, malfunctions, or performance degradation, either remotely or on-site, within reasonable response times. All corrective actions taken during the pilot shall be recorded and reported as part of the Phase 3 results.

#	Description	Max. Points	Performance Criteria (KPIs)	Measurement Method
<b>A.</b>	<b>IMPACT ON THE CHALLENGE</b>	<b>70</b>		
<b>A1.</b>	<b>Removal Rates</b>	<b>20</b>		
A1.1	<p>The solution shall demonstrate a removal efficiency at least 80%, which will lead to an absolute post-treatment concentrations below specific threshold values (to be defined in Phase 1), or, where applicable, verified transformation into non-toxic metabolites for the selected cytostatic drugs (A 2.1., A2.6 &amp; CRR 1.1.). This requirement shall apply to all mandatory cytostatics and to any optional / nice-to-have cytostatics included in the offer.</p> <p>0 points - 80% or less  3 point - 81 to 90%  4 points - 91 to 100%</p> <p>Describe briefly how the proposed efficiency will be achieved and the targets in Phase 2 (laboratory environment) and Phase 3</p>	4	<p>Phase 1: Compliance Level with Minimum Removal Efficiency for Declared Cytostatic Compounds. Unit: % of cytostatics from the declared list with documented removal efficiency at a minimum of 80</p> <p>Phase 2/3: Validated Cytostatic Removal Index. Unit: number of cytostatics ( included in the synthetic wastewater used for testing with removal efficiency at a minimum of 80% vs initial concentration. Removal threshold determined based on the concentration of the selected cytostatic drugs in synthetic wastewater used for testing in Phase 2 and Phase 3</p>	<p>Phase 1: Qualitative, analysis of the documentation/proofs submitted (test data, peer-reviewed publications, technical specifications for the unit processes).</p> <p>Phase 2: Quantitative, concentration measurement data for inlet/outlet presented in test report.</p>

	(Operational conditions) . This shall be further developed in detail in the Solution Design of PCP Phase 1. Points will be awarded if the solution clearly demonstrates the removal efficiency approach . If not, zero points will be awarded.			
A1.2	<p>The solution shall demonstrate a removal efficiency of at least 40%, which will lead to an absolute post-treatment concentrations below specific threshold values (to be defined in Phase 1) of the selected contrast media (A2.2, A2.3, A2.5&amp; CRR1.2., CRR1.3)</p> <p>0 points - &gt; 40% or less  2 point - 41 to 60%  3 points- 61 to 80%  4 points- 81 to 100%</p> <p>Describe briefly how the proposed efficiency will be achieved and the targets in Phase 2 (laboratory environment) and Phase 3 (Operational conditions) . This shall</p>	4	<p>Phase 1: Compliance Level with Minimum Removal Efficiency for declared X ray contrast agents  Unit: number of x-ray contrast agents with declared removal efficiency above 40%  Phase 2/3: Validated X-ray contrast agents removal  Unit: number of x-ray contrast agents ( included in the synthetic wastewater used for testing with removal efficiency at a minimum of 40% vs initial concentration. Removal threshold determined based on the concentration of x-ray contrast agents in synthetic wastewater used for testing in</p>	<p>Phase 1: Qualitative, analysis of the documentation/proofs submitted (test data, peer-reviewed publications, technical specifications for the unit processes).  Phase 2/3: Quantitative, concentration measurement data for inlet/outlet presented in test report.</p>

	be further developed in detail in the Solution Design of PCP Phase 1. Points will be awarded if the solution clearly demonstrates the removal efficiency approach . If not, zero points will be awarded.		Phase 2 (min 2 used as representatives of each x-ray contrast groups)	
A1.3	<p>The solution shall demonstrate a removal efficiency of at least 90%,which will lead to an absolute post-treatment concentrations below specific threshold values (to be defined in Phase 1) of antibiotics (A2.4 &amp; CRR1.4):</p> <p>0 points - 90% or less 4 point - 91 to 100%</p> <p>Describe briefly how the proposed efficiency will be achieved and the targets in Phase 2 (laboratory environment) and Phase 3 (Operational conditions) . This shall be further developed in detail in the Solution Design of PCP Phase 1. Points will be awarded if the solution clearly demonstrates the</p>	4	<p>Phase 1: Compliance Level with Minimum Removal Efficiency for declared antibiotics. Unit: number of antibiotics per family with documented removal efficiency above 90%</p> <p>Phase 2/3: Validated antibiotics removal index. Unit: number of antibiotics per family (included in the synthetic wastewater used for testing with removal efficiency at the minimum declared removal efficiency vs initial concentration. Removal threshold determined based on the concentration of selected antibiotics representing individual families in synthetic wastewater used for testing in</p>	<p>Phase 1: Qualitative, analysis of the documentation/proofs submitted (test data, peer-reviewed publications, technical specifications for the unit processes).</p> <p>Phase 2/3 : Quantitative, concentration measurement data for inlet/outlet presented in test report.</p>

	removal efficiency approach . If not, zero points will be awarded.		Phase 2 (specific antibiotics to be spiked to synthetic wastewater)	
A1.4	<p>The solution shall demonstrate a removal efficiency (log reduction) of at least 90%, which will lead to an absolute post-treatment concentrations below specific threshold values (to be defined in Phase 1) of ARB (CRR1.5).  0 points - 90% or less  4 point - 91 to 100%  Provide a concise description of how your solution achieves the required removal rate, including the key treatment mechanisms, process steps, and any supporting evidence from laboratory, pilot, or full-scale applications.</p>	4	<p>Phase 1: Documented ARB Removal Capability (log reduction). Unit: Binary compliance indicator (Yes = 1 / No = 0)  Phase 2/3: Validated ARB Strain Reduction Performance. Unit: number of strains representing the following families removed above the declared removal efficiency.</p>	<p>Phase 1: Qualitative, analysis of the documentation/proofs/data submitted (test data, peer-reviewed publications, technical specifications for the unit processes).  Phase 2/3: Quantitative count of:  - Enterobacterales resistant to 3rd generation cephalosporins  - Carbapenem-resistant Enterobacterales  - Carbapenem-resistant Acinetobacter  IMPORTANT: Assessment will be done with an experiment based on real hospital wastewater on the top of the experiment with synthetic wastewater</p>



A1.5	<p>The solution shall demonstrate a removal efficiency of at least 90%, which will lead to an absolute post-treatment concentrations below specific threshold values (to be defined in Phase 1) ARG patterns (A2.7) :</p> <p>0 points - 90% or less 4 point - 91 to 100%</p> <p>Describe briefly how the proposed efficiency will be achieved and the targets in Phase 2 (laboratory environment) and Phase 3 (Operational conditions) . This shall be further developed in detail in the Solution Design of PCP Phase 1. Points will be awarded if the solution clearly demonstrates the removal efficiency approach . If not, zero points will be awarded.</p>	4	<p>Phase 1: Documented ARG Removal Capability. Unit: Binary compliance indicator (Yes = 1 / No = 0)</p> <p>Measurement method: Phase 2/3: Validated ARG Reduction Performance</p> <p>ARG Quantitative reduction of Priority Antibiotic Resistance Genes based on quantitative measurement of selected genes. Unit: Log<sub>10</sub> reduction value (LRV) per priority ARG (gene copies/mL). Minimum requirement ≥ 2 log<sub>10</sub> reduction (≥99% reduction) for each detected priority gene</p> <p>Target performance: ≥ 3 log<sub>10</sub> reduction (≥99.9% reduction) for the majority (&gt;70%) of detected genes</p>	<p>Phase 1 :Qualitative, analysis of the documentation/proofs/data submitted (test data, peer-reviewed publications, technical specifications for the unit processes).</p> <p>Phase2/3: Quantitative determination of priority ARG gene copy numbers in influent and effluent samples using validated qPCR or dPCR methods under controlled Phase 2 prototype testing conditions, with defined LOD/LOQ and paired sampling.</p>
<b>A2.</b>	<b>Contaminants</b>	<b>15</b>		

A.2.1	The solution shall demonstrate removal/degradation performance of cytostatic drugs, specifically: IFOSFAMIDE; TEMOZOLOMIDE; CYCLOPHOSPHAMIDE; ENZALUTAMIDE; FLUOROURACIL; METHOTREXATE; ABIRATERON; MYCOPHENOLATE; CISPLATIN; CARBOPLATIN; OXALIPLATIN Suppliers may propose additional cytostatic compounds (CYTARABINE, GEMCITABINE, HYDROXYCARBAMIDE, CAPECITABINE, SORAFENIB, ALPELISIB, ALECTINIB) beyond the listed substances (as long as the ones listed above are addressed).	3	Phase1: Declared Target Cytostatic Drugs Removal Coverage. Unit: number of contrast agents declared for removal from the target list Phase 2/3	Phase 1: Analysis of the documentation/proofs submitted (test data, peer-reviewed publications, technical specifications for the unit processes) Phase2/3 Phase 2/3: Quantitative and qualitative data on the concentration measurement in raw and treated wastewater are presented in test reports.
A.2.2	Solution shall demonstrate removal of watersoluble, nephrotropic, high osmolar Iodinated CT contrast media (ATC code: V08AB). Substances include: Iohexol ; Iopamidol ; Iopromide ; Iodixanol. Solution shall demonstrate removal of Paramagnetic Gadolinium based contrast media (ATC code: V08CA). Substances include: Gadopentetic acid; Gadoteric acid ; Gadodiamide; Gadoteridol;; Gadobutrol; Gadoxetic acid ; Gadopiclenol. The solution supports additional	3	Phase 1 : Declared Target X-ray Contrast Agents ( watersoluble, nephrotropic, high osmolar Iodinated CT contrast media ATC code: V08AB) Removal Coverage Unit: number of X-ray contrast agents declared for removal from the target list Phase 1: Declared Target X-ray Contrast Agents ( Paramagnetic Gadolinium based contrast media ATC code V08CA) Removal Coverage Unit number of x-ray contrast	Phase 1: Analysis of the documentation/proofs submitted (test data, peer-reviewed publications, technical specifications for the unit processes) Phase 2/3: Quantitative and qualitative data on the concentration measurement in raw and treated wastewater are presented in test reports.

	contrast media removal in any of the the below categories (as long as the ones listed above are addressed) : Watersoluble, nephrotropic, high osmolar x-ray contrast media (ATC code V08AA), Watersoluble, hepatotropic x-ray contrast media (ATCcode: V08AC), Non-watersoluble x-ray contrast media (ATC code: V08AD), X-ray contrast media, non-iodinated(ATC code:V08B).		agents declared for removal Phase2/3 Validated Contrast Agent Removal Coverage	
A.2.3	Solution shall demonstrate removal of Paramagnetic Gadolinium based contrast media (ATC code: V08CA). Substances include: Gadopentetic acid; Gadoteric acid ; Gadodiamide; Gadoteridol; Gadobutrol; Gadoxetic acid ; Gadopiclenol (X points each). Each additional contrast media for which validated removal/degradation performance is demonstrated will be awarded X additional points (max X points).		Phase 1: Declared Target X-ray Contrast Agents ( Paramagnetic Gadolinium based contrast media ATC code V08CA) Removal Coverage Unit number of x-ray contrast agents declared for removal	Phase 1: Analysis of the documentation/proofs submitted (test data, peer-reviewed publications, technical specifications for the unit processes)

A.2.3	<p>Solution shall demonstrate the removal of antibiotics classified according to the families listed below:</p> <p>ATC-Code                      Sub-group</p> <p>J01CA Penicillins with extended spectrum</p> <p>J01CE Beta-lactamase sensitive penicillins</p> <p>J01CF Beta-lactamase resistant penicillins</p> <p>J01CR Combinations of penicillins, incl. beta-lactamase inhibitors</p> <p>J01DD                      Third-generation cephalosporins</p> <p>J01DH                      Carbapenems</p> <p>J01FA                      Macrolides</p> <p>J01MA                      Fluoroquinolones</p> <p>J01XA Glycopeptide antibacterials</p> <p>Each additional antibiotic (regardless) of the family for which validated removal/degradation performance is demonstrated is welcome (as long as the initial list above is addressed).</p>	3	<p>Phase 1: Declared Antibiotics Removal Coverage Phase 2/3 Validated Antibiotic Removal Coverage</p> <p>Unit: number of antibiotic families with removal potential (at least 1 antibiotic with demonstrated removal)</p>	<p>Phase 1: Analysis of the documentation/proofs submitted (test data, peer-reviewed publications, technical specifications for the unit processes) Phase 2/3: Quantitative and qualitative data on the concentration measurement in raw and treated wastewater are presented in test reports.</p>
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A.2.4	<p>The solution shall demonstrate removal/degradation performance of ARB (log reduction) , as follows:  <i>Enterobacteriales carbapenem resistant; Enterobacteriales 3rd generation cephalosporin resistant; Acinetobacter baumannii carbapenem resistant</i>  Suppliers are expected to provide a concise description of how their solution achieves the required removal in these particular contaminants, including the key treatment mechanisms, process steps, removal rates and any supporting evidence from published data, literature, technical specifications of the units processes, validated test results and/or technical documentation. The solution shall demonstrate a removal efficiency and an absolute post-treatment concentrations below specific threshold values (to be defined in Phase 1). Both criteria must be met.</p>	3	<p>Phase1: Declared Priority ARB Group Reduction Phase2/3 Validated Priority ARB Group Reduction For each ARB group:  <math>\text{Log Reduction} = \log_{10} \left( \frac{C_{\text{influent}}}{C_{\text{effluent}}} \right)</math> AND <math>C_{\text{effluent}} \leq \text{Threshold value}</math>  Where:  <math>C_{\text{influent}}</math>= measured influent concentration  <math>C_{\text{effluent}}</math>= measured post-treatment concentration  Threshold Value = predefined concentration limit  Compliance with the absolute concentration threshold is mandatory. Log reduction alone is not sufficient if the threshold is exceeded.  Method of measurement:</p>	<p>Suppliers shall provide: Phase 1 : Description of analytical methods used (e.g., culture-based selective media, molecular methods, or validated equivalent methods); influent and effluent concentration data; limits of detection (LOD) and quantification (LOQ); description of treatment mechanisms and process steps responsible for ARB removal (e.g., membrane separation, disinfection, advanced oxidation, etc.); supporting evidence such as: Laboratory validation data if available, published peer-reviewed studies; Technical documentation.  For Phase 2 and Phase 3: Controlled experimental validation; replicate sampling, reporting of analytical uncertainty. For phase 3 the performance data shall originate from ISO/IEC 17025 accredited laboratories with the relevant measurement methods in the scope of accreditation.</p>
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A.2.6	The solution supports additional contrast media removal in any of the the below categories : Watersoluble, nephrotropic, high osmolar x-ray contrast media (ATC code V08AA), Watersoluble, hepatotropic x-ray contrast media (ATCcode: V08AC), Non-watersoluble x-ray contrast media (ATC code: V08AD), X-ray contrast media, non-iodinated(ATC code:V08B).		Phase 1: Expanded Contrast Media Removal Capability	Phase 1: Analysis of the documentation/proofs submitted (test data, peer-reviewed publications, technical specifications for the unit processes)
A.2.7	The solution supports the removal/degradation performance of additional cytostatic drugs, in any of the below categories : CYTARABINE, GEMCITABINE, HYDROXYCARBAMIDE, CAPECITABINE, SORAFENIB, ALPELISIB, ALECTINIB		Phase 1: Expanded Cytostatics Removal Capability	Phase 1: Analysis of the documentation/proofs submitted (test data, peer-reviewed publications, technical specifications for the unit processes)
A.2.5	The solution supports the ARG removal, in any of the below categories: blaKPCgr, blaVIMgr, blaNDMgr, blaIMPgr, blaOXA-48gr, blaCTX-M-1gr,blaCTX-M-9gr, blaCTX-M-2gr, blaCTX-M-25gr, blaSHVESBL (-2, 5, ...), blaDHAPampC, blaCMYPampC	3	Phase1: Declared Priority ARG Group Reduction Phase2/3 Validated Priority ARG Group Reduction	Phase 1: Analysis of the documentation/proofs submitted (test data, peer-reviewed publications, technical specifications for the unit processes) Phase 2/3: Quantitative and qualitative data on the ARG measurement in raw and treated wastewater are presented in test reports.

A3.	Operational and Technical Criteria	12		
A3.1	<p>Automated or advanced monitoring dashboards shall be considered (i. automatically acquires data from sensors, processes and visualises data in real time, generates automated alerts, calculates performance indicators, supports operational decision-making). Monitoring parameters controlling the quality of the effluent (treatment efficiency) shall be depicted.</p>	3	<p>Phase 1: Monitoring System Design Maturity - Assess the robustness and sophistication of the proposed automated or advanced monitoring dashboard at conceptual design level. i.e. assess the degree to which the proposed solution includes: automated data acquisition, real-time monitoring capability, integration of sensors (quality, flow, process parameters), data logging and traceability, alarm and threshold management, user interface/dashboard visualisation, predictive analytics or AI-based optimisation</p> <p>Phase 2: Basic Automated Monitoring Functionality - Verify that the prototype includes a functioning automated monitoring dashboard capable of real-time data acquisition and basic process supervision during controlled laboratory operation i.e. Extent to which the prototype monitoring system: automatically acquires data from installed sensors, displays key parameters in real time, logs data digitally,</p>	<p>Phase 1: Qualitative evaluation based on submitted documentation: system architecture diagrams, list of monitored parameters, description of dashboard functionalities, data management structure, cybersecurity and data integrity approach, description of automation logic.</p> <p>Phase 2: During prototype testing under controlled conditions: Live demonstration of dashboard, verification of automatic sensor data acquisition, verification of continuous data logging, demonstration of at least one automatic alarm function. If applicable, predictive analytics, optimisation algorithms, remote cloud integration, or digital twins.</p> <p>Phase 3: During pilot testing: live demonstration of dashboard, verification of automated data acquisition, verification of alarm triggering, verification of data logging continuity, demonstration of KPI computation, evaluation of user interface usability</p>

			generates basic alarms when predefined thresholds for its operation are exceeded Phase 3: Monitoring Automation Performance - Evaluate the operational functionality and level of automation of the monitoring dashboard during prototype testing under controlled conditions i.e. extent to which the implemented dashboard: automatically acquires data from sensors, processes and visualises data in real time, generates automated alerts, calculates performance indicators, supports operational decision-making.)	
A3.2	The proposed solution will be evaluated on its durability and dependency on consumables over its expected service life.	3	<p>KPI 1: Consumables, Replacement &amp; Maintenance</p> <p>KPI 2: Durability &amp; Service Life of System Components</p>	<p>KPI 1: Consumables intensity and replacement frequency Consumables include membranes, activated carbon, filters, UV lamps, etc. The solution will be evaluated on its dependency on consumables and replaceable components over its expected service life.</p> <p>Phase 1: KPI1: Description of consumables with indicative/estimated service life and projected replacement frequency, as well as any description of indicative</p>



				<p>maintenance frequency, cleaning procedures and estimated downtime</p> <p>Evaluation method: Technical documentation review, consumables list, projected replacement schedule, reference installations, and supporting evidence. The evaluation shall consider: number and type of consumables required; expected replacement frequency; durability of key components; clarity and credibility of supporting evidence.</p> <p>KPI 2: Durability and service life of system components.</p> <p>Evaluation method: Technical documentation review for indicative lifetime of major components and overall system lifetime provided with at least one form of supporting justification</p> <p>In phase 2-3, suppliers should be expected to report on: Actual consumable consumption reported from pilot operation, with projected replacement frequency and recorded maintenance logs (frequency, duration, downtime) Observed performance trends over pilot period reported (e.g. degradation indicators), with updated lifetime</p>
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				projections based on pilot data and/or reference to comparable installations with longer track records
A3.3	The proposed solution will be evaluated on its space efficiency in relation to treatment capacity and deployment feasibility in hospital environments. Higher scores will be awarded to solutions demonstrating compact physical footprint relative to treatment capacity without compromising treatment performance.	6	<p><b>Phase 1 KPI 1 – Performance-Adjusted Concept Space Efficiency</b></p> <p>The projected spatial efficiency of the proposed solution concept shall be relative to its declared treatment capacity and expected/declared removal efficiency of target contaminants to demonstrate that the compactness of the solution does not compromise its performance in removing target contaminants.</p> <p>Phase 2/3 KPI: <b>Verified Space-Performance Efficiency</b></p> <p>Phase 2/3 prototype shall demonstrate compact spatial</p>	<p>Phase 1 evaluation: Unit: m<sup>2</sup> per (m<sup>3</sup>/day × performance factor)</p> <p>Where: Performance Factor = Declared average removal efficiency of target contaminants Performance Factor=Declared average removal efficiency of target contaminants (Expressed as decimal, e.g., 0.90 for 90%)</p> <p>Measurement method: The Contractor shall provide: Total installation footprint (m<sup>2</sup>); Declared treatment capacity (m<sup>3</sup>/day or equivalent functional unit); Declared expected/claimed average removal</p>

			<p>design relative to its functionally representative treatment capacity, while maintaining high verified removal efficiency under controlled testing conditions.</p>	<p>efficiency of key target contaminants; Description of deployment configuration.</p> <p>The evaluation shall calculate: Performance-Adjusted Space Index (PASI)</p> <p>Performance-Adjusted Space Index (PASI)= (Footprint (m<sup>2</sup>))/(Capacity × Performance Factor )</p> <p>Lower PASI values indicate better space-performance efficiency. Only realistic and technically justified removal efficiencies will be accepted.</p> <p>Phase 2/3</p> <p>Evaluation should focus on checking that the prototype capacity is consistent with the approved Phase 2/3 Test Plan; Space efficiency is not achieved by reducing treatment performance and that the compactness does not compromise target pollutants removal efficiency; the prototype configuration remains scalable as declared in Phase 1. IMPORTANT: For the evaluation the following shall be ensured: Footprint must include all functional components (reactor, pumps, tanks, control panels, pre-treatment units); capacity must be consistent with Phase 2/3 general testing requirements and Test Plan approval; the verified removal efficiency</p>
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				<p>must be based on complete dataset (not selective values); Solutions demonstrating unstable operation shall not receive high scores; artificial inflation of throughput for scoring purposes shall not be accepted.</p> <p>Unit: <math>\text{m}^2</math> per <math>(\text{m}^3/\text{day} \times \text{verified performance factor})</math></p> <p>Where:</p> <p>Footprint (<math>\text{m}^2</math>) = measured installed footprint of the complete functional prototype</p> <p>Capacity (<math>\text{m}^3/\text{day}</math>) = average operational treatment capacity during the Phase 3 testing period, consistent with the approved Test Plan</p> <p>Verified Performance Factor = average verified removal efficiency of key target contaminants (expressed as decimal)</p> <p>Verified Space-Performance Efficiency (VSPE) = <math>(\text{Measured footprint}) / (\text{Approved Operational Capacity} \times \text{Verified Removal Efficiency})</math></p> <p>Lower VSPE values indicate better space-performance efficiency.</p> <p>The evaluation shall be based on:</p>
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				<p>Measured installed footprint during Phase 2/3 testing (including all operational components);</p> <p>Verified operational capacity demonstrated during the Phase 3 testing period;</p> <p>Approved Phase 2/3 Test Plan confirming that the tested capacity is functionally representative;</p> <p>Verified average removal efficiency across key contaminants;</p> <p>Operational logs confirming stable operation.</p> <p>Capacity used in the calculation shall:</p> <ul style="list-style-type: none"> <li>Correspond to the declared operational regime in the approved Test Plan;</li> <li>Be supported by runtime logs;</li> <li>Reflect stable operation (not peak instantaneous flow).</li> </ul> <p>If the tested capacity deviates significantly from Phase 1 justification without technical explanation, the score may be reduced.</p>
<b>A4.</b>	<b>Sustainability aspects</b>	<b>23</b>		
A4.1	Solutions demonstrating lifecycle cost efficiency, credible cost models, and favourable cost-performance balance will receive higher scores.	5	KPI WA-SCA-COSTI: Lifecycle cost per unit treated wastewater This KPI builds on the cost information reported under mandatory requirement SCA1.2	KPI WA-SCA-COSTI: Lifecycle cost per unit treated wastewater The solution will be evaluated on estimated lifecycle cost per m <sup>3</sup> treated wastewater, including CAPEX, OPEX,

		<p>and evaluates the cost-efficiency of the proposed solution. While SCA1.2 ensures that cost information is reported, this KPI rewards solutions that demonstrate cost-efficient performance and a credible, well-justified cost model. The solution will be evaluated on its estimated and verified lifecycle cost per m<sup>3</sup> of treated wastewater, encompassing CAPEX, OPEX, maintenance, consumables, and replacement costs.</p>	<p>maintenance, consumables, and replacement costs.</p> <p>Phase 1</p> <p>Supplier shall provide: Estimated CAPEX (€/m<sup>3</sup> or total €) including installation, equipment, engineering, design, and system integration.</p> <p>Estimated OPEX (€/m<sup>3</sup> or €/year) including, but not limited to: energy consumption, reagents and consumables, maintenance, replacement of parts, waste management, labour where relevant. Estimates may include justified ranges or assumptions.</p> <p>Description of main cost drivers and assumptions, where available.</p> <p>Evaluation method: Cost model and financial documentation review. Higher scores will be awarded to solutions demonstrating cost efficient, transparent and credible cost assumptions and favourable cost-performance balance relative to treatment performance and environmental benefits.</p> <p>Phase 2</p>
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			<p>Supplier shall provide Updated CAPEX and OPEX estimates reflecting the refined system design and prototype development. Updated description of cost drivers and assumptions, where changes occur. Where available, preliminary operational data supporting operational cost estimates. Evaluation method: Technical and financial documentation review of updated cost models and supporting evidence.</p> <p>Scoring Scores may be refined based on improved cost estimates and supporting data provided during prototype development.</p> <p>Phase 3 Cost Verification Suppliers shall provide the following documentation to enable calculation of the verified lifecycle cost per m<sup>3</sup> treated wastewater.</p> <p>1. CAPEX Final cost breakdown covering equipment, installation, civil works, engineering, and system integration where relevant. Where actual costs differ from Phase 1 estimates, suppliers</p>
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			<p>shall briefly explain the reasons for any significant changes.</p> <p>2. OPEX - verified operational cost components recorded during the pilot testing period, including:  Energy costs (based on measured consumption and applicable energy tariff)  Reagents and consumables (based on recorded usage and unit costs)  Maintenance and replacement parts (based on testing period or estimated)  Waste disposal (based on disposal receipts or documented estimates where direct costing was not feasible)  Labour where relevant  Where a cost component could not be directly measured or verified within the testing period, suppliers shall provide a justified estimate with clearly stated assumptions.</p> <p>3. Main cost drivers  Identification of operational cost drivers influencing lifecycle cost.</p> <p>Evaluation method: Review of operational and financial records collected during pilot deployment, cross-referenced with ENVI operational data where relevant.</p>
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				Higher scores will be awarded to solutions demonstrating cost-efficient lifecycle costs per m <sup>3</sup> of treated wastewater, supported by complete and transparent operational and financial records and a favourable cost-performance balance relative to demonstrated treatment performance and environmental benefits.
A4.2	The proposed solution will be evaluated on the magnitude of operational environmental impacts per unit of treated wastewater, complementing the environmental added value assessment performed under the corresponding mandatory requirement.	7	<p>KPI WA-SCA-ENVI: Operational Resource and Environmental Intensity</p> <p>This KPI evaluates the magnitude of operational environmental impacts generated by the proposed solution per unit of treated wastewater. It complements the environmental added value assessment by capturing what the technology consumes and generates in order to achieve the removal rate. The evaluation focuses on environmental aspects that can be quantitatively expressed relative to the volume of treated wastewater, including energy consumption, chemical/resource use and secondary waste generation.</p>	<p>The evaluation will assess the magnitude of environmental impacts per unit of treated wastewater. Solutions demonstrating lower impact intensity per unit of treated wastewater will receive higher scores. In Phase 1, the assessment will be based on a review of technical documentation provided by suppliers, including estimates, assumptions, supporting references, and design descriptions. In Phases 2 and 3, the evaluation will be based on measured operational data and test results obtained during laboratory testing and pilot operation. The assessment will also consider the credibility and transparency of the information provided, as well as design features intended to minimise operational environmental impacts.</p> <p>Phase 1 Supplier shall provide:</p>

		<p>Higher scores will be awarded to solutions demonstrating lower operational resource consumption and lower residual waste generation per m<sup>3</sup> of treated wastewater, while maintaining the required treatment performance.</p>	<p>(1) Estimated energy consumption (kWh/m<sup>3</sup> treated wastewater), with supporting assumptions or reference data Higher scores will be awarded to more energy-efficient solutions demonstrating lower energy consumption per m<sup>3</sup> of treated wastewater (e.g. 0.5–2 kWh/m<sup>3</sup> receiving the highest score), while solutions with very high energy demand (e.g. &gt;5.5 kWh/m<sup>3</sup>) will receive no points.</p> <p>(2) Estimated chemical consumption (kg/m<sup>3</sup> or equivalent) and hazard classification of chemicals used (CLP), if applicable Higher scores will be awarded to solutions demonstrating low chemical dependency and lower chemical consumption per m<sup>3</sup> of treated wastewater. Solutions with high dependency on chemicals (including hazardous chemicals) will receive no points.</p> <p>(3) Identification of all expected secondary waste streams (e.g. sludge, brine, spent media), with estimated generation intensity if available and proposed disposal or recovery pathways Higher scores will be awarded to</p>
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			<p>solutions demonstrating low generation of secondary waste streams (e.g. sludge, brine, spent media) per m<sup>3</sup> of treated wastewater, with clear identification of waste streams and proposed recovery or disposal pathways. Solutions generating higher quantities of secondary waste will receive no points.</p> <p>Phase 2 and 3 The proposed solution will be evaluated on its demonstrated environmental performance during prototype and pilot testing. Suppliers shall provide measured operational data across key environmental dimensions: energy consumption, chemical use, secondary waste generation, treatment by-products, and circularity of materials. Higher scores will be awarded to solutions demonstrating a measurably lower environmental burden per unit of treated wastewater, supported by data collected under controlled testing conditions</p> <p>Supplier shall expect to provide: (1) Measured energy consumption (kWh/m<sup>3</sup> treated wastewater) recorded during the testing period Data collected under stable, representative operating conditions,</p>
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			<p>supported by runtime logs and meter readings</p> <p>Where applicable: measured or calculated energy recovery (kWh/m<sup>3</sup>) and net energy consumption (kWh/m<sup>3</sup>)</p> <p>(2) Identification and quantification of potential air emissions associated with the treatment process (where applicable).</p> <p>(3) Measured chemical consumption per m<sup>3</sup> treated wastewater (kg/m<sup>3</sup>), recorded during the testing period, broken down by chemical type if feasible, confirmation of hazard classification of all chemicals used (CLP regulation), evidence of any measures implemented to reduce hazardous chemical dependency during operation</p> <p>(4) Measured water consumption relative to treated wastewater volume (m<sup>3</sup> consumed / m<sup>3</sup> treated), including process water and cooling water where applicable</p> <p>(5) Measured quantities of secondary waste streams generated during the testing period shall be reported. For solid and semi-solid residuals (e.g. sludge, spent media, exhausted carbon,</p>
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				and other solid residuals), quantities shall be expressed as kg/m <sup>3</sup> of treated wastewater, where applicable. For liquid reject streams generated by membrane-based technologies (e.g. brine or concentrate), quantities shall be expressed as m <sup>3</sup> of reject per m <sup>3</sup> of treated wastewater, where applicable. Suppliers shall describe the disposal, treatment, regeneration, or recovery route for waste streams. Where direct measurement is not feasible (e.g. due to infrequent media replacement, batch-operated processes, or very small residual quantities), estimates may be provided based on previous operational data or supplier specifications. All assumptions underlying such estimates shall be explicitly stated and justified.
A4.3	The proposed solution will be evaluated on environmental aspects related to environmental safety, circularity of consumables and operational compatibility with hospital environments, which cannot be expressed per unit of treated wastewater.	4	<p>KPI WA-SCA-ENV2: Environmental Safety, Circularity and Operational Compatibility</p> <p>This KPI evaluates environmental aspects of the proposed solution that relate to environmental safety of the treatment process, circular use of materials, and operational compatibility with hospital</p>	<p>The evaluation will assess the extent to which potential environmental and operational impacts of the proposed solution are identified, monitored, and effectively mitigated.</p> <p>Phase 1 (1) Description of known or expected treatment by-products and transformation products in the effluent. If yes, mitigation / polishing / monitoring</p>

		<p>environments, which cannot always be expressed as a unit rate per m<sup>3</sup> of treated wastewater.</p>	<p>approaches. Evaluation based on identification and management of treatment by-products or transformation products potentially generated during treatment. Higher scores will be awarded to solutions that demonstrate that no relevant treatment by-products or transformation products are generated, or that clearly identify and properly address potential by-products in the effluent through appropriate monitoring, mitigation, or polishing measures where relevant. Solutions that do not address potential by-products will receive no points.</p> <p>(2) Evaluation based on the demonstrated ability of the proposed system to regenerate, reuse, recycle, or responsibly manage consumables and components during operation and at end-of-life, thereby reducing resource consumption and environmental burden. Suppliers shall describe or propose how consumables and system components (e.g. membranes, sorbents, filters, catalysts, ion-exchange resins) can be regenerated, reused, recycled, or otherwise managed at end-of-life. Higher scores will be awarded to</p>
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			<p>solutions demonstrating circularity measures, supported by evidence such as regeneration cycles achieved or projected, recovery rates achieved or projected, or proposed/documentated end-of-life pathways. Solutions with no circularity measures will receive no points.</p> <p>(3) Description of expected noise emissions or if available any measured operational noise level (dB(A)) recorded during normal operating conditions of the prototype/pilot. Where applicable, proposal or confirmation of noise mitigation measures implemented (e.g. acoustic insulation, enclosure, vibration damping) and their demonstrated effectiveness Higher scores will be awarded to solutions demonstrating low operational noise levels during normal operation (e.g. <math>\leq 40</math> dB(A)) and/or the implementation of effective noise mitigation measures. Solutions with higher noise levels (e.g. <math>&gt; 40</math> dB(A)) and no mitigation measures will receive no points.</p> <p>(4) Description of expected odour emissions (or if available measured (<math>\text{ouE}/\text{m}^3</math>)) in operation during previous</p>
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			<p>pilots and proposed odour mitigation measures</p> <p>Higher scores will be awarded to solutions demonstrating low expected odour emissions during operation and/or the implementation of appropriate odour mitigation measures. Solutions with significant expected odour emissions and no mitigation measures will receive no points.</p> <p>In Phase 1, the assessment will be based on a review of documentation and evidence provided by suppliers, evaluating the completeness and credibility of information provided on expected treatment by-products or transformation products, proposed monitoring or mitigation measures, circularity of consumables and components, and expected operational impacts such as noise and odour emissions.</p> <p>Phase 2–3</p> <p>In Phases 2 and 3, suppliers shall update and substantiate the information provided in Phase 1 based on observed performance. Where applicable, suppliers shall report on the following:</p>
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			<p>(1) Treatment by-products and transformation products Suppliers shall report any treatment by-products or transformation products observed or detected during testing, including their identity and concentrations where measurable. Where mitigation or polishing measures were implemented, suppliers shall describe their effectiveness based on observed data. Where no relevant by-products were detected, suppliers shall confirm this with reference to evidence.</p> <p>(2) Suppliers shall report on circularity measures observed or implemented during the testing period, including: Regeneration cycles completed during the testing period and observed regeneration efficiency (where applicable) Consumption or replacement of consumables during testing (where applicable) Any reuse or recycling of components demonstrated during testing Documented disposal, regeneration, or recovery route for consumables replaced during the testing period Where a consumable's expected lifespan exceeds the testing period and direct demonstration is not possible,</p>
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			<p>suppliers shall provide technical documentation on expected regeneration, reuse, recycling, or end-of-life management, together with a brief explanation and evidence (e.g. evidence of reuse or refurbishment of components, certifications, etc).</p> <p>(3) Noise emissions Suppliers shall report measured operational noise levels (dB(A)) recorded during normal operating conditions of the prototype or pilot. Where noise mitigation measures were implemented, suppliers shall describe the measures applied and provide evidence of their effectiveness.</p> <p>(4) Odour emissions Suppliers shall report on odour emissions. Where odour mitigation measures were implemented, suppliers shall describe the measures applied and their observed effectiveness.</p> <p>In addition, suppliers are expected to consider:</p> <p>(5) Ecotoxicity assessment of the treated effluent where applicable (e.g. for technologies applying advanced oxidation, UV treatment, or chemical dosing), based on standardised bioassay</p>
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			<p>methods or equivalent validated approaches</p> <p>Ecotoxicity testing is also expected where transformation products may be generated or identified during treatment.</p> <p>Evaluation will be based on the extent to which potential environmental and operational impacts are identified, monitored, and effectively mitigated during prototype development and pilot operation. Higher scores will be awarded to solutions demonstrating effective identification and mitigation of treatment by-products or transformation products, circular use of consumables and components, and low operational impacts compatible with hospital installations.</p>
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A4.4	<p><b>The proposed solution shall enable the safe reuse of treated effluent and demonstrate a system configuration that technically supports such reuse in hospital environments. The proposed solution shall be designed so that treated effluent can be reused to a maximum possible level for at least one practical urban or industrial application (e.g. cleaning, toilet flushing, cooling water or other relevant uses). The treated effluent intended for reuse shall comply with the minimum quality requirements applicable to urban or industrial reuse classes defined in Spanish Royal Decree 1085/2024 of 22 October 2024 regulating water reuse. The solution architecture shall demonstrate that reuse can be technically implemented through an appropriate configuration enabling the treated effluent to be directed to reuse points within hospital infrastructure or to additional polishing or reuse modules where required.</b></p> <p>At the concept stage (Phase 1), the</p>	7	<p>Phase 1 KPI: Planned Water Reuse Capability</p> <p>The proposed solution concept shall demonstrate the capability to enable reuse of treated effluent meeting at least Class B (urban use) quality requirements under Spanish Royal Decree 1085/2024, and the proportion of treated effluent expected to be reusable for practical urban or industrial applications in hospital environments.</p> <p>Unit: Percentage (%) of treated effluent expected to meet Class B of the Spanish Royal Decree 1085/2024 water reuse quality requirements.</p> <p>Scoring (max 7 points)</p> <table><tr><td>Reuse capability (max 5 points)</td><td></td></tr><tr><td>Planned proportion of treated effluent meeting Class B reuse quality</td><td></td></tr><tr><td>&lt; 20%</td><td>0 points</td></tr><tr><td>≥ 20% – &lt; 50%</td><td>3 points</td></tr><tr><td>≥ 50%</td><td>5 points</td></tr></table> <p>Bonus – reuse integration readiness (max 1 point)</p>	Reuse capability (max 5 points)		Planned proportion of treated effluent meeting Class B reuse quality		< 20%	0 points	≥ 20% – < 50%	3 points	≥ 50%	5 points	<p><b>Measurement / Evaluation Method – Phase 1</b></p> <p>Evaluation shall be based on technical documentation submitted by the contractor describing the concept design and expected treatment performance.</p> <p>The contractor shall submit :</p> <ul style="list-style-type: none"><li>- expected effluent quality ranges based on the proposed treatment processes and supporting evidence (literature, pilot studies, comparable installations);</li><li>- demonstration that the treated effluent is expected to meet minimum reuse quality requirements corresponding to Class D as defined in Spanish Royal Decree 1085/2024;</li><li>- hydraulic mass balance or process flow diagrams indicating the proportion of treated effluent expected to comply with reuse-quality requirements;</li><li>- identification of intended reuse applications (e.g. cleaning, toilet flushing, cooling water);</li><li>- description of system configuration enabling reuse integration, including hydraulic routing of treated effluent toward reuse points or polishing modules.</li></ul>
Reuse capability (max 5 points)														
Planned proportion of treated effluent meeting Class B reuse quality														
< 20%	0 points													
≥ 20% – < 50%	3 points													
≥ 50%	5 points													

<p>evaluation will focus on the technical feasibility of enabling at least 20% reuse of treated effluent, based on the proposed treatment configuration, expected effluent quality and system architecture. In Phase 2 and Phase 3, the evaluation will consider the actual reuse capability demonstrated by the prototype and pilot systems, including:</p> <p>the proportion of treated effluent that can be reused, and the reuse quality class achieved according to Spanish Royal Decree 1085/2024.</p> <p>Higher scores will be awarded to solutions demonstrating: a greater proportion of treated effluent suitable for reuse, compliance with higher reuse quality classes, and the ability to achieve such reuse without disproportionate increases in operational impacts such as energy consumption, chemical use or secondary waste generation. This criterion therefore promotes solutions that combine high reuse potential, compliance with reuse quality requirements, and</p>	<p>Condition: System configuration clearly enables routing treated effluent to hospital reuse infrastructure or reuse module without major redesign +1 point</p> <p>Examples of acceptable design provisions:</p> <p>defined reuse outlet or diversion point</p> <p>modular reuse/polishing stage</p> <p>identified reuse application within hospital infrastructure</p> <p>KPI Phase 2/3 : Validated Reuse Capability</p> <p>Based on prototype testing results, the solution shall demonstrate the capability to produce treated effluent compliant with at least Class B reuse quality requirements as defined in Spanish Royal Decree 1085/2024 of 22 October 2024, and to enable the reuse of a measurable proportion of the treated effluent for at least one practical urban or industrial application under controlled operating conditions.</p>	<p>Where applicable, the planned reuse capacity may be estimated as:</p> $\text{Planned Reuse Capacity(\%)} = \left( \frac{\text{Planned volume meeting Class D reuse quality}}{\text{Total treated effluent}} \right) \times 100$ <p>Assessment shall be based solely on the expert review of concept documentation submitted by the contractor and supporting technical evidence.</p> <p><b>Measurement/Evaluation method - Phase 2/3</b></p> <p>Evaluation shall be based on analytical measurements of treated effluent obtained during prototype testing under controlled laboratory conditions using synthetic wastewater representative of hospital wastewater characteristics. The composition of the effluent to be treated shall be defined and justified in the Phase 2/3 Test Plan. The effluent to be treated shall be characterised for key parameters relevant to treatment performance and reuse assessment, including where relevant COD, BOD, TSS, conductivity, and microbiological indicators, as well as the relevant pharmaceutical contaminants addressed by the technology.</p>
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	<p>technically feasible integration with hospital reuse infrastructure.</p>		<p>During testing, treated effluent samples shall be analysed for parameters relevant to water reuse applications. Measured values shall be compared against the full set of threshold values applicable to reuse classes for urban or industrial uses, as defined in Spanish Royal Decree 1085/2024 of 22 October 2024.</p> <p>Compliance shall be assessed per reuse class, meaning that all applicable threshold parameters for the given reuse class must be met simultaneously for the effluent to be considered suitable for that reuse option. The reuse capability shall be expressed as the percentage of treated effluent meeting the requirements of at least one defined reuse class, calculated as:</p> <p>Reuse Capability(%)=((Volume of treated effluent compliant with a given reuse class/total treated effluent volume))x100</p> <p>For Phase 2, since prototype testing will be conducted under fixed-flow conditions producing a single treated effluent stream, the assessment shall determine whether the treated effluent quality achieved during stable operation meets the requirements of the targeted reuse class. In such cases, the reuse</p>
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			<p>capability shall correspond to the proportion of treated effluent produced under compliant operating conditions. The evaluation shall also consider the highest reuse class achieved by the treated effluent under the tested conditions.</p> <p>Assessment shall be based on the Phase 2/3 Test Report, analytical datasets, and updated system design documentation submitted by the contractor.</p>
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<b>B. VALIDITY OF THE TECHNICAL APPROACH</b>		<b>10</b>		
<b>B.1. Quality of the methodology – Design, development and installation of the solution</b>		<b>3</b>		
B1.1.	Explain briefly in TD8 – Point 5 how the proposed solution will be designed, developed and installed during the PCP phases. The description should outline the engineering methodology and implementation process that will be used to realise the proposed solution. A thorough explanation will receive the maximum points. This shall be further developed in detail in the Solution Design of PCP Phase 1. Depending on the shortcomings of the explanation, the score will be reduced.		Evaluate -Clarity and structure of the development methodology -Suitability of the proposed engineering approach -Feasibility of the development and deployment plan -Completeness of the proposed development lifecycle	Paper based evaluation
<b>B.2. Technical validity and robustness of the solution proposed</b>		<b>7</b>		
B2.1	Explain briefly in TD8 point 5 how your proposal addresses this point. The extent to which the proposed solution design demonstrates coherence, feasibility, robustness, novelty and effective alignment of		Evaluate: -scientific/engineering soundness - overall feasibility of the concept - robustness of the architecture - reliability of the proposed technologies	Paper based evaluation





	its components to deliver the intended objectives. A thorough explanation will receive the maximum points. This shall be further developed in detail in the Solution Design of PCP Phase 1. Depending on the shortcomings of the explanation, the score will be reduced.		-novelty of the solution -Impact / operational benefits	
<b>C. QUALITY OF THE TENDER</b>		<b>10</b>		
<b>C.1. Commercial potential</b>		<b>5</b>		
C.1.1.	The extent to which the proposal contributes to a sustainable market introduction and scaling of the solution, assessed on: - Market Entry and scaling strategy - Target market segments and end-user groups -Planned marketing channels and dissemination approach - IPR plan: arrangements on ownership, usage rights, and transparency. Transparency of exploitation arrangements and possible royalty models -Tenderers shall demonstrate how they will establish connections with funding mechanisms (national,	5	Evaluate: -Clarity of the market introduction strategy -Potential for long-term market uptake -Credibility of the proposed investment and financing strategy - Planned engagement with investors or funding bodies - Potential to attract follow-up funding	Paper based evaluation



<p>private or EU or own funding) before the end of PCP Phase 3 in order to support the commercialisation of the solution. This includes activities aimed at preparing the commercialisation of the solutions beyond the project on the one hand and ensuring their uptake and future procurements by additional buyers on the other hand.</p> <p>Explain briefly in TD8 point 5 how your proposal addresses this point. This shall be further developed in detail in the Solution Design of PCP Phase 1. A thorough explanation – addressing all the above-mentioned aspects - will receive the maximum points. Depending on the shortcomings of the explanation, the score will be reduced.</p>			
<b>C.2. Implementation methodology</b>	<b>5</b>		



C2.1.	First draft plan of Project management methodology for the contract implementation for the three phases of the PCP. Suppliers should also include potential risks and mitigation measures - Application Risk Management methodology aimed at ensuring schedule adherence, financial management, delivery of final outcomes, and maintaining effective relationships among clients, users, and contractors. Explain in TD8 point 5 how your proposal addresses this point. A thorough explanation – addressing all the above mentioned aspects - will receive the maximum points. Depending on the shortcomings of the explanation, the score will be reduced.	5	<p>Evaluate:</p> <ul style="list-style-type: none"> <li>-Clarity of the project management structure</li> <li>-Effectiveness of coordination mechanisms</li> <li>-Adequacy of monitoring and reporting procedures</li> <li>-Ability to ensure efficient contract implementation</li> <li>-Completeness of risk identification</li> <li>-Credibility of mitigation measures</li> <li>-Ability to ensure schedule adherence</li> <li>-Consideration of financial, operational and stakeholder risks</li> </ul>	Paper based evaluation
<b>Total</b>		<b>90</b>		



# Annex 6. Phase 2 testing strategy & requirements

## 1. Prototype development and controlled testing requirements

### 1.1. Purpose and scope of Phase 2

Phase 2 consists of:

- Up to seven (7) months of prototype development, installation and optimisation.
- Followed by three (3) months of controlled operational testing.

Phase 2 is a **comparative prototype performance assessment stage in controlled laboratory conditions reflecting real operational environment of the solution for its intended application (purpose and matrix).**

Phase 2 is **not**:

- a hospital deployment phase under **GER1.2**;
- nor a verification or certification phase under **GER1.3**.

#### Objectives of Phase 2

##### Primary objective

The primary objective of Phase 2 is to develop and demonstrate a prototype system capable of removing target contaminants from hospital wastewater.

The contractor shall demonstrate that the prototype system is capable of removing target contaminants under controlled testing conditions, in line with: **CRR1.1, CRR1.2, CRR1.3 and CRR1.4**, and generate performance data supporting evaluation under: **A1.1, A1.2 and A1.3**.

Please note that contractors must perform tests not only in line with the requirements and award criteria but also in accordance with the commitments and performance claims made in their proposal for the Phase 2.

##### Additional objectives

Phase 2 shall also:

1. Generate evidence on ARB and ARG removal (**A1.4, A1.5, A2.4, A2.5**)
2. Demonstrate applicability to contaminant groups (**A2.1–A2.5**)
3. Assess effluent quality and indicative reuse potential (**WR1.1, A4.4**)
4. Assess operational stability and robustness (**OPR1.1, OPR1.2, OPR1.3, OPR1.4, OPR1.5, OPR1.7; A2**)
5. Generate environmental and resource performance data (**SCA1.1, SCA1.5; A4.2, A4.3**)
6. Demonstrate monitoring and data handling capability (**OPR1.10, OPR1.12; A3.1**)
7. Demonstrate prototype-level cybersecurity (**OPR1.8**)
8. Ensure safe operation (**SCA1.3**)



9. Produce technically credible and traceable data supporting Phase 3 upscaling (**GER1.3**)
10. Assess operational operability and maintainability of the prototype system under controlled conditions.( **OPR1.6**)

**DISCLAIMER: The information provided in the following sections is complementary to the specification of the requirements provided in Annex 5 and therefore should be interpreted aways in relation to this Annex.**

**Please note that** this phase is not a hospital field deployment or a regulatory certification phase.

## Evaluation approach

Evaluation shall be based on:

- Test-based evaluation including:
  - contaminant removal performance (**A1**)
  - applicability to contaminant groups (**A2**)
  - ARB/ARG performance
  - effluent quality
  - robustness under variability (**A2**)
  - environmental performance parameters per m<sup>3</sup> (**A4.2**)
- Documentation-based evaluation including :
  - reuse concept and feasibility (**A4.4**)
  - environmental aspects not expressed per m<sup>3</sup> (**A4.3**)
  - monitoring, data handling and cybersecurity (**A3, OPR1.8, OPR1.10, OPR1.12**)
  - safety and risk management (**SCA1.3**)

## Governance and Roles

### Role of SAS / CHV

SAS (FPS) and CHV shall:

- Define the overall Phase 2 testing framework and applicable KPIs.
- Coordinate and supervise testing activities.
- Approve all Phase 2 test plans prior to testing.
- Define technical specifications for artificial matrix preparation where applicable.
- Ensure methodological comparability across prototypes.
- Coordinate microbiological and chemical analyses through designated consortium laboratories.
- Validate completeness and consistency of reported results.

The Department of Microbiology, University of Seville, shall perform microbiological and molecular analyses under the coordination of SAS, as described in section 13. SAS Microbiology laboratory description of this document.

### Role of the Contractor



The Contractor shall:

- Develop, install and operate the prototype.
- Propose and justify testing conditions.
- Submit a Phase 2 test plan for approval.
- Ensure safe operation and optimisation.
- Cooperate with analytical laboratories;
- Provide full access to operational data.
- Bear all operational, consumable, shipment and waste handling costs.

No Phase 2 testing may commence without formal approval of the test plan by SAS.

## 2. Prototype Requirements

### 2.1 Functional Scale

The prototype capacity shall be **functionally representative of the intended deployment configuration** (centralised, decentralised, source-separated, polishing step, etc.) and sufficient to demonstrate full treatment performance and operational stability.

The Contractor shall justify:

- Selected treatment capacity;
- Hydraulic configuration;
- Operational mode;
- Statistical adequacy of the testing volume.
- Consistency with the scalability strategy declared in Phase 1.

The objective is performance-representative scale, not pilot replication.

### 2.2 Operational Mode

The prototype may operate in:

- Continuous mode;
- Batch mode;
- Intermittent mode;

provided the operational regime reflects intended real-life application and demonstrates stable and repeatable performance during the three-month testing period.

## 3. Prototype Installation and Test Site Requirements



### 3.1 Test Site Selection

Phase 2 testing – under contractor´s budget – will be conducted at:

- the premises of SAS (FPS); or
- the Contractor's premises; or
- another suitable laboratory facility proposed by the Contractor,

if testing conditions allow methodological comparability and supervision by SAS/CHV.

The selected testing location shall be clearly identified in the Phase 2 test plan and justified in relation to:

- the nature of the technology.
- matrix selection.
- operational requirements.
- accessibility for supervision.

SAS/CHV shall approve the selected testing location prior to the start of formal testing.

### 3.2 Test Site Description Requirements

The Contractor shall provide a detailed description of the selected testing site – if SAS premises are not the selected option - including:

- Physical location and installation layout.
- Available space and installation configuration.
- Electrical supply and technical utilities.
- Wastewater handling arrangements.
- Sampling points and accessibility.
- Safety measures and hazard controls.
- Waste management procedures.
- Access conditions for SAS/CHV supervision.

Where testing is conducted outside SAS premises, the Contractor shall ensure that:

- SAS/CHV has reasonable access for supervision.
- Analytical coordination is possible.
- Testing conditions remain transparent and traceable.

### 3.3 Additional Conditions Applicable Only if Testing is Conducted at SAS Premises

If the contractor elects to conduct testing at SAS premises, the prototype shall be compatible with the infrastructure described in section 13. SAS Microbiology laboratory description of this document.

In particular, the contractor shall ensure compatibility with:

- Limited installation space per prototype.
- Standard electrical supply.
- Absence of centralised flow control systems.
- Laboratory-based testing conditions.



Any additional infrastructure requirements beyond those described in section 13. SAS Microbiology laboratory description of this document shall be:

- Clearly specified in the test plan.
- Technically justified.
- Subject to prior written approval by SAS
- Provided by the contractor

SAS reserves the right to reject installation proposals that are incompatible with the available infrastructure.

### **3.4 Full Operational Responsibility**

Throughout phase 2, the Contractor shall retain full technical and operational responsibility for the prototype, including:

- Installation and commissioning.
- Operation and optimisation.
- Process control.
- Maintenance and servicing.
- Safe handling of chemicals and reagents.
- Management of by-products and wastes.
- Compliance with safety procedures.

This responsibility remains with the Contractor irrespective of the test site location.

## **4. Test Matrix Selection**

### **4.1 Matrix Responsibility and Approval**

The contractor shall propose a matrix (i.e. material for which the technology is intended for) appropriate for the technology and demonstration of its performance in relation to PCP THERESA target contaminants. The proposed matrix must be approved by SAS prior to testing.

The matrix shall be characterised in detail (based on Phase 1 results) including where relevant:

- COD;
- BOD<sub>5</sub> (if applicable to process);
- TSS;
- pH;
- Temperature;
- Conductivity;
- Background organic load;
- Potential performance-influencing interferents;
- Hydraulic loading profile.





Matrix characterisation shall be documented before the start of performance testing and presented in the test plan.

## 4.2 Real Hospital Wastewater

Where feasible and relevant, real hospital wastewater or effluent may be used, subject to:

- Documentation of source and variability.
- Safety and handling procedures;
- SAS approval;
- Performance interpretation in relation to matrix characteristics.

## 4.3 Synthetic Spiked Wastewater

Where real wastewater is unavailable or not technically appropriate:

- Artificial wastewater may be used.
- Spiking with target contaminants defined in Phase 1 shall be justified.
- Concentrations and preparation procedures shall follow specifications defined or approved by SAS.
- Representativeness shall be documented.

The purpose is to ensure credible and comparable testing conditions across prototypes.

# 5. Performance Verification Scope of the Prototype

## 5.1 Pharmaceutical Removal

The Contractor shall demonstrate that the prototype system removes:

- Cytostatic drugs;
- Water-soluble iodinated CT contrast media (ATC V08AB);
- Gadolinium-based contrast media (ATC V08CA);
- Antibiotics.

Measures of concentration must include at least the following range; 0,1-5.000 nanogr/ml

And any other to which the contractor has committed to tackle in their offer.

Results – whose ranges will be finetuned after phase 1 results - shall include:

- Influent and effluent concentrations;
- Percentage removal;
- Absolute post-treatment concentrations;
- Analytical limits and uncertainty.



ARB, ARG, transformation products and effluent quality shall be assessed in line with the original specification, supporting:

- A1 (performance)
- A2 (coverage and robustness)
- A4.3 (environmental aspects)
- A4.4 (reuse potential)

## 5.2 Antibiotic-Resistant Bacteria (ARB)

**Corresponding requirements: A1.4 ,A1.5,A2.4, A2.5**

Quantitative assessment must include both quantitative culture and quantitative molecular detection in actual samples of hospital waste and spiked water samples with whole-genome sequenced characterized strains at a bacterial count of  $10^3$ - $10^7$  CFU/ml.

The strains must belong to these three groups:

- Carbapenem-resistant Enterobacterales;
- Third-generation cephalosporin-resistant Enterobacterales;
- Carbapenem-resistant Acinetobacter spp.

Quantitative molecular detection of priority resistance genes (min  $10^1$  copies/ml):

<b><i>blaKPCgr</i></b>
<b><i>blaVIMgr</i></b>
<b><i>blaNDMgr</i></b>
<b><i>blaIMPgr</i></b> <b><i>blaOXA-23</i></b> <b><i>blaOXA-58</i></b>
<b><i>blaOXA-48gr</i></b>
<b><i>blaCTX-M-1gr</i></b>
<b><i>blaCTX-M-9gr</i></b>
<b><i>blaCTX-M-2gr</i></b>
<b><i>blaCTX-M-25gr</i></b>
<b><i>blaSHVESBL (-2, 5, ...)</i></b>



<b><i>bla</i>DHAPampC</b>
<b><i>bla</i>CMYPampC</b>

And any other to which the contractor has committed to tackle in their offer.

Microbiological analyses shall be performed by the designated laboratory section 13. SAS Microbiology laboratory description of this document.

If the contractor chooses to perform the microbiological analyses at the SAS premises, the contractor shall be responsible for organizing all logistics and covering all transportation costs, including:

- the transport of the samples provided by SAS to the contractor's facilities, and
- the transport of the resulting (post-test) samples back to the SAS facilities once the prototype has been installed at the contractor's site.

## 5.3 Transformation Products and Residual Ecotoxicity

**Corresponding requirements: SCA1.5, A4.3**

Where relevant to the technology, the Contractor shall perform:

- Screening of transformation products;
- Directional ecotoxicity assessment.

## 5.4 Effluent Quality and Reuse Potential

- The contractor shall perform assessment of the effluent treated by the prototype system including such parameters as: COD;
- BOD<sub>5</sub> (if feasible);
- TSS;
- Conductivity;
- Basic microbiological indicators.

Results – whose ranges will be finetuned after phase 1 results - shall be compared to selected reuse-relevant benchmarks.

# 6. Operational Monitoring and Variability

Operational parameters - whose ranges will be finetuned after Phase 1 results - shall be technology-specific and defined in the test plan.

The Contractor shall demonstrate that the prototype system:

- operates within defined ranges (**OPRI.1– OPRI.7**);
- maintains stable performance;



- demonstrates operability under realistic operating conditions, including the ability to maintain performance

At minimum the following parameters shall be controlled:

- Flow rate or batch volume.
- pH;
- Temperature;
- Conductivity;
- Pressure or hydraulic indicators;
- At least one process-specific control parameter.

## 6.1 Controlled Variability Verification

Testing shall include controlled verification within declared operating ranges – whose ranges will be finetuned after phase 1 results - including where relevant:

- pH variability;
- Temperature variation;
- Flow or batch variability;
- Suspended solids loading.

During variability testing:

- Operational parameters shall be logged.
- Selected performance indicators measured;
- Alarm activation recorded;
- Recovery time documented.

Performance – whose ranges will be finetuned after phase 1 results - shall be interpreted in relation to operating conditions.

## 7. Environmental Indicators

**Corresponding requirement(s): SCA1.1, SCA1.5**

**A4.2 – quantitative environmental performance (per m<sup>3</sup> parameters)**

**A4.3 – qualitative environmental performance (noise, odour, circularity, environmental safety)**

### Scope of parameters

The Contractor shall quantify, where applicable, the following environmental parameters:

energy consumption (kWh/m<sup>3</sup> treated wastewater);  
chemical and consumable use;  
generation of hazardous and non-hazardous waste;  
water consumption associated with treatment;



In addition, the Contractor shall describe, where relevant:

- noise and odour emissions;
- circularity aspects, including reuse, regeneration or recycling of consumables and components;
- environmental safety considerations, including emissions, by-products and potential environmental trade-offs.

**Reporting requirements**

Environmental parameters shall be reported in accordance with the KPI definitions and reporting requirements set out in Annex 5.

Where applicable, reporting shall include:

- energy consumption and, where relevant, energy recovery or net energy balance;
- chemical consumption, including hazard classification (CLP) where applicable;
- water consumption expressed per volume of treated wastewater;
- secondary waste streams, including generation intensity and disposal or recovery routes;
- screening of treatment by-products and transformation products, with mitigation measures where relevant;
- circularity measures, including regeneration cycles, consumable replacement and end-of-life management;
- noise and odour emissions and mitigation approaches;

Phase	2	applicability
At	Phase	2:

these parameters are indicative and may be based on measured data, estimates or engineering assumptions, depending on the maturity of the prototype system; the level of detail shall be sufficient to support comparative evaluation and to inform Phase 3 testing and verification.

All detailed evaluation methods, thresholds and scoring approaches are defined in Annex 5 and may be refined following Phase 2 results.

**8. Sustainability Indicator**

**Corresponding requirement(s): SCA1.4**

The Supplier shall confirm compliance with Regulation (EU) 2017/821 and provide supporting documentation demonstrating, or committing to, responsible sourcing and supply chain due diligence practices.

## 9. Durability and Performance

### Corresponding requirement(s): A3.2

Given that Phase 2 involves a minimum of three (3) months of controlled prototype testing, the evidence requirements under this section are calibrated to what is realistically achievable within that timeframe. Full long-term durability validation is not expected at this stage and will be further assessed in Phase 3 under pilot operational conditions. The Contractor shall provide the following evidence, to the extent achievable during the Phase 2 testing period:

- Consumable consumption recorded during the Phase 2 testing period, including quantities used per m<sup>3</sup> treated where measurable. Where consumable lifespans exceed the testing period (e.g. membranes, UV lamps, ion-exchange resins), contractors shall provide manufacturer-validated service life data or evidence from comparable installations instead of direct measurement;

- Maintenance logs recorded throughout the Phase 2 testing period, covering:

frequency,

duration, and

operational downtime per intervention;

Observed performance trends over the testing period, including early-stage indicators of potential degradation where detectable, such as membrane fouling rates or other process-specific indicators, where applicable and measurable within the testing period. Where no significant degradation is observed, contractors shall confirm this with reference to monitoring data;

Lifetime projections for key consumables and critical components. Given the limited duration of Phase 2 testing, these projections shall be based on one or more of the following, listed in order of preference:

- observed consumption or degradation trends from the Phase 2 testing period, where sufficient data exist;

- manufacturer-validated service life specifications or technical documentation for components whose design lifetime exceeds the testing period;

This information shall support the assessment of:

- operational reliability and stability over the Phase 2 testing period;

- maintenance requirements and actual intervention frequency observed during testing;

- any early indicators of performance degradation observed during testing and their projected impact on system operation, or confirmation that no such indicators were detected.



## 10. Costs Reporting

**Corresponding requirements: SCA1.4 & A4.1**

**Supplier shall provide:**

- Updated CAPEX and OPEX estimates reflecting the refined system design and prototype development
- Updated description of cost drivers and assumptions, where changes have occurred relative to Phase 1 submission
- Where available, preliminary operational data from prototype testing supporting operational cost estimates (e.g. measured energy consumption, chemical use, consumable replacement frequency)

## 11. Operational Autonomy, Staffing and Maintenance

**Corresponding requirement(s): OPR1.6**

Given that Phase 2 involves controlled prototype testing, the evidence requirements for this phase are calibrated to what is realistically achievable within that timeframe. The Contractor shall, during the defined prototype testing campaign:

- Log all manual interventions during the testing period, recording:
  - number of routine interventions;
  - number of corrective interventions;
  - time spent per intervention;
- Demonstrate operator interaction with the system under testing conditions;
- Provide updated SOPs at the end of Phase 2 reflecting actual prototype behaviour, including any deviations from the draft SOPs submitted in Phase 1.

The following quantitative indicators shall be reported where measurable during the testing period:

- Intervention frequency (events/month);
- Manual intervention time per m<sup>3</sup> treated;
- Operator presence requirement (hours/week);
- Ratio of planned vs unplanned interventions.

## 12. Monitoring System and Dashboard Verification

**Corresponding requirements: OPR1.10, A3.1**

The Contractor shall demonstrate that the prototype system:



- monitors key parameters;
- generates alarms;
- records time-stamped data;
- provides a basic dashboard.

## 13. Data Export and Interoperability Readiness

Corresponding requirement **OPR1.12**.

The Contractor shall demonstrate that the prototype system:

- supports structured data export;
- ensures traceability of operational data.

## 14. Cybersecurity – Prototype Level

**Corresponding requirement: OPR1.8**

The Contractor shall demonstrate that the prototype system is able to provide:

- authentication mechanisms;
- basic data protection logic.

## 15. Safety and Risk Management

**Corresponding requirement: SCA1.3**

The Contractor shall demonstrate that the prototype system:

- operates safely;
- includes risk assessment and mitigation measures.

## 16. Test and Analytical Methods

The Contractor shall define and apply appropriate test and analytical methods to generate reliable and traceable data on prototype system performance.

- Standard methods (ISO, EN, EPA, APHA) should be used where available.
- Non-standard methods shall be justified and described.

Analytical methods shall:

- be fit for purpose;
- support comparative performance assessment;
- provide sufficient quality for Phase 3 planning.

**Target contaminants**





- detection range: **0,1–5.000 ng/mL**
- report: LOD, LOQ, uncertainty (where available)

Removal efficiency:

$$\text{Removal (\%)} = \frac{C_{\text{influent}} - C_{\text{effluent}}}{C_{\text{influent}}} \times 100\%$$

### ARB and ARG

- ARB: log reduction
- ARG: qPCR/dPCR, LRV or % reduction

### Transformation products and ecotoxicity

- screening or indicative methods shall be acceptable

### Sampling

- composite samples (chemicals)
- grab samples (microbiology)

### Quality assurance

Accredited laboratories (e.g. ISO/IEC 17025) are **not required at Phase 2**.

However, the Contractor shall demonstrate:

- technical competence of laboratories;
- suitability of analytical methods;
- sufficient data quality for evaluation and Phase 3 preparation.

## 17. Sampling Governance

No matter how and where sampling is performed:

- By SAS.
- By CHV.
- By consortium laboratories; or
- By any designated third party,

the Contractor shall:

- Provide documented sampling protocols.
- Define safe sampling points.
- Conduct hazard identification and operational risk briefing.
- Provide appropriate training to personnel involved in sampling.
- Clearly describe risks related to pressure, chemicals, biological agents, electrical components, confined space, or other hazards.

Sampling shall not be performed unless:

- Safe sampling procedures have been validated.



- HAZOP-related aspects have been communicated.
- Appropriate PPE (Personal protective equipment) requirements are defined.

## 18. HAZOP and Risk Communication

Prior to testing, the Contractor shall provide:

- A simplified HAZOP (Hazard and Operability Study) or risk assessment information covering the prototype.
- Identification of mechanical, chemical, electrical and biological hazards.
- Emergency shutdown procedures.
- Incident reporting procedures.

This applies no matter how and where testing is performed:

- By SAS;
- By CHV.
- By consortium laboratories; or
- By any designated third party,

## 19. Test Plan and Reporting

Testing shall be conducted in accordance with:

- TD12. Generic test plan template.
- Section 13. SAS Microbiology laboratory description.

The Phase 2 test plan must be approved by SAS prior to testing.

At the end of Phase 2, the Contractor shall submit a comprehensive Test Report including:

- Complete datasets;
- Matrix characterisation;
- Operational logs;
- Monitoring and alarm records - whose ranges will be finetuned after phase 1 results;
- Sustainability and resource performance indicators - whose ranges will be finetuned after phase 1 results;
- KPI compliance results - whose ranges will be finetuned after phase 1 results;
- Variability analysis- whose ranges will be finetuned after phase 1 results;
- Preliminary upscaling considerations.

The Test Report shall form part of the End of Phase 2 Report.



The results shall:

- support evaluation under **A1-A4**;
- support preparation of Phase 3 (**GER1.3**).

## 20.SAS Microbiology laboratory description

### 20.1. Scope of Activities in Phase 2

During Phase 2, the prototypes provided by each supplier will be comparatively assessed under controlled **in vitro laboratory conditions**.

No installation within hospital facilities will take place at this stage. The objective of this phase is strictly comparative performance assessment between prototypes, not clinical validation or regulatory certification.

Therefore, the testing does not require ISO-certified laboratory facilities.

The **Department of Microbiology, Faculty of Medicine, University of Seville**, will be responsible for the microbiological and molecular analyses. Additional chemical analyses (e.g., antibiotics, antineoplastics, and other pharmaceutical compounds) are currently under discussion and will be performed in vitro by other consortium partners, under the coordination of SAS.

### 20.2. Microbiological Assessment Protocol

The core procedure consists of **quantitative before/after measurements** using hospital wastewater samples processed through each prototype.

Two categories of analyses will be performed:

#### A) Quantitative culture-based bacterial counts

- Enterobacterales resistant to 3rd-generation cephalosporins
- Carbapenem-resistant Enterobacterales
- Carbapenem-resistant Acinetobacter spp.

#### B) Quantitative molecular detection of antimicrobial resistance genes (ARGs)

Priority genes include:

blaKPC, blaVIM, blaNDM, blaIMP, blaOXA-48, blaCTX-M, blaSHV, blaDHA, blaCMY

It should be noted that formal accreditation schemes for quantitative antimicrobial resistance gene measurement are currently not established.

### 20.3. Scientific Background and Expertise

The Department of Microbiology has extensive experience in antimicrobial resistance surveillance and environmental microbiology under a **One Health framework**.

The research group has led multiple projects investigating the dissemination of resistance genes in wildlife (including migratory birds), environmental reservoirs, and wastewater systems.



The laboratory is led by L. López-Cerero, microbiologist and Technical Manager of the Regional Reference Laboratory for Molecular Typing of Multidrug-Resistant Pathogens. Her expertise includes:

- Molecular epidemiology and traceability of emerging clones in Andalusia
- Characterization of novel carbapenemases and associated genetic platforms
- Environmental surveillance of antimicrobial resistance

Relevant projects include:

- **Canalis Project:** Quantification of carbapenemase-producing organisms in four Andalusian hospitals
- **Vastum Project:** Evaluation of wastewater treatment plant efficacy in reducing carbapenemase-producing organisms in the metropolitan area of Seville, including correlation with antibiotic prescription data
- **PredicGen Project:** Development of advanced algorithms to predict antimicrobial resistance from bacterial genomic sequences

## 20.4. Laboratory Equipment and Facilities

The laboratories of the Department of Microbiology (University of Seville) and the Microbiology Service of the University Hospital Virgen Macarena are equipped with:

### General Laboratory Equipment

- Orbital shakers
- Magnetic stirrers
- Autoclaves
- pH meters
- Ultrasonic baths
- Thermoregulated stirring baths
- Thermal cyclers
- Hybridization oven

### Microbiology Infrastructure

- Laminar flow cabinets
- Centrifuges and refrigerated microcentrifuges
- Sonicators
- -30°C and -80°C freezers
- Incubators (including CO<sub>2</sub> incubators)
- Refrigerators

### Quantification and Analytical Equipment

- Spiral plater for logarithmic plating



- IuL Colony Counter with Fast & Go software
- Peristaltic pumps
- Thermostatic cabinets
- UV/visible spectrophotometer
- Spectrofluorimeter
- Multimode microplate reader (Infinite Pro 200, TECAN)

### **Genomics and Molecular Biology**

- Whole-genome sequencing platforms: MiSeq (Illumina)
- Automated DNA extraction and library preparation platforms (TECAN)
- Sequence analysis software:
  - CLC Genomics Workbench (Qiagen)
  - Ridom™ SeqSphere+ (cgMLST and whole-genome typing)
  - BioNumerics

### **Advanced Chemical Analysis**

- LC-MS/MS mass spectrometer (TQ EVOQ Qube, Bruker)

## **20.5 Available Infrastructure for Prototype Testing**

The following infrastructure is available for prototype evaluation:

- Dedicated installation space: 2 m<sup>2</sup> per prototype (large bench/table)
- Electrical supply: Standard 220V connection
- Flow control systems: Not available
- Preparation of spiked samples: Available
  - Artificial spiking of antimicrobial-resistant bacteria (ARB) and antimicrobial resistance genes (ARGs) at different concentrations
  - Testing under variable real wastewater conditions from University Hospital Virgen Macarena.



# Annex 7. Phase 3 verification strategy & requirements

## 1. Purpose and scope of Phase 3

Phase 3 consists of:

- up to one (1) month of technical arrangements between hospitals, Contractor, Test Body and ETV Body IETU regarding the pilot location, installation conditions, access requirements, sampling arrangements and ETV application;
- up to four (4) months of pilot installation, commissioning and optimisation;
- minimum three (3) months of pilot testing under real operational conditions;
- up to one (1) month for preparation and submission of the Test Report;
- verification reporting by ETV Body IETU following assessment of the Test Report and the accepted test data.

Phase 3 is a pilot deployment and independent verification stage in a real operational environment. It is intended to confirm in an independent way, under real hospital conditions, that the performance claims proposed by the Contractor based on Phase 2 results and results from the pilot pre-testing in Phase 3 where relevant.

Therefore, the primary purpose of Phase 3 testing is to generate evidence including quality assured and traceable test data suitable in order to verify the compliance of the pilot with the THERESA PCP mandatory requirements and weighted award criteria and the corresponding KPIs.

More specifically, in Phase 3 the following will be verified:

- **Technical, functional and environmental performance claims of the solution expressed as performance parameters and numerical values verifiable through testing relevant to the intended application of the solution** and THERESA PCP KPIs as stated in Annex 5. including the **removal performance of target contaminants, the treated effluent quality and its reuse suitability** under real, site-specific conditions of the hospitals considering real variability conditions (e.g variable wastewater characteristics, hydraulic peaks and relevant environmental conditions as of the pilot sites at the designated hospitals). The verification of these parameters shall follow the standardised ETV process based on ISO 14034 and shall be performed by ETV Body IETU as described in the verification strategy.
- **Additional performance parameters** directly related to the buyers' needs and requirements related to the weighted award criteria specified in Annex 5 such as:
  - **System Design & Integration (SSI1.1–SSI1.4) including:**
    - integration with hospital infrastructure,
    - layout and footprint,
    - scalability,
    - installation feasibility,



- climate adaptability. The Integration-related parameters (SSI1.1–SSI1.4) shall be assessed based on demonstrated pilot implementation and documented evidence from Phase 3 deployment

- **Operational & Organisational Aspects (OPR1.6, OPR1.10–1.11) including:**

- operational autonomy (staffing, maintenance),
- monitoring system usability,
- fault handling procedures,
- helpdesk and support,
- user feedback.

- **The Operational & Organisational Aspects (OPR1.6, OPR1.10–1.11)**

shall be assessed based on documented evidence, design description, and operational observations during Phase 3.

- **Digitalisation & Cybersecurity (OPR1.8, OPR1.12) including:**

- cybersecurity measures,
- access control,
- authentication,
- data export and interoperability,
- IT system compatibility.

The Digitalisation & Cybersecurity (OPR1.8, OPR1.12) shall be assessed based on documented evidence, design description, and operational observations during Phase 3.

- **Environmental Qualitative Aspects (SCA1.5, A4.3, A5) including:**

- circularity of consumables and components,
- regeneration/reuse potential,
- end-of-life management,
- qualitative environmental trade-offs.

Unless explicitly included in claim, qualitative environmental aspects (A4.3) shall be assessed based on documented evidence, design description, and operational observations during Phase 3.

- **Transformation Products & Ecotoxicity (SCA1.5, A4.3) including:**

- identification of transformation products,
- ecotoxicity assessment.

Unless explicitly included in claim, Transformation Products & Ecotoxicity (SCA1.5, A4.3), shall be assessed based on documented evidence, design description, and operational observations during Phase 3.

- **Safety and Compliance (SCA1.3) including:**

- safety procedures, risk assessments (HAZOP),
- compliance with hospital safety rules,
- Economic Aspects (SCA1.2),
- CAPEX,
- OPEX.

Safety and Compliance (SCA1.3) aspects shall be assessed based on documented evidence, design description, and operational observations during Phase 3

As indicated above, these parameters will not be verified through ETV process (unless specifically included in the claim referring to the technical/functional or environmental performance as indicated above) , however, any test data produced in that respect may be considered as additional parameters relevant from the buyers' perspective and included as deemed relevant in the Verification Report and Statement of Verification as additional parameters. The methods of evaluation and presentation of this information shall be further specified upon completion of Phase 2.

Please note that contractors must perform tests not only in line with the requirements and award criteria but also in accordance with the commitments and performance claims made in their proposal for the Phase 3.

**DISCALIMER: At this stage the exact Phase 3 KPIs and evaluation criteria are not yet finalised and will be defined separately in the tender documentation upon completion of Phase 2. However, the testing and verification in Phase 3 shall be designed to support the verification of the performance areas corresponding tender requirements (CRR, OPR, WR, SCA, SSI, GER and A1–A5) as indicated in Annex 5. The information provided in the following sections is complementary to the specification of the requirements provided in Annex 5 and therefore should be interpreted away in relation to this Annex.**

## 2. Governance and Roles

This section defines the roles and responsibilities of the entities involved in the Environmental Technology Verification (ETV) process implemented under phase 3, including Verification Body IETU (ETV Body IETU), the Contractor (Applicant), the Test Body and the Pilot Hospitals (Test Site Providers).

The responsibilities are described across the stages of the ETV process: application, pre-verification, verification, reporting, and Phase 3 operational implementation.

### Role of Verification Body IETU (ETV Body IETU)

ETV Body IETU acts as an independent Verification Body, conducting verification in accordance with ISO 14034 and applicable requirements for impartiality and independence.

#### Application Stage

ETV Body IETU shall:





- provide guidance to the contractor on the development of the ETV Application file as provided in Appendix 8 Guide for ETV Applicants within the limits of impartiality based on:
- initial information about the technology provided in the Quick Scan as provided in Appendix 8 Guide for ETV Applicants, and results from Phase 2;
- results of Phase 3 pre-testing,
- perform a formal and technical review of the application file.

### Pre-verification Stage

ETV Body IETU shall:

- provide guidance to the contractor on the definition of the final performance claim;
- define, together with the contractor, the final set of performance parameters to be verified, including:
- numerical values and ranges;
- conditions, assumptions and limitations;
- applicable test methods;
- agree with the contractor on additional (non-verified) parameters relevant for interested parties to be included in the Verification Report and Statement of Verification;
- develop the Specific Verification Protocol (SVP) tailored to each technology;
- present the Verification Plan/SVP to the contractor for approval.

### Verification Stage

ETV Body IETU shall:

- approve the Test Body proposed by the contractor,
- cooperate with the Test Body and the contractor in developing the Test Plan
- review and approve the Test Plan,
- supervise the testing and verification process from the viewpoint of:
- compliance with the SVP,
- relevance and adequacy of the testing,
- quality and traceability of data;
- perform test system assessment to confirm that testing and reporting meet the relevant quality requirements, including ISO/IEC 17025 where applicable;
- review and approve the Test Report
- assess test data against the performance claim and the SVP;

NOTE: ETV Body IETU **does not perform testing**. Testing shall be performed by Test Bodies independent from ETV Body IETU.

- review and approve the Test Report;
- assess test data against the performance claim and SVP;
- confirm the achieved performance.

### Reporting Stage

ETV Body IETU shall:



- develop the Verification Report presenting verification activities and confirmed performance;
- develop the Statement of Verification summarising the results.

## **Post -verification**

ETV Body IETU shall provide the Contractor with the Verification Report and the Statement of verification and publish at a minimum the Statement of Verification in the public domain including ETV Body IETU web site).

## **Costs**

The costs of verification procedures other than third-party testing shall be covered by ETV Body IETU. This includes:

- formal and technical review of the Application file;
- development of the SVP;
- assessment of Test Body competence;
- test system assessment and audit;
- review and approval of Test Plan and Test Report;
- preparation of Verification Report and Statement of Verification;
- site visits required for verification.

## **Role of the Test Body**

During the verification stage the Test Body shall:

- be independent from both the Contractor and ETV Body IETU;
- demonstrate competence to perform the required testing, including compliance with ISO/IEC 17025;
- enter into a contractual arrangement with the Contractor;
- develop the Test Plan in accordance with TD12. GENERIC TEST PLAN TEMPLATE and the SVP;
- submit the Test Plan for approval to ETV Body IETU and the Contractor;
- undergo training provided by the Contractor on technology operation, where relevant;
- perform testing in accordance with the approved Test Plan;
- ensure testing quality, data integrity, traceability and proper reporting including data reporting formats as provided in the Test Plan;
- cooperate with ETV Body IETU during test system assessment;
- prepare the Test Report in accordance to TD13. GENERIC TEST REPORT TEMPLATE, provide it to the Contractor for submission, review and approval by ETV Body IETU.

## **Role of the Contractor (ETV Applicant)**

The Contractor acts as the ETV Applicant. The contractor is responsible for:



- deployment, installation, commissioning, optimisation and operation of the pilot systems at the selected 2 hospitals and ensuring that the pilot will operate in a stable for test data generation for ETV purposes.
- ensuring safe operation, maintenance, servicing, waste handling and data logging;

### **Application Stage**

The Contractor shall:

- enter contractual arrangement with ETV Body IETU (contract template is Annex 9)
- develop and submit the Quick Scan and the ETV Application file in accordance with formal and technical requirements as provided in the Guide for ETV Applicants (Annex 8) ;
- provide sufficient and relevant information and documentation to:
- demonstrate eligibility for ETV including stable operation of the pilot;
- assess conformity of the technology with the performance claim;
- substantiate the performance claim with available test data from phase 2 and pre-testing in Phase 3 if available;
- demonstrate the environmental added value;
- demonstrate relevance of the performance claim to PBG needs;
- respond to requests for clarification and provide additional data where required.

### **Pre-verification Stage**

The Contractor shall:

- agree with ETV Body IETU on the final set of parameters to be verified;
- agree on additional (non-verified) parameters for inclusion in reporting;
- review and approve the SVP.

### **Verification Stage**

The Contractor shall:

- ensure access to the technology, including all relevant accessories and manuals;
- provide all relevant test data (test plans, reports and datasets) to ETV Body IETU;
- select and contract the Test Body;
- ensure coordination between the Test Body and ETV Body IETU;
- ensure safe operation and availability of the system for testing;
- facilitate testing, monitoring and data collection;

No Phase 3 testing may commence without:

- approved SVP;
- approved Test Body;
- approved Test Plan.



## Reporting Stage

The Contractor shall:

- review the Verification Report and provide comments where necessary.

## Operational Responsibilities of the Contractor (Phase 3)

The Contractor shall:

- deploy, install, commission, optimise and operate pilot systems at two selected hospitals;
- ensure system operation, maintenance, servicing and data logging;
- ensure safe handling of materials and waste;
- provide all technical documentation and operational information required for verification;
- ensure access to pilot sites, operational data and documentation.
- ensure cooperation of ETV Body IETU with the Test Body for the review and approval of the Test Plan and Test Report and performance of test system audit.

## Costs

The Contractor shall bear all costs related to:

- pilot installation and operation;
- testing (including analytical work where applicable);
- sampling and logistics;
- consumables and materials;
- waste handling;
- transport and shipping;
- training of hospital and Test Body staff, where relevant;
- support to the verification process
- 

## Role of the Hospitals (Test Site Providers)

The hospitals (HUN, AZM, PERH, WSS) act as test site providers supporting Phase 3 implementation under real operational conditions.

The hospitals shall:

- provide access to suitable installation locations and infrastructure, including:
- wastewater connection points;
- electrical supply;
- space and utilities;
- facilitate integration of pilot systems into hospital infrastructure in coordination with the Contractor;
- ensure that pilot installation and operation do not interfere with critical hospital functions;
- support access to representative wastewater streams, including information on:
- wastewater sources;



- variability;
- operational constraints;
- available historical data where relevant;
- allow site access for installation, monitoring, sampling, inspection and verification to:
  - Contractor;
  - Test Body;
  - ETV Body IETU;
  - procurers' representatives;
- support coordination of on-site activities (installation, maintenance, sampling);
- provide site-specific safety requirements, including:
  - access procedures;
  - hygiene and infection control;
  - emergency procedures;
  - cooperate in addressing site-specific constraints such as:
    - space limitations;
    - access restrictions;
    - safety requirements.

### 3. Test Site Requirements

The solution shall be implemented at a minimum of two hospital sites (to be defined during Phase 2), in close coordination with the procurers and relevant end users.

Phase 3 pilot testing shall be conducted in the following hospital sites:

- **HUN** – Hospital Universitario de Navarra (Spain)
- **AZM** – Maastricht University Medical Center (Netherlands)
- **PERH** – Põhja-Eesti Regionaalhaigla (Estonia)
- **WSS** – Wojewódzki Szpital Specjalistyczny in Olsztyn (Poland)

Each solution shall be tested in **minimum two hospitals**<sup>3</sup>.

The allocation of pilot sites shall ensure **coverage of representative northern and southern European climatic conditions** relevant to the declared operating envelope of the solution.

Unless otherwise agreed by the procurers, **no hospital shall host more than one pilot installation simultaneously**.

The selected testing locations for each Contractor shall be confirmed during the transition from Phase 2 to Phase 3 and reflected in the Application file, the SVP and the Test Plan.

Prior to installation, the contractor shall conduct site visits to verify technical feasibility, infrastructure compatibility, spatial constraints, safety conditions, and integration requirements. After selection of pilot location by the PBG, the

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<sup>3</sup> I.e., if the solution is tested in only two hospitals, then the other solution will be tested in the other two.



contractor shall document the site assessment and confirm installation feasibility before deployment. A diagram showing where the solution will be integrated into the hospitals' existing infrastructure, along with a detailed description of the connection method, should be provided.

The pilot must be installed in a in such a way as to ensure:

- compliance with applicable regulations and safety requirements;
- no disruption to critical hospital functions;
- continuous operation
- the ability to collect samples of raw and treated wastewater
- the ability to monitor process parameters critical to the operation of the technology
- the ability to monitor environmental indicators (including energy demand, water demand, waste generation and environmental emissions).

Throughout Phase 3, the Contractor shall retain full technical and operational responsibility for the pilot, including:

- installation and commissioning;
- optimisation during pre-testing phase;
- stable operation and process control during testing;
- maintenance and servicing;
- safe handling of chemicals and reagents if relevant;
- management of by-products and wastes;
- compliance with safety procedures.

During the first stage of Phase 3, from the 2nd to the 5th month, the contractor should conduct complete commissioning and pre-testing activities to ensure stable and safe operation under real-site conditions. All necessary documentation for installation, operation, maintenance, safety, and troubleshooting shall be provided. The contractor will provide on-site training for to designated hospital staff including risk assessment, operational safeguards, emergency procedures, and required protective measures.

After the end of the pre-testing period the contractor shall provide to ETV Body IETU a technical report the demonstrating that:

- the process of integrating the solution into the hospital's infrastructure has been completed;
- the installed system operates correctly and safely according to design specifications;
- baseline operating conditions for the pilots at the dedicated hospital site together with all relevant assumptions, application constraints and limitations are defined and documented;
- matrix characteristics including key parameters affecting the pilot performance is provided;
- monitoring and data logging systems are fully operational;
- the pilot demonstrates stable, predicable operation ensuring at least (3) months continuous operation and testing under real site conditions;
- operational parameters of the pilot remain within declared ranges as defined in Phase 2.



In months 6 to 8 of Phase 3 the contractor shall ensure stable and predictable operation of the pilot under real operational conditions for a minimum continuous testing period of at least three full months. Performance shall be monitored against Phase 3 KPIs, operational data shall be documented, deviations recorded, and structured user feedback collected. During the test data generation period for the purpose of verifying performance, no changes should be made to the design or configuration that could affect performance. Data integrity and traceability must be ensured, and complete operational logs must be maintained.

### 3.1 Pilot Installation Requirements

The Phase 3 installation shall be a **pilot-scale system representative of the intended deployment configuration**, including where relevant:

- decentralised treatment unit,
- source-separated treatment unit,
- polishing step,
- pre-treatment plus polishing train,
- modular treatment train.

The pilot shall be large enough to:

- operate continuously under real hospital conditions;
- provide statistically adequate and traceable test data;
- reflect the intended hydraulic and process configuration for upscaling and deployment.

The Contractor shall justify:

- selected treatment capacity;
- hydraulic configuration;
- operational mode;
- retention time or batch cycle logic where applicable;
- representativeness of the pilot size for the intended deployment strategy;
- consistency with the scalability and deployment strategy declared in earlier phases.

The objective is not laboratory representativeness, but **deployment-representative pilot operation under real conditions**.

The pilot size shall be justified in the ETV Application File and technical documentation with reference to:

- expected wastewater flow from the selected hospital source or connection point;
- intended deployment model (whole-site, building-level, department-level, side stream, source-separated stream, polishing loop, etc.);
- minimum treated volume required to generate representative verification data;
- minimum operating period required to demonstrate stable operation and collect sufficient samples.

The Contractor shall define:

- nominal treatment capacity;
- minimum and maximum operational flow;
- turndown range;
- allowable peak loads;
- storage / equalisation requirements where applicable.

The pilot shall operate in a continuous mode. Based on phase 2 results other modes semi-continuous mode; batch mode; intermittent mode can be allowed provided that the selected regime:

- reflects the intended real-life application;
- is justified in the ETV Application File;
- demonstrates stable and repeatable performance during the minimum three-month formal testing period.
- 

The Contractor shall provide a detailed description of pilot installation in the ETV Application file at each selected Phase 3 site, including:

- physical location and installation layout;
- available space and configuration;
- hydraulic connection point(s);
- electrical supply and utilities;
- wastewater handling arrangements;
- equalisation or pre-storage arrangements if used;
- sampling points and accessibility;
- monitoring points and sensor positions;
- safety measures and hazard controls;
- waste management procedures;
- access conditions for:
  - Test Body,
  - ETV Body IETU,
  - procurers' representatives.

A diagram with a description showing the point of integration of the solution into the hospital infrastructure and the connection method shall be provided together with information enabling the understanding of the system operation when installed in real conditions.

This information will be required for the ETV Application file and further used for the definition of the test system in the SVP.

The pilot shall be installed to ensure:

- compliance with applicable regulations and safety requirements;
- no disruption to critical hospital functions;
- continuous operation capability;
- the ability to collect representative samples of:
  - raw wastewater,
  - treated effluent,





- intermediate streams where relevant;
- the ability to monitor process parameters critical to operation;
- the ability to monitor environmental parameters relevant to the solution, including but not limited to:
  - energy demand,
  - water demand, if relevant,
  - chemical use if relevant
  - waste generation if relevant;
  - relevant emissions,
  - noise and odour where relevant.

During the initial installation and optimisation period, the Contractor shall carry out commissioning and pre-testing to ensure that:

- the system operates safely and correctly;
- baseline operating conditions are defined and documented;
- monitoring, alarms, and logging are fully operational;
- the pilot demonstrates stable and predictable operation;
- the system remains within declared operating ranges;
- no critical safety or integration issues remain unresolved.

At the end of the pre-testing phase in Month 4, for the needs of developing the SVP the Contractor shall submit a data set confirming the technical readiness of the pilot demonstrating that:

- integration into hospital infrastructure has been completed;
- the installed system operates according to design specifications;
- baseline operating conditions, assumptions, constraints and limitations are documented (these conditions will determine the testing conditions under ETV);
- matrix characteristics relevant to pilot performance are defined and characterised to the extend enabling to demonstrate the performance of the system in its intended application and in particular removal scope and removal efficiency of target contaminants and other contaminants to achieve the declared treated effluent quality;
- monitoring and data logging are functional;
- the pilot is ready for formal continuous testing.

## 4. Test Matrix Selection

The matrix for Phase 3 shall be **real hospital wastewater only** representative of the intended application and connection point selected for the pilot.

The Contractor shall propose and justify the matrix in relation to:

- intended application;
- selected hospital site;



- contaminant profile;
- variability of flow and composition;
- expected operational loads.

The Contractor shall document:

- source of wastewater;
- sampling point(s);
- representativeness of the wastewater stream;
- expected variability;
- any pre-treatment, equalisation or conditioning applied before treatment.

The matrix shall be characterised in detail, including:

- presence and concentrations of THERESA PCP target contaminants (as indicated in Annex 5)
- TSS;
- pH;
- temperature;
- conductivity;
- organic load characterised by COD and BOD<sub>5</sub> as applicable.

Matrix characterisation shall be documented before formal testing starts and included in the ETV Application File.

## 5. Testing and Performance Verification Requirements

This section specifies the testing and performance verification requirements corresponding to the tender requirements (CRR, OPR, WR, SCA, SSI, GER1.3 and A1–A5).

The Contractors shall use the tender requirements, particularly the weighted award criteria, as guidance for defining the **performance claim** and the corresponding parameters related to technical, functional and environmental performance to be verified under ETV.

### **IMPORTANT:**

The exact scope of performance verification for each solution shall be defined individually following the review of the ETV Application File and formalised in the Specific Verification Protocol (SVP). Only parameters included in the performance claim agreed with the contractor in the ETV Application file and referred to in the SVP shall be subject to testing and verification under ETV in accordance with ISO 14034.

All parameters listed below shall be considered indicative and shall support the definition of Phase 3 KPIs as per Annex 5.

### 5.1 Pharmaceutical Removal

**Corresponding requirements: CRR1.1–CRR1.4, A1.1–A1.3**



Verification shall include, at minimum, removal of:

- **Cytostatic drugs** (CRR1.1, A1.1): ifosfamide, temozolomide, cyclophosphamide, enzalutamide, fluorouracil, methotrexate, abiraterone, mycophenolate, cisplatin, carboplatin, oxaliplatin
- **Water-soluble iodinated CT contrast media** (CRR1.2, ATC V08AB)
- Gadolinium-based MRI contrast media (CRR1.3, ATC V08CA)
- **Antibiotics** (CRR1.4, A1.3) belonging to at least the following ATC families: J01CA, J01CE, J01CF, J01CR, J01DD, J01DH, J01FA, J01MA, J01XA

Test results shall include:

- influent concentration
- effluent concentration
- removal efficiency (%)
- detection limits (LOD)
- quantification limits (LOQ)
- measurement uncertainty
- number and representativeness of samples
- operating conditions under which results were obtained

These parameters support **award criteria A1.1–A1.3**.

### **Antibiotic-Resistant Bacteria (ARB)**

#### **Corresponding requirement: A1.4 (log reduction KPI).**

Testing shall include quantitative assessment of:

- carbapenem-resistant Enterobacterales;
- third-generation cephalosporin-resistant Enterobacterales;
- carbapenem-resistant Acinetobacter spp.

### **Antibiotic Resistance Genes (ARG)**

#### **Corresponding requirement A1.5 (ARG removal KPI).**

Testing shall include quantitative molecular detection of ARGs including:

blaKPC, blaVIM, blaNDM, blaIMP, blaOXA groups, blaCTX-M groups, blaSHV ESBL, blaDHA, blaCMY, and others as declared by the Contractor.

## **5.2 Environmental Parameters**

### **Corresponding requirements SCA1.1, SCA1.5, A4.2, A4.3, A5**

The scope of verified environmental parameters will be determined based on the results of Phase 2 and the specificity of the technological solution. For the development of the ETV Application File, the Contractor shall provide as much as possible quantifiable information where applicable on:

- specific energy consumption (kWh/m<sup>3</sup> of effluent treated)
- water consumption associated with treatment; (m<sup>3</sup>/m<sup>3</sup> of effluent treated)
- chemicals/consumables use (kg/m<sup>3</sup> of effluent treated or equivalent),
- hazardous and non-hazardous waste generation (kg/m<sup>3</sup> of effluent treated);
- sludge generation where relevant;

- other environmental trade-offs and emissions where relevant, including:
  - odour,
  - noise,
  - air emissions,
  - residual chemical burden

The solution should demonstrate the environmental added value (In the ETV Application file) the Contractor shall provide information on any existing solutions with the same function currently used if available to which the solution is an alternative. This should **enable comparison of measured environmental performance with a relevant alternative**, confirming that the solution does not introduce disproportionate negative environmental impacts and demonstrates environmental added value in line with the requirement SCA 1.5. Therefore, where applicable, Phase 3 testing data shall be used to substantiate the comparison with the identified relevant alternative

The testing scope during verification and the testing requirements for the environmental parameters specific to the solution and the performance claim shall be determined in the SVP. ETV Body IETU reserves the right to impose verification of environmental parameters related to the claim if not proposed by the contractor but deemed relevant from the buyer's viewpoint and THERESA PCP objectives. However, at this stage, for the testing needs of these parameters the following requirements shall be applied:

- energy consumption shall be measured and expressed per cubic meter of treated wastewater (kWh/m<sup>3</sup>). For this purpose, the system must be equipped with energy meters (valid calibration) that guarantee real measurement of energy consumption.
- water consumption shall be measured and expressed per cubic meter of the treated wastewater. For this purpose, the system must be equipped with water meters (valid calibration) that guarantee real measurement of water consumption.
- chemicals used in the system (if applicable) shall be monitored including their type, quantity (in kg or liters), and method of storage and disposal. Chemical consumption shall be expressed as kg/m<sup>3</sup> or equivalent. If applicable, hazard classification for the chemicals used (CLP) is required.

Identified waste streams (e.g. sludge, brine, spent media) shall be characterized in terms of volume and composition if related to the claim. Their generation intensity shall be monitored. Their quantity, type, and disposal method (if applicable) must be measured and expressed per cubic meter of treated wastewater. All waste must be collected in dedicated, closed containers so that its mass or volume and characteristics, if relevant can be determined.

Noise and odour and other, not mentioned above environmental parameters shall be **verified if included in the performance claim**, otherwise reported.

NOTE: If reporting of a given environmental parameter in m<sup>3</sup> is not possible, the contractor shall justify the alternative way.

### 5.3 Sustainability Indicator

#### Corresponding requirement(s): SCA1.4

*The sustainability requirement in this section is not subject to Environmental Technology Verification (ETV) under ISO 14034.*

The Supplier shall confirm compliance with Regulation (EU) 2017/821 and provide supporting documentation demonstrating, or committing to, responsible sourcing and supply chain due diligence practices.

## **5.4 Durability and Performance**

### **Corresponding requirement(s): A3.2**

*NOTE: The durability and performance evidence requirements set out in this section are not subject to Environmental Technology Verification (ETV) under ISO 14034.*

The Contractor shall provide evidence on the durability and operational performance of the prototype system based on pilot operation, including:

- Actual consumable consumption recorded during pilot operation, including quantities used per m<sup>3</sup> treated where applicable;
- Projected replacement frequency based on observed pilot data, supported by maintenance logs recording:
  - frequency,
  - duration, and
  - operational downtime per intervention;
- Observed performance trends over the pilot period, including any degradation indicators identified, such as:
  - reduced removal efficiency,
  - increased energy consumption,
  - membrane fouling rates, or other process-specific indicators;
- Updated lifetime projections for key consumables and critical components, based on:
  - pilot data;
  - and/or reference to comparable installations with longer operational track records.

This information shall support the assessment of:

- operational reliability and stability over time;
- maintenance requirements and intervention frequency;
- potential performance degradation and its impact on system operation.

## **5.5 Transformation Products/By-products and Ecotoxicity**

### **Corresponding requirements SCA1.5, A4.3**

Where relevant to the technology and the performance claim, testing shall include:

- screening and identification of relevant transformation products or degradation by-products;

- assessment of their occurrence in treated effluent;
- ecotoxicity screening or directional ecotoxicity assessment where applicable.

These parameters support **environmental added value (SCA1.5)** and award criterion **A4.3**. They shall be verified if included in the performance claim; otherwise reported as additional information.

## 5.6 Treated Effluent Quality and Water Reuse

### Corresponding requirements: WR1.1, A4.4

Testing of the treated effluent shall include at least the following parameters:

- COD, BOD<sub>5</sub>, TSS, pH, conductivity, turbidity;
- E. coli, Legionella spp., Nematodes;

The treated effluent shall be assessed for compliance with at least the minimum applicable reuse class (at least Class B as defined in Royal Spanish Decree 1085/2024), and where achieved, higher reuse classes if declared by the Contractor.

Test data shall support:

- compliance with minimum declared reuse class (depending on final definition);
- calculation of reuse ratio (%), supporting **A4.4 KPI**.

## 5.7 Costs Reporting

### Corresponding requirements: SCA1.4 & A4.1

#### Supplier shall provide:

CAPEX Final cost breakdown covering equipment, installation, civil works, engineering, and system integration where relevant. Where actual costs differ from Phase 1 estimates, suppliers shall briefly explain the reasons for any significant changes.

OPEX - verified operational cost components recorded during the pilot testing period, including: Energy costs (based on measured consumption and applicable energy tariff) Reagents and consumables (based on recorded usage and unit costs) Maintenance and replacement parts (based on testing period or estimated) Waste disposal (based on disposal receipts or documented estimates where direct costing was not feasible) labour where relevant. Where a cost component could not be directly measured or verified within the testing period, suppliers shall provide a justified estimate with clearly stated assumptions.

Main cost drivers Identification of operational cost drivers influencing lifecycle cost.

## 5.8 Operational Monitoring and Variability

### Corresponding requirements: OPR1.1–OPR1.7, A2 (robustness and stability KPIs)

Operational parameters shall be technology-specific and shall be established individually for each solution based on Phase 2 testing results and Phase 3 pre-



testing provided by the Contractor. They shall be defined in SVP and the Test Plan, monitored during the testing, and include:

- flow rate or batch volume (mandatory);
- pH (mandatory);
- temperature (mandatory);
- organic load (mandatory)
- conductivity where relevant;
- pressure or hydraulic indicators where relevant;
- dissolved oxygen where relevant;
- oxidation-reduction potential where relevant;
- current / voltage / power draw where relevant;
- membrane pressure / flux / fouling indicators where relevant;
- other process-specific control parameters as relevant.

For monitoring of operational parameters, such as temperature and wastewater flow, online measurement using calibrated sensors is required. Calibration requirements apply to all sensors installed in the solution, such as pH meters, manometers, dissolved oxygen meters, and others, depending on the technological requirements. The location of these devices should be clearly indicated in the pilot installation scheme provided in the ETV Application file. The Contractor is responsible for ensuring proper operation of these devices (e.g. valid calibration) during the testing phase.

For calculable operational parameters, the calculation method must be specified. The obligatory parameter, i.e. organic load, should be expressed as COD/m<sup>3</sup>d and calculated based on the influent COD value and wastewater flow per day.

### **Real Variability Verification**

Since Phase 3 is conducted under real hospital conditions, during the testing the variability shall be documented and assessed in relation to:

- fluctuations in flow;
- peak loading;
- contaminant variability;
- pH variability;
- TSS variability;
- temperature variation;
- operational disruptions;
- climatic conditions where relevant.

During the testing period:

- operational parameters shall be continuously or periodically logged;
- selected operational performance parameters shall be measured;
- alarm activation shall be recorded;
- recovery times after disturbances shall be documented.



## 6. Test and Analytical Methods

**Corresponding criteria: CRR / A1, A2, A4**

### 6.1 General testing requirements

Whenever available for measured parameters and in particular analytic methods related to matrix characteristics, treated effluent characteristics including its potential for reuse, standardised reference methods (e.g., ISO, EPA, APHA standards) shall be used.

The use of in-house methods shall be accepted only if a standardized method does not exist however, the method of their validation shall be provided. All analytical methods shall specify detection limits (LOD), quantification limits (LOQ), measurement uncertainty and method accuracy/precision where applicable.

Analytical testing shall be performed by laboratories demonstrating competence in accordance with ISO/IEC 17025 for the analytical methods used.

Quality assurance and quality control (QA/QC) procedures shall be applied, including calibration, blanks, duplicates, and control samples where applicable.

The datasets generated during the testing shall ensure representativeness of operating conditions and shall include sufficient number of samples to support statistically reliable evaluation of performance.

All measurements shall be linked to the corresponding operational conditions under which they were obtained

### 6.2 Target pharmaceuticals

For target pharmaceuticals measurement, the analytical limits and uncertainty shall be given. The detection range shall be at least within the range 0,1-5,000 ng/mL.

Calculations shall be done as follows:

Target contaminants removal efficiency

$$\text{Removal efficiency (\%)} = \left( \frac{C_{\text{influent}} - C_{\text{effluent}}}{C_{\text{influent}}} \right) \times 100$$

*Where:*

$C_{\text{influent}}$  = measured influent concentration

$C_{\text{effluent}}$  = measured post – treatment concentration

### 6.3 Antibiotic-resistant bacteria (ARB)



For antibiotic-resistant bacteria (ARB), the reduction shall be expressed as  $\log_{10}$  reduction values based on quantitative measurements of selected bacteria in influent and effluent samples. The log reduction shall be calculated as:

$$\text{Log Reduction} = \log_{10}(C_{\text{influent}}/C_{\text{effluent}})$$

where:

$C_{\text{influent}}$  = measured influent concentration (e.g. CFU/mL),

$C_{\text{effluent}}$  = measured effluent concentration (e.g. CFU/mL).

Testing shall be performed using culture-based methods (CFU/mL) or other equivalent validated quantitative methods. Sampling shall be conducted at influent and effluent points under representative operating conditions. The number and frequency of samples, as well as detection limits and measurement uncertainty where applicable, shall be specified."

### 6.3 Antibiotic Resistance Genes (ARG)

The quantitative reduction of priority antibiotic resistance genes (ARG) shall be determined based on quantitative measurement of selected genes in influent and effluent samples using validated molecular methods (e.g. qPCR or dPCR). Results shall be expressed as  $\log_{10}$  reduction values (LRV) per priority ARG, calculated from gene copy concentrations (copies/mL) as  $\log_{10}(C_{\text{influent}} / C_{\text{effluent}})$ . The assessment shall include specification of sampling approach, representativeness of samples, analytical detection and quantification limits (LOD/LOQ), and measurement uncertainty.

### 6.5 Sampling Requirements

The Contractor shall ensure that the installation enables representative sampling during testing.

A detailed sampling plan shall be defined in the Test Plan and approved by the Verification Body.

Composite samples for target pharmaceuticals shall be collected at influent and effluent using autosamplers.

Composite sampling shall be time- or flow-proportional and cover a defined period representative of system operation.

The location of autosamplers shall be agreed between the Contractor, the Test Body and the hospital.

Grab samples for microbiological analysis shall be collected at influent and effluent no later than 2 hours after completion of composite sampling.

Sampling shall:

- be conducted under representative operating conditions;
- capture variability in flow, load and wastewater characteristics, including peak and average conditions where relevant;

- include specification of sampling frequency and number of samples sufficient to ensure reliable performance evaluation;
- ensure representativeness of the dataset.

Sample preservation, storage and transport shall be defined in accordance with the applied analytical methods to ensure sample integrity.

Sampling quality control procedures shall be applied, including field blanks, duplicates and documentation of sampling conditions where applicable.

Traceability of samples shall be ensured through proper labelling, documentation and chain-of-custody procedures and described in the Test Plan

The sampling during the testing for ETV shall be performed by the Test Body. Prior to testing, the contractor shall ensure that the Test Body staff performing the sampling has sufficient and adequate knowledge of the pilot installation enabling proper sampling, reading, understanding and integration of all parameters including operational parameters during testing. For that purpose, the contractor shall provide adequate training and instructions to the Test Body.

The Contractor shall ensure that the Test Plan developed by the Test Body follows the provided generic Test Plan template and:

- provides documented sampling protocols including staff competent to perform sampling;
- defines safe sampling points;
- identifies hazards related to sampling if relevant;
- define PPE requirements if relevant;
- confirms provision of training and instructions to Test Body relevant for sampling
- ensure that safe and representative sampling is possible.

## 7. Monitoring System and Data Integrity

**Corresponding requirements: OPR1.10 (operational verification), A2 support (robustness and traceability)**

During the testing the contractor shall ensure that the pilot demonstrates:

- at a minimum monitoring of critical operational parameters;
- alarm generation when operational parameters are exceeded;
- time-stamped data logging;
- operational event logging;
- dashboard or interface displaying:
  - real-time data,
  - historical data,
  - alarm history.

ETV Body IETU and the Test Body shall review monitoring records for consistency and traceability during testing. The reporting of the test data shall be provided in conjunction with these parameters. The test data reporting requirements form shall be agreed between the ETV Body IETU, the contractor and the Test Body at the stage of the Test Plan development based on the specification of the technical/

functional parameters to be verified and operational parameters to be verified in the SVP.

## 8.Data Export and Interoperability

### **Corresponding requirement: OPR1.12.**

During the testing the Contractor shall ensure that the system demonstrates:

- structured data export capability (e.g. CSV, API, equivalent structured format);
- clearly defined timestamps and metadata;
- documented communication logic;
- traceability between logged operational data and test results.

Where full hospital IT integration is not feasible, the Contractor shall ensure that the system demonstrates at a minimum interoperability readiness and export capability.

## 9.Cybersecurity

### **Corresponding requirement: OPR1.8**

During the testing the Contractor shall ensure that system demonstrates:

- no default or publicly accessible credentials;
- restricted access to control interfaces;
- authentication mechanisms;
- documented access control logic;
- documented data storage and protection logic;
- evidence that cybersecurity controls implemented in the pilot are compatible with hospital requirements.

## 10. HAZOP/Risk Communication during Phase 3

Prior to formal testing, the Contractor shall provide to the hospital, the Test Body and ETV Body IETU:

- simplified HAZOP or equivalent risk assessment;
- identification of:
  - mechanical hazards,
  - chemical hazards,
  - electrical hazards,
  - biological hazards;
- emergency shutdown procedures;
- incident reporting procedures;



- waste handling arrangements;
- decontamination and cleaning procedures where relevant.

## 11. Reporting Requirements

At the end of the pre-testing phase in Month 4 , for the needs of developing the SVP the Contractor shall submit a data set confirming the **technical readiness of the pilot for verification testing**.

In Month 5 The Contractor shall submit a **Test Plan** developed by the Test Body following the template **TD12. GENERIC TEST PLAN TEMPLATE** based on the SVP detailing the testing process covering the requirements specified in subsections 8.2.3- 8.2.10.

In the ninth month of Phase 3, the Contractor shall submit a **Test Report** developed by the Test Body in accordance with **TD13. GENERIC TEST REPORT TEMPLATE** and Annex 8. Guide for ETV applicants. The test report must include:

- INTRODUCTION including name, description of, the condition of, and unique identifier of the technology tested, the purpose of the technology, the matrix and its parameters, name and contact of contractor, name and contact of test body, unique identification reference of the test report;
- IMPLEMENTED TEST DESIGN DESCRIPTION including reference to test plan and specific verification protocol, parameters and test methods used to produce test data for verification, sampling methods;
- TEST RESULTS including date(s) and location(s) of performance of the tests, schedule for sampling and data collection, quality control of samples, representativity of the samples, test results with estimation of the uncertainty, information on specific test conditions, such as operational conditions, test data summary, test performance observation, including opinions and interpretations where appropriate and needed, additional information if required by specific methods, test quality assurance summary, incl. audit results where applicable, amendments to and deviations from test plan.
- REPORT APPROVAL with the name(s), function(s) and signature(s) or equivalent identification of person(s) authorizing the test report from the side of the Test Body.

In the tenth (10) month of Phase 3, the ETV Body IETU shall prepare a **Verification Report and a Statement of Verification** as independent inspection/inspection body documents. Verification results (verified performance claim), obtained for two different locations, will then be evaluated to determine whether they meet THERESA PCP's requirements (KPIs). Its main parts shall include:

- a detailed description of the technology and its application,
- the verified performance,
- operational conditions, constraints, and limitations under which the verified performance is achieved,
- all measurement uncertainties and relevant assumptions taken into consideration during the verification process,
- description of the tests performed and the obtained results,



- description on how the requirements for the verification of the performance and for the test data, as specified in the verification plan, were met, including reporting of any deviations,
- final assessment of all data from the test report and from acceptable existing data prior to verification,
- quality management and control procedures applied,
- any other information necessary to understand and use the performance claim; this may include information not verified under the ETV, however this should be clearly stated and explained.

All relevant documents produced during verification should be attached to the verification report as appendices.

The contractor shall get acquainted with the report and the statement and has the right to comment; however, ETV Body IETU reserves the right to consider contractor's comments to the extent considered relevant and necessary.

## 12. Benchmarking the pilot system's efficiency for different testing sites

The results of verifying each pilot (verified performance claim) at two different locations will then be evaluated to determine whether they demonstrate compliance with defined performance thresholds and KPI requirements, stable operation under real hospital conditions, fulfillment of the needs of procurers and users (including regulatory requirements) and an absence of unresolved safety or integration concerns.

The evaluation will assess whether the technologies meet the requirements regarding:

- the effectiveness of removing target pharmaceuticals, ARB, ARG and achieving the required thresholds for them in treated wastewater (if relevant). It will be verified whether contaminants from the following group have been detected in all treated HWW (row HWW):
- Cytostatic drugs specifically: ifosfamide; temozolomide; cyclophosphamide; enzalutamide; fluorouracil; methotrexate; abirateron; mycophenolate; cisplatin; carboplatin; oxaliplatin;
- Water-soluble iodinated CT contrast media (ATC V08AB);
- Gadolinium-based contrast media (ATC V08CA);
- Antibiotics classified according to the families listed below:
  - J01CA Penicillins with extended spectrum
  - J01CE Beta-lactamase sensitive penicillins
  - J01CF Beta-lactamase resistant penicillins
  - J01CR Combinations of penicillins, incl. beta-lactamase inhibitors
  - J01DD Third-generation cephalosporins
  - J01DH Carbapenems
  - J01FA Macrolides
  - J01MA Fluoroquinolones
  - J01XA Glycopeptide antibacterials
- Antibiotic-Resistant Bacteria (ARB) belonging to groups:

- Carbapenem-resistant Enterobacterales;
- Third-generation cephalosporin-resistant Enterobacterales;
- Carbapenem-resistant Acinetobacter spp.;
- ARB: blaKPCgr, blaVIMgr, blaNDMgr, blaIMPgr, blaOXA-23, blaOXA-58, blaOXA-48gr, blaCTX-M-1gr, blaCTX-M-9gr, blaCTX-M-2gr, blaCTX-M-25gr, blaSHVESBL (-2, 5, ...), blaDHAPampC, blaCMYPampC
- process efficiency depending on the selected process parameters resulting from variations in wastewater characteristics, wastewater flow and peaks, pH, TSS, temperature, and other environmental conditions;
- the potential for water recovery based on the quality of the treated wastewater, the technical solutions designed for this purpose, and the strategies adopted for this purpose at the hospital where the pilot was tested;
- environmental aspects related to energy consumption, chemical/resource use and secondary waste generation (per unit of treated wastewater);
- pilots' architecture compatibility with cybersecurity controls - cybersecurity systems have been implemented in pilots;

The results of the detailed comparative analysis for each pilot tested in Phase 3 shall be included in the End of Phase 3 report.



## Annex 8. Guide for ETV applicants

[https://etv-hub.eu/Downloads/GuideForETVapplicants/Guide\\_for\\_ETV\\_applicants\\_EN.pdf](https://etv-hub.eu/Downloads/GuideForETVapplicants/Guide_for_ETV_applicants_EN.pdf)



# Annex 9. ETV Contract template

**DRAFT VERSION (NOT FINAL)**

**Contract No. \_\_\_/20\_\_**

**For Performance of Environmental Technology Verification of technology  
under THERESA PCP**

This .....-..... in Katowice:

**Instytut Ekologii Terenów Przemysłowych** (The Institute for Ecology of Industrial Areas), with the registered office in Katowice at Kossutha 6 street, PL 40-844 Katowice, Poland, entered into the National Court Register maintained by the District Court for Katowice-East in Katowice, Commercial Division No. 8, under number KRS 0000058172, the holder of the tax identification number (in Polish: NIP) 634-01-25-519 and the statistical identification number (in Polish: REGON) REGON 271590804,

represented by:

Ms **Marta Pogrzeba, Professor** – IETU Director

hereinafter referred to as **“ETV Body”**

and

....., with the registered office in ..... at....., .....,

....., the holder of the tax identification number.....,

represented by:

.....;

hereinafter referred to as **“Applicant”**,

hereinafter jointly referred to as **“Parties”**,

have entered into the following Contract, hereinafter referred to as

**“Contract”**:

## PREAMBLE

*This Contract is concluded within the framework of the THERESA Pre-Commercial Procurement (PCP) project.*

*Within THERESA PCP, Phase 3 aims to validate innovative wastewater treatment technologies under real hospital conditions and to verify their performance through Environmental Technology Verification (ETV) in accordance with ISO 14034.*

*For technologies selected for Phase 3, verification constitutes a mandatory contractual requirement. Verification shall be conducted based exclusively on test data generated under stable and representative operating conditions in accordance with the Specific Verification Protocol (SVP)*





## Article 1 - Glossary of Terms and Abbreviations

The Parties mutually agree that in this Contract the following terms shall have the following meaning:

- a. **verification** – confirmation through the provision of objective evidence;
- b. **Environmental Technology Verification (ETV)** – a process following the standard ISO 14034 “Environmental management – Environmental technology verification”, aimed at verifying the performance of an environmental technology;
- c. **ISO 14034** – “Environmental management – Environmental technology verification”, a technical standard that describes the principles, procedures and requirements used by the ETV Body to verify the performance of an environmental technology;
- d. **technology** – application of scientific knowledge, tools, techniques, crafts or systems in order to solve a problem or to achieve an objective which can result in a product (i.e. any good or service) or process;
- e. **environmental technology** – technology that either results in an environmental added value or measures parameters that indicate an environmental impact;
- f. **environmental added value** – more beneficial or less adverse environmental impact of a technology with respect to the relevant alternative;
- g. **environmental impact** – change to the environment, whether adverse or beneficial, wholly or partially resulting from material acquisition, design, production, use or end-of-use of a technology;
- h. **relevant alternative** – technology applied currently in a similar situation to the environmental technology for which performance will be verified through ETV;
- i. **performance claim** – statement of performance of the environmental technology declared by the Applicant;
- j. **Quick Scan** – a contact form containing information about the technology presented by the Applicant to the ETV Body in order to perform an initial check of the environmental technology eligibility for ETV;
- k. **Application for Verification (Application)** – an application for verification of an environmental technology submitted by the Applicant upon positive evaluation of the Quick Scan by the ETV Body and prior to the development of the Specific Verification Protocol (SVP);
- l. **Specific Verification Protocol (SVP)** – referred to as the verification plan in ISO 14034; a planning document detailing the implementation of environmental technology verification for the technology proposed for ETV, including the parameters to be verified, test methods, conditions, assumptions and data quality requirements;
- m. **Verification Report** – a document detailing the environmental technology verification process and its results, developed by the ETV Body and provided to the Applicant;
- n. **Verification Statement** – a document summarising the results of environmental technology verification, developed and published by the ETV Body and provided to the Applicant upon completion of the verification;
- o. **proposed technology** – the technology proposed by the Applicant for ETV in the Application and assessed under this Contract;
- p. **THERESA PCP** – the Pre-Commercial Procurement project under which this Contract is implemented;
- q. **Phase 2 (Prototype Phase)** – the stage of the THERESA PCP during which the technology is developed and tested at prototype level under controlled or semi-



controlled conditions; results from this phase may support the formulation of the performance claim but shall not be used for verification;

r. **Phase 3 (Pilot and Verification Phase)** – the stage of the THERESA PCP during which the technology is deployed as a pilot system under real operating conditions and where verification of performance is carried out;

s. **pilot system** – the technology deployed, installed and operated under real conditions at hospital sites within Phase 3 of THERESA PCP;

t. **pre-testing (Phase 3 pre-testing)** – activities including installation, commissioning and optimisation of the pilot system prior to verification testing; data generated during this phase shall not be used for verification;

u. **verification testing** – testing carried out under stable and representative operating conditions in accordance with the SVP, the results of which are used for verification of performance;

v. **stable operation** – operation of the pilot system under controlled and representative conditions demonstrating consistent performance over a defined period prior to verification testing.

## Article 2 - Representations of the ETV Body

1. The ETV Body represents to be established under the law of the Republic of Poland and to be a legal entity.
2. The ETV Body represents to hold a valid accreditation certificate number AK026 regarding compliance with the PN-EN ISO/IEC 17020 standard “*Compliance Assessment. Requirements for Activities of Various Inspection Bodies*” for type A inspection body awarded by the Polish Centre for Accreditation to perform ETV compliant to standard ISO 14034 for technologies belonging into the following technology areas: IETV. 1 Water Treatment & Monitoring, IETV.2 Materials, Waste & Resources, IETV.3 Energy technologies; as at the conclusion date hereof.
3. The ETV Body represents to carry out any verification activities with the due professional integrity and the requisite technical competence in the specific field and to guarantee impartial verification activities as well as observance of the professional confidentiality principle.
4. Based on the assessment of the Quick Scan submitted by the Applicant, the ETV Body represents that the technology proposed by the former has qualified for the development, review and assessment of the Application.
5. The ETV Body represents and warrants that it has not been involved in any work related to the development or testing of the technology proposed for verification.

## Article 3 - Representations of the Applicant

1. The Applicant represents: to understand the objectives of the (ETV) verification activities carried out by the ETV Body under ISO 14034 - “Environmental



management – Environmental technology verification (ETV)"and to accept any and all ETV procedure-based limitations and requirements.

2. The Applicant represents that he shall comply with the ETV procedures and requirements as far as necessary to verify the performance of the technology proposed for ETV and obtain the Verification Statement. In particular, he shall cooperate with the ETV Body to provide all necessary information as requested by the ETV Body to satisfy the ETV application requirements, implement ETV Body instructions and guidance pertaining to the verification procedures including technology testing if relevant, as defined in ISO 14034.
3. The Applicant represents to hold the legal title to the proposed technology as the technology owner/manufacturer/an authorised representative of either mandated under contract \_\_\_\_\_<sup>4</sup>, in witness whereof it presents \_\_\_\_\_<sup>5</sup>, being Appendix No. 1 hereto and thus he may perform any and all activities pertaining to the performance of the ETV.
4. The Applicant represents that the technology proposed for verification makes use /does not make use<sup>6</sup> of third-party intellectual property the rights whereof are owned by the persons other than the Applicant.
5. The Applicant represents that no other persons than the Applicant also hold/do not hold rights to the proposed technology<sup>7</sup>.
6. The Applicant represents that it is highly probable that the proposed technology satisfies the definition of an environmental technology.
7. The Applicant represents to have filled in the information in the Quick Scan with utmost due diligence and reliability, and upon using all the knowledge held and that the data and information presented by it are true.
8. The Applicant represents to accept a positive assessment of the ETV Body as to the technology recommendation for ETV based on the Quick Scan and resolves to continue with the ETV process.
9. The Applicant represents that he shall neither exert pressure nor place the ETV Body under coercion for the purpose of approval of the technology proposed for verification for the subsequent ETV procedure stages. Further, the Applicant represents that he shall not take any action which could impact the impartiality or independence of the ETV Body, or its personnel.
10. The Applicant represents to be aware of the risk that upon the application review and assessment by the ETV Body, the technology proposed for verification may not meet the eligibility criteria in particular in terms of demonstrating sufficient technology maturity level and/or compliance to the

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<sup>4</sup> Please delete as appropriate.

<sup>5</sup> Insert the title of the document confirming the legal title to the proposed technology, provided that the Applicant holds it (e.g., a patent, a power of attorney or another mandate for use, etc.). Please delete this fragment of the provision otherwise.

<sup>6</sup> Please delete as appropriate.

<sup>7</sup> Please delete as appropriate.



definition of environmental technology and that in consequence be not be recommended for performance verification through ETV.

11. The Applicant represents that the technology proposed for verification has reached a level of maturity enabling its deployment and stable operation under Phase 3 conditions of the THERESA PCP and that the pilot system will achieve stable performance suitable for verification within the contractual timeframe.

## **Article 4 - Subject-matter of the Contract**

1. Until the conclusion hereof, the Parties have carried out the following stages of the ETV process:
  - a. the Applicant has developed and submitted the Quick Scan;
  - b. the ETV Body has received and assessed the Quick Scan; and
  - c. based on the Quick Scan assessment recommended the technology to develop the application to verify its performance through ETV.
2. Hereunder, the ETV Body undertakes to review and assess the Application submitted by the Applicant with an objective to state the eligibility of the technology for verification of its performance through ETV and conclude on its recommendation to proceed to the subsequent stages of the verification process.

The Application for Verification and the associated performance claim shall be based on all available technical information, including results of PCP Phase 2 prototype testing where relevant. Such data shall serve exclusively as supporting information for the formulation of the performance claim and for the design of the verification approach.

Only test data generated during Phase 3 under stable and representative operating conditions, in accordance with the Specific Verification Protocol (SVP), shall be used for the purpose of performance verification.

Test data generated during Phase 2 or during pre-testing activities in Phase 3 shall not be used for verification of performance.

3. The conclusion hereof shall not place the ETV Body under the obligation to deliver a final positive recommendation of the technology presented by the Applicant for verification in the subsequent stages of the process. It shall not authorise the Applicant to claim that the proposed technology is recommended for the subsequent ETV process stages either.
4. In case the ETV Body delivers a final positive recommendation of the technology presented by the Applicant for verification, the ETV Body undertakes to verify the proposed technology according to ISO 14034 "Environmental management – Environmental technology verification" and the Applicant undertakes to perform his obligations contained in this Agreement. For technologies selected for Phase 3 of the THERESA PCP, verification under this Contract constitutes a mandatory contractual requirement. Notwithstanding the mandatory nature of the verification process, the outcome of verification shall remain independent and shall be



determined solely on the basis of the evidence provided and its compliance with the applicable standards and the SVP.

5. The subject-matter of the Contract as referred to in section 4 herein shall be performed in the following stages:

Stage number	Stage description	Terms of stage performance
<b>Stage 1 (Pre-verification)</b>	Specification of performance parameters to be verified and their numerical values resulting from the performance claim and the intended application of the technology as agreed in the Application for Verification Development of a Specific Verification Protocol (SVP) to plan the verification and specify test data requirements pertaining to the specified performance parameters to be verified	detailed in Article 7 hereof
<b>Stage 2 (Verification)</b>	1. Assessment and validation of test data to verify the performance parameters specified in the SVP if additional testing was needed. 2. Analysis and assessment of all test data qualified to verify the performance parameters generated in accordance with the SVP to confirm technology performance	detailed in Articles 8-11 hereof
<b>Stage 3 Reporting</b>	1. Development of the verification report and Verification Statement ;	detailed in Article 12 hereof
<b>Stage 4 Post-verification</b>	2. Publication of the Verification Statement at a minimum.	detailed in Article 16 hereof

- 5a. The verification process under Phase 3 shall include: installation and commissioning of the pilot system; optimisation and pre-testing phase; testing for verification phase.  
Verification testing shall only commence once stable operation of the pilot system has been demonstrated.
6. The conclusion hereof shall not place the ETV Body under the obligation to confirm the performance parameters for the verified technology and their numerical values as declared by the Applicant in the Application for Verification against the gathered data and obtained test results.
7. This ETV implementation is adapted to the THERESA PCP framework while remaining compliant with ISO 14034 and, where relevant, ISO/IEC 17020.
8. Appendix No. 3 hereto provides for the General Contract Schedule in case the ETV Body accepted the proposed technology for verification.



9. The General Contract Schedule set out in section 1 herein may be modified only as provided for hereby.
10. The dates given in the schedule set out in section 1 herein shall be automatically postponed should the circumstances beyond control of the ETV Body occur (e.g., should the expertise development time be extended by the third party, etc.) by the time needed to complete the activities or a given stage.
11. When justified, the Applicant may request in writing suspension of the ETV process, stating the time of its subsequent execution – however not later than after 6 (in words: six) months from the Application submission date. The ETV Body may refuse to suspend the ETV process for important reasons. Be it the case, Article 25.4.t hereof shall apply.

## **Article 5 -Terms of Contract Performance**

1. The Applicant shall develop the Application according to the template provided in Appendix No. 4 to this contract and shall submit it to the ETV Body together with supplementing documents set out in Article 6.1 within ... calendar days after the conclusion of this contract.
2. The Application referred to in section 1 herein shall have 2 parts:
  - a. Part one: to be completed by the Applicant and include all information relevant and sufficient for the ETV body to assess if:
    - i. the technology fulfils the definition of environmental technology ;
    - ii. the performance claim for the intended application of the technology addresses the needs of the interested parties;
    - iii. the information on the technology is sufficient to review the performance claim and to support the specification of the testing to be carried out under Phase 3 in accordance with the SVP;
  - b. Part two: completed by the ETV Body to assess the Application and communicate the assessment result to the Applicant.
3. The Applicant shall be fully liable for the correct development of the Application part set out in section 2.a herein.
4. The ETV Body shall not demand documentation or information from the Applicant which is not relevant to assess the Application and conclude on the eligibility of the technology for ETV as defined in section 2 herein.
5. Upon submission of a completed Application by the Applicant, the ETV Body shall:
  - a. make a formal review of the information provided for consistency and completeness; and once this is completed
  - b. make a technical review of the Application.
6. When reviewing the Application, the ETV Body may provide the Applicant with technical advice and additional explanations necessary to complete or correct the information provided in this section to satisfy the application requirements – provided that it does not breach its impartiality or independence. Any explanations or guidance provided by the ETV Body during the review of the



Application shall be limited to clarification of applicable requirements, identified deficiencies and procedural aspects. Such explanations shall not extend to advising the Applicant on how to achieve a specific performance result or how to formulate or optimise the performance claim or how to influence verification outcomes under Phase 3.

7. Should the ETV Body find out in the course of its formal review of the part of the Application referred to in section 2.a herein that the Application is incomplete, non-exhaustive, incorrect or lacking any required data, it shall request the Applicant to:
  - a. provide explanations;
  - b. revise the Application;
  - c. complete the Application;
  - d. deliver additional information, data or documents;
  - e. deliver other documents than those set out in Article 6.1 ("convalidation activities") hereof.
8. For the case set out in section 7 herein, the Applicant should provide explanations, revise or complete the Application or deliver additional information or data within 14 ..... calendar days after the date of being notified thereof electronically, by phone or in writing by the ETV Body. Article 6.5 hereof shall apply to section 7.e herein.
9. Should the Applicant not be able to fulfil the request of the ETV Body by the date set out in section 8 herein, the Parties shall mutually agree on another date making it possible to rectify the Application.
10. As part of convalidation procedure, the procedure set out in sections 7-9 herein can be renewed until the ETV Body finds out that it can start with the activity given in section 5.b hereof.
11. Article 25.4.d hereof shall apply, should the Applicant fail to fulfil the request of the ETV Body as set out in section 7 herein at the time given in section 8 or in section 9 herein or should it file a representation that it will not rectify the Application as requested.
12. Upon the formal review of the part of the Application set out in section 5.a and stating its correctness as deemed necessary under the procedure set out in sections 6-8 herein, in keeping with section 5.b herein, the ETV Body shall perform the technical review of the Application. The technical review shall be completed not later than within the period of ..... calendar days.
13. The ETV Body shall make the technical review of the Application under section 12 herein, considering:
  - a. the ISO 14034 requirements concerning sufficiency and adequacy of information about the technology pertaining to carry out assessments as indicated in article 6, section 2a;
  - b. the technical standards or reference documents for the technology;
  - c. environmental added value, including the key environmental aspects and impacts of the technology proposed for verification in relation to relevant alternatives, in line with the environmental added value requirement





defined in this Contract; the assessment at the application stage shall primarily consider operational impacts and shall be based on available information, recognising that final verification of environmental performance shall be carried out under Phase 3;

- d. the protocols developed for similar technologies under the EU Environmental Technology Verification (ETV) Programme, non-EU ETV Programmes and other research and pilot projects.

14. Should the ETV Body find out in the course of technical review of the part of the Application referred to in section 2.a herein that the Application is incomplete, non-exhaustive, incorrect or lacking any required data, it shall request the Applicant to:

- a. provide explanations;
- b. revise the Application;
- c. complete the Application;
- d. deliver additional information, data or documents;
- e. deliver other documents than those set out in Article 6.1 (“convalidation activities”) hereof.

15. For the case set out in section 14 herein, the Applicant should provide explanations, revise or complete the Application or deliver additional information or data within 14 (*in words: fourteen*) calendar days after the date of being notified thereof electronically or in writing by the ETV Body. Article 6.5 hereof shall apply to section 14.e herein.

16. Should the Applicant not be able to fulfil the request of the ETV Body by the date set out in section 15 herein, the Parties shall mutually agree on another date making it possible to rectify the Application.

17. Upon completion of the technical review of the Application under section 13 herein, the ETV Body shall:

- a. conclude on the eligibility of the proposed technology to verify its performance through ETV, and
- b. reject the proposed technology for verification and communicate to the Applicant the need to close the ETV process or
- c. accept the proposed technology for verification and propose conclusion of the contract for verification to the Applicant.

The acceptance of the Application does not constitute confirmation of performance and does not imply that the performance claim will be verified. Verification of performance shall be carried out exclusively on the basis of test data generated during Phase 3 testing for verification.

18. The ETV Body shall resolve any issues related to the acceptance or rejection of the Application that may arise from the administrative or the technical review prior to the verification. Acceptance or rejection of the Application shall be communicated to the Applicant within the period of ..... calendar days.

19. Regardless of Application acceptance or rejection, the Applicant shall acknowledge the assessment of the Application provided by the ETV Body by signing the assessed Application as indicated in the template. If the





Application is accepted, acknowledging its assessment by signature, the Applicant consents to the verification of the proposed technology by the ETV Body. The Applicant acknowledges that acceptance of the Application enables progression to verification but does not guarantee successful verification outcomes

20. In the case of application rejection referred to in section 17.b herein, the ETV Body shall provide a detailed justification explaining to the Applicant the reasons for the rejection.
21. The Parties shall sign an acknowledgement protocol regardless of acceptance or rejection of the Application – within ..... calendar days upon the date when the Applicant was informed about the Application assessment result.
22. The reviewed and approved Application serves as a basis for the specification of performance to be verified and for the development of the Specific Verification Protocol (SVP), including definition of verification testing to be carried out under Phase 3.

## **Article 6 - Terms of Document Delivery**

1. Together with the Application as referred to in Article 5.1 hereof, the Applicant shall deliver to the ETV Body the following documents:
  - a. any and all information about the proposed technology and the documents produced therefore – as indispensable for the full understanding of technology performance; and
  - b. existing test data pertaining to the performance of the technology (e.g., reports and data from technology testing generated prior to Application, etc.); where the technology has undergone prototype testing during PCP Phase 2, the Applicant shall provide the ETV Body with the relevant Phase 2 test data and related supporting information together with the Application for Verification; such data shall serve exclusively as supporting information for the development and assessment of the performance claim and for the preparation of the Specific Verification Protocol (SVP), and shall not be used for verification of performance.
2. The Applicant shall deliver to the ETV Body the Application as referred to in Article 5.1 hereof and the documents set out in section 1 within ..... calendar days after the conclusion date hereof.
3. Should the Applicant not be able to meet the deadline set out in section 2 herein, it shall notify the ETV Body thereof .... calendar days before the expiry of the deadline at the latest – stating the cause of failure and indicating the planned time no longer than ..... subsequent calendar days.
4. Should the ETV Body not receive the Application referred to in Article 5.1 hereof or the documents set out in section 1 herein at the time set out in sections 2-3 herein, it shall call upon the Applicant to file the same within ..... calendar days



at maximum after the notification date. Article 25.4.f hereof shall apply to the ineffective expiry of the said time.

5. For the case set out in Article 5.7.e and in Article 5.14.e hereof, the ETV Body shall call upon the Applicant to deliver the requisite documents, defining the deadline therefore. Sections 3-4 herein shall apply accordingly.
6. All the documents shall be duly described, secured against loss and damage and later delivered to the ETV Body as hard and soft copies on an agreed electronic medium or secure digital platform, unless otherwise agreed by the Parties.
7. The Applicant shall bear any and all costs and risks of the documents delivery. In observance of full confidentiality as detailed under Article 26 hereof, the Quick Scan and the Application hereof may be shared with national accreditation bodies; any sharing of information shall respect the distinction between supporting data (including Phase 2 data and pre-testing data) and verification data generated under Phase 3.

## **Article 7 - SVP Development**

1. The SVP shall be developed based on the processed Application for Verification, approved by the Applicant. The SVP shall be developed by the ETV Body, taking into account the performance claim proposed by the Applicant and the available supporting information, including supporting data from Phase 2 and other sources, which shall be used exclusively for the definition of the performance claim and the design of the verification approach. The Applicant shall be consulted during the development of the SVP to ensure that the intended application, system configuration and operational conditions are correctly reflected. The ETV Body shall remain solely responsible for the final content of the SVP.
2. The ETV Body shall develop the SVP at the time set out in Appendix No. 3 hereto.
3. The SVP shall include:
  - a) identification of the ETV Body,
  - b) identification of the Applicant,
  - c) unique identification of the SVP and date of issue,
  - d) unique identifier and a description of the verified technology,
  - e) a specification of performance parameters and their numerical values to be verified and the description of how they will be verified based exclusively on test data generated during Phase 3 testing for verification,
  - f) technical and operational details of the planned verification, including deployment and operation of the pilot system under representative conditions,
  - g) specification of the requirements for the test data, including quality and quantity and test conditions for verification data generated under Phase 3;
  - h) a description of methods for the assessment of the test data and their quality, including traceability of verification data to the conditions defined in the SVP;



4. The ETV Body and the Applicant shall mutually agree on the elements given in section 3.a-h herein on the terms of section 6 herein. The ETV Body shall consult the Applicant on the elements given in section 3.a-h herein; however, the ETV Body shall retain sole responsibility for defining the final content of the SVP in accordance with ISO 14034 and the requirements of the THERESA PCP.
5. Upon developing the draft SVP, the ETV Body shall enable the Applicant access thereto – for review at the time set out in Appendix No. 3 hereto.
6. Upon review of the SVP, the Applicant may:
  - a. approve it without any reservations – then the ETV process is continued hereunder;
  - b. provide comments to the SVP prior to approval – then the ETV Body shall have additional ..... calendar days for their review; the ETV Body may accept or reject the comments – in their entirety or in part. It shall notify the Applicant of its decision and the Applicant shall have ..... calendar days to take a decision to accept or not the SVP as developed by the ETV Body and continue with the ETV process.
7. Upon developing the SVP, the Parties shall sign the acknowledgement protocol confirming completion of Stage 1 works under this contract and confirming readiness to proceed to Phase 3 verification testing.
8. Article 25.4.g-h shall apply, should the Parties not make the arrangements referred to in section 4 herein or should the Applicant not approve the SVP under section 6 herein.

## **Article 8 - Assessment and Validation of Phase 2 Test Data**

1. Existing test data generated during PCP Phase 2 may be used exclusively as supporting information for the development of the performance claim and the preparation of the Specific Verification Protocol (SVP). Such data shall not be used for verification of performance parameters. Only test data generated during Phase 3 verification testing, in accordance with the SVP and applicable standards, shall be accepted for verification purposes.
2. The ETV Body may:
  - a. accept the existing test data as supporting information for the development of the performance claim and the SVP;
  - b. reject the existing test data as insufficient or not relevant for supporting the performance claim;
  - c. identify, based on the existing data, the need for additional testing to be carried out during Phase 3 verification testing in accordance with the SVP.

## **Article 9 - Test Data Generation**



1. In accordance with the SVP, the ETV Body shall ensure that test data used for verification are generated during Phase 3 verification testing under stable and representative operating conditions.
2. Subject to section 7 herein, the Applicant – in liaison with the ETV Body – is required to select a competent test body at the time set out in Appendix No. 3 hereto, considering:
  - a. it satisfies the requirement to produce and report the test data according to the requirements of ISO/IEC 17025;
  - b. it demonstrates competence in accordance with ISO/IEC 17025 and shall be independent from the Applicant and free from conflict of interest; the Applicant shall provide the ETV Body with the information necessary to assess such competence and independence;
  - c. any other requirements, if specified in the SVP.
3. Save for section 7 herein, upon selection, the Applicant shall conclude an adequate contract with the test body specifying the tasks as defined in sections 6, 9-10 herein and including the clauses given in Article 10.4 hereof.
4. The rules of testing-related liability are governed by Article 24.1-3 hereof.
5. The rules of bearing the testing costs are governed by Article 21.5 hereof.
6. The test body shall be responsible for:
  - a. developing a test plan complying to the testing requirements specified in the SVP and in accordance with the ETV Body requirements stated in Appendix No. 5,
  - b. liaison with the ETV Body and the Applicant for the test plan approval;
  - c. delivering the agreed test plan to the Applicant and the ETV Body,
  - d. performing the tests in accordance with the test plan;
  - e. assuring quality in the test performance and reporting according to the requirements of ISO/IEC 17025 and other requirements of the ETV Body, if applicable ; and
  - f. developing a test report in accordance with the ETV Body requirements and delivering the same to the Applicant.
7. When justified, the Applicant may carry out the tests as in-house tests on condition that he can demonstrate compliance to the requirements for test bodies set-out in section 2 a and b, and section 9 herein, provided that such tests are conducted under conditions equivalent to independent testing and are subject to validation and oversight by the ETV Body in accordance with the SVP.
8. For the case set out in section 7 herein, the Applicant may commission the test body to:
  - a. develop a test plan or review the test plan developed by the Applicant – in liaison with the ETV Body;
  - b. observe the tests carried out by the Applicant; and
  - c. approve the test report developed by the Applicant.
- 8a. Where appropriate for the THERESA PCP, testing may be carried out in parallel across more than one site, provided that the comparability of testing



conditions and the consistency of the generated data are ensured and documented.

9. Test site :
  - a. should in no way depend on the Applicant, subject to letters b-c herein;
  - b. when tests should be carried out at the installation and operation site of the verified technology the Applicant must ensure that no interests, the commercial ones included, will impact the test results including conditions of operation of the pilot system under Phase 3; and
  - c. should it be impossible to carry out under letter a herein, the decision to choose the venue should be justified and included in the SVP; further, extra safety measures should be applied therefor (e.g., an access log).
10. The ETV Body may refuse to approve the test plan, the test report or other documents produced by the test body, should they not satisfy the requirements of SVP and/or quality requirements of ISO/IEC 17025 or should they be unacceptable for other reasons for the ETV Body. Be it the case, the ETV Body shall return the documents received to the Applicant for completing or revision together with due justification and the rectification date.
11. The Applicant shall remain fully responsible for the development and submission of the Test Plan, which may be prepared by the selected test body. Review and approval of the Test Plan by the ETV Body shall be limited to its compliance with the SVP and applicable standards and shall not constitute acceptance of responsibility by the ETV Body for the design, execution or results of the tests, including responsibility for ensuring that test data used for verification comply with the Phase 3 requirements defined in this Contract and in the SVP.
12. Article 25.4.h hereof shall apply, should no test body be selected at the time given in Appendix No. 3 hereto. Further, Article 25.4.i-j shall apply, should the Applicant not carry out the necessary tests or carry them out in an improper manner.

## **Article 9A - Multi-site testing and climatic representativeness**

1. Where test data are generated across multiple sites, the ETV Body shall assess their consistency and comparability in accordance with the SVP, including confirmation that such data are generated under Phase 3 verification testing conditions. Acceptance of such data shall not imply endorsement of the Applicant's testing strategy beyond its compliance with the SVP and applicable standards.
2. Where relevant to the intended application and declared operating envelope of the technology, the testing and verification activities shall take into account representative northern and southern European climatic conditions, as defined in the SVP and demonstrated during Phase 3 verification testing.



## **Article 9B - Partial verification**

1. Where only part of the performance claim can be verified on the basis of the available compliant evidence, the ETV Body may issue a Verification Statement that clearly distinguishes between the verified parameters and any non-verified parameters, together with the relevant conditions, constraints and limitations, and clearly indicating that verification is based exclusively on Phase 3 verification testing data.
2. Such partial verification shall not be interpreted as acceptance or endorsement of any non-verified claim.

## **Article 9C - Impartiality and iterative correction procedure**

1. The ETV Body shall conduct the verification process in an impartial, independent and objective manner in accordance with ISO 14034 and ISO/IEC 17020 requirements.
2. Without prejudice to its independence, the ETV Body shall provide the Applicant with clear, transparent and timely information regarding identified deficiencies in the Application, the Test Plan, the Test Report or the test data, including the reasons for such deficiencies and the applicable requirements.
3. The ETV Body shall allow the Applicant a reasonable opportunity to address such deficiencies and to resubmit revised documentation or data, provided that all actions remain compliant with the SVP and applicable quality standards, and without prejudice to the requirement that only Phase 3 verification testing data shall be used for verification.
4. Nothing in this Article shall be interpreted as requiring the ETV Body to advise the Applicant on how to achieve specific performance results or to influence, modify or accept the Applicant's performance claim or test results.

## **Article 9D - Failure / fallback mechanism**

1. Where deficiencies are identified in the Application for Verification, the Test Plan, the Test Report, or the test data, the ETV Body shall communicate such deficiencies to the Applicant in a clear and transparent manner, specifying the relevant requirement not met and the supporting reasons.
2. The Applicant shall be given a reasonable opportunity, within timelines compatible with the THERESA PCP Phase 3 implementation, to submit revised documentation, revised plans, or additional or corrected test data for reassessment.
3. The ETV Body shall reassess any revised documentation or data submitted by the Applicant. Termination of the verification process due to technical or procedural deficiencies shall be considered only as a last resort, after the Parties have documented that no reasonable corrective path remains



available, including confirmation that verification requirements under Phase 3 cannot be met.

4. Nothing in this Article shall be interpreted as requiring the ETV Body to influence, modify, or accept the Applicant's performance claim or test results.

### **Article 9E - Continuity between PCP Phase 2 and Phase 3**

1. The verification process under this Contract shall ensure continuity between PCP Phase 2 and Phase 3. Phase 2 prototype test data shall form the baseline supporting information for the Application for Verification and the proposed performance claim, unless duly justified otherwise, provided that such Phase 2 data are used exclusively as supporting information and shall not be used for verification of performance.
2. Phase 3 testing shall be designed to confirm, refine or expand the Phase 2 results under real operational conditions. Any substantial deviation between Phase 2 and Phase 3 results shall be identified, justified and documented, and shall be reflected in the assessment of the performance claim and in the Verification Report.
3. Where testing is performed at multiple sites, the Applicant shall ensure consistency of test methodology and comparability of data across sites. The ETV Body shall assess the site-specific data and, where relevant, their aggregated interpretation in accordance with the SVP.
4. All verification activities, including testing, review, assessment and reporting, shall be planned and carried out in alignment with the THERESA PCP Phase 3 timeline and deliverables, including the requirement to complete verification based on Phase 3 verification testing.

### **Article 10 - Test Data Quality Control Activities of the ETV Body**

1. In order to assess and validate the test data for acceptance to verify the performance parameters as specified in the SVP, provided that such test data have been generated during Phase 3 verification testing in accordance with the SVP, the ETV Body shall perform an assessment of their quality, taking into account the requirements of ISO/IEC 17025 for test data generation.
2. The ETV Body shall be responsible for the definition of the quality assessment scope, considering in particular if the test body performing the testing has been accredited for compliance to ISO/IEC 17025 and the test methods used to perform the testing were included in the scope of its accreditation,
3. The Applicant shall ensure that the contract closed with the test body includes provisions enabling the ETV Body to perform the quality control activities referring to the test data set out in Article 8.1, noting that only test data eligible for verification in accordance with Article 8 (i.e. Phase 3 verification testing data) shall be subject to acceptance. Lack of such ability and failure to perform





the quality control activities shall result in rejection of the test data on the terms of Article 8.2.b hereof.

4. In the contracts referred to in Article 9.3 hereof, the Applicant shall include provisions which will guarantee that the ETV Body is provided with:
  - a) all relevant items of information necessary to assess the quality of the test data including, but not limited to: valid certificate and scope of accreditation, management and operational procedures of the test body applied to perform the testing for the needs of verification, quality control and assurance plan and equivalent documents in the absence of accreditation, including documentation demonstrating traceability of the generated data to the conditions specified in the SVP;
  - b) access to the test body facilities, including access necessary to confirm compliance with Phase 3 verification testing conditions to perform an on-site assessments, witness the testing activities.
5. Should the test body refuse to undergo freely the quality control activities as far as required under section 1 herein, the ETV Body shall not accept the data delivered, including where such data do not meet the requirements for Phase 3 verification testing defined in this Contract and in the SVP, and:
  - a) the procedure under Article 9 hereof would have to be reiterated and in particular, new contracts would have to be concluded with new test bodies – to deliver the acceptable test data – or
  - b) the Contract would have to be terminated under Article 25.4.k-l hereof, should the Applicant not agree to reiterated of the procedure under Article 9 hereof.
6. When the tests are carried out as in-house tests by the Applicant, the Applicant shall not refuse the ETV Body the right to carry out the quality control activities; the ETV procedure shall be discontinued and the Contract shall be terminated under Article 25.4.m hereof otherwise, including verification that such testing complies with the requirements applicable to Phase 3 verification testing.
7. The quality control and validation activities of the ETV Body shall be limited to the assessment of compliance of the test data and shall apply exclusively to test data intended for verification under Phase 3, the testing arrangements with the SVP and applicable quality requirements. Such activities shall not constitute operational control over the testing process or responsibility for the generation of the data.

## **Article 11 - Assessment of Test Data and Verification of Performance**

1. The ETV Body may confirm the performance of the technology only when:
  - a) the test data is sufficient, relevant and adequate to confirm the verified performance, and has been generated in accordance with the SVP during Phase 3 verification testing under stable and representative operating conditions;





- b) the quality of the test data has been approved, in accordance with Article 10 and applicable quality requirements.
- 2. As a result of the final data assessment, the ETV Body shall confirm the performance of the technology, achieved under the same conditions, constraints and limitations as those specified for the generation of the test data used for verification, at the time set out under the Appendix No. 3 hereto , and based exclusively on test data generated during Phase 3 verification testing.
- 3. Verification under this Contract shall focus on the operational performance parameters defined in the SVP. Any conclusions regarding environmental added value shall be limited to the verified parameters, the verified operating conditions and shall not extend beyond the scope of the evidence assessed and shall be based exclusively on verified data obtained during Phase 3 verification testing.

## **Article 12 - Development and Publishing of the Verification Report and Verification Statement**

- 1. Upon confirmation of performance referred to in Article 11 hereof, the ETV Body shall develop a verification report and a Verification Statement as required by the ISO 14034 standard – at the time set out in Appendix No. 3 hereto. The Verification Report and Verification Statement shall be prepared in a manner consistent with ISO 14034 and the THERESA PCP Phase 3 reporting requirements and shall clearly identify the verified parameters, the conditions of verification, and any relevant limitations or constraints.
- 2. The ETV Body shall deliver the following to the Applicant as hard and soft copies:
  - a) a copy of the verification report,
  - b) a copy of the Verification Statement.
- 3. The documents referred to in section 2 herein shall be provided based on the acknowledgement of the verification report. Should the Applicant refuse to accept the acknowledgement protocol of the verification report, the ETV Body shall be authorised to develop and accept it on its own.
- 4. The Applicant shall review the documents referred to in section 2 herein, and provide comments, if relevant.
- 5. Upon review of the verification report and the Verification Statement, the Applicant may submit comments to the verification report and Verification Statement to the ETV Body with a request for their acceptance at the time set out under Appendix No. 3 hereto.
- 6. The ETV Body shall assess whether the comments are justified, reserving the right to consider them as deemed necessary. In no case shall the Applicant demand the ETV Body to remove unfavourable information about the verified technology or refuse to accept the documents given , including any



information related to discrepancies between Phase 2 supporting data and Phase 3 verification results.

7. For the verification report, the Applicant may:
  - a) refuse to publish the verification report in its entirety;
  - b) consent to publishing the report in its entirety but without appendices – when publication of appendices could put the Applicant at risk of damage due to breach of his intellectual property; or
  - c) consent to publishing the report in its entirety together with the appendices.
8. The Verification Statement shall be published in its entirety by the ETV Body in a publicly available directory (e.g. ETV Body website), in accordance with the transparency requirements of the THERESA PCP.
9. Notwithstanding section 7 herein, even without the Applicant's consent thereto, the verification report may be shared, in observance of full confidentiality as detailed under Article 26 hereof, with:
  - a) national accreditation bodies;
  - b) EU and national authorities, including the EU Court of Auditors and Anti-Fraud Office.
10. Upon numbering and registration, the Verification Statement shall be delivered to the Applicant.
11. The Verification Statement shall apply as long as the conditions wherefore it has been issued do not change, and in particular as long as the technology is not changed in the manner affecting its performance, and shall apply only to the operating conditions and performance demonstrated during Phase 3 verification testing as defined in the SVP.

### **Article 13 - Terms of Use of the Verification Report, Verification Statement and ETV Logo**

1. The Applicant undertakes to use the documents produced in the course of the ETV process solely as set out in the ISO 14034 standard and herein.
2. The ETV process-based verification shall not be considered as endorsement, approval, authorisation or warranty of verified technology operation of any kind.
3. The verification results shall reflect the performance of the verified technology under the conditions of the ETV procedure; they cannot be understood as guaranteeing the same level of verified technology performance under other conditions. Further, the determined performance parameters shall not be referred to those for any other technology or application, and shall be understood as reflecting only the performance demonstrated during Phase 3 verification testing under the specific conditions defined in the SVP.
4. The ETV Body reserves the right to include in the Verification Statement a clause on the legal compliance of the technology, e.g.: "Unless otherwise provided herein, this publication is neither an assessment of compliance nor



guarantees that the technology satisfies certain legal requirements. The Applicant shall be liable for legal compliance thereof.”

5. The Applicant undertakes not to use the received verification report or the Verification Statement for any technology other than the one actually verified under the ETV process.
6. The Verification Statement shall be used solely in its entirety. It is absolutely forbidden to use a part thereof only.
7. The Applicant may refer to the Verification Statement by stating the following, provided that such reference does not imply verification beyond the scope, conditions and limitations defined in the Verification Statement: *The \_\_\_\_\_ technology<sup>8</sup> was verified within the framework of the Environmental Technology Verification (ETV) for the application \_\_\_\_\_<sup>9</sup> by the ETV Body — The Institute for Ecology of Industrial Areas — on \_\_\_\_\_. The Verification Statement has been registered under number \_\_\_\_ and is accessible at the following address: \_\_\_\_\_*
8. The Applicant may use the Verification Statement:
  - a) in contacts with other organisations;
  - b) for marketing purposes; and
  - c) as a part of the technical documents gathered for the official technology approval purposes.

The use of the Verification Statement for marketing or communication purposes shall not imply general certification, approval or endorsement of the technology, nor shall it extend the verified performance beyond the parameters and conditions confirmed during Phase 3 verification testing.

9. The ETV logo may be used in the materials rendered into the public domain by the Applicant together with the reference to the Verification Statement, as long as any confusion with endorsement or approval of the technology is avoided on the part of its reader. It is forbidden to use the ETV logo in breach of those terms and conditions.
10. The ETV logo shall not be used for labelling the Applicant’s products.
11. Should the verification report, the Verification Statement or the ETV logo be misused, the ETV Body may withdraw the Verification Statement under Article 15.3.a hereof, including cases where the verified performance is presented in a manner inconsistent with the conditions of Phase 3 verification testing.

## Article 14 - Validity of the Statement of Verification

1. The Applicant shall notify the ETV Body of any change pertaining to the verified technology which occurred from the time of the ETV process institution to the

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<sup>8</sup>Please insert the technology name.

<sup>9</sup>Please insert the application purpose and matrix.



time of the Verification Statement development, including any changes affecting the conditions under which Phase 3 verification testing is performed or planned. Should the ETV Body receive such a notification, it may:

- a) refuse to continue with the ETV process – until the impact of the change on the technology verification conditions has been established;
  - b) continue with the ETV process – should it establish that the change does not impact the technology verification conditions; or
  - c) order ETV process re-performance – should it establish that the change substantially impacts the verification conditions; Article 25.4.o hereof shall apply accordingly.
2. The Applicant shall ensure that upon completion of the ETV process, the technology used complies with the Verification Statement, including the conditions, constraints and operational parameters under which the verification was performed during Phase 3 verification testing.
  3. Upon receiving the Verification Statement, the Applicant is required to notify the ETV Body in writing of the following technology changes:
    - a) a change to the entities authorised to use the technology;
    - b) a technology name change;
    - c) a company name change.
    - d) design changes;
    - e) a change of intended application;
    - f) a change to operational conditions; and
    - g) other changes likely to impact the parameters in the Verification Statement, , including any modification that may affect the performance demonstrated during Phase 3 verification testing or the conditions defined in the SVP.
  4. For the case set out in section 3 herein, the Applicant shall notify the ETV Body of the technology change and shall deliver thereto the data and documents required by the ETV Body.
  5. Based on the information provided by the Applicant, the ETV Body shall determine the impact of these changes on the verified performance of the technology to the verification conditions, and therefore the validity of the verification statement and the verification report, with specific reference to the conditions and results established during Phase 3 verification testing. If it is determined that the Verification Statement and verification report are no longer valid, it shall be communicated to the Applicant and made publicly available.

## **Article 15 - Withdrawal of the Verification Statement**

1. The Verification Statement may be withdrawn at any time:
  - a) upon the Applicant's request — as set out in section 2 herein; and
  - b) upon the ETV Body's initiative — as set out in section 3 herein;



2. Upon receiving the Verification Statement, the Applicant may request the ETV Body in writing to withdraw the same enclosing with his request the declaration that he will discontinue to use the Verification Statement, make references thereto or use the ETV logo.
3. The Verification Statement may be withdrawn upon the ETV Body's initiative when the Applicant:
  - a) misuses the verification report or the Verification Statement, in particular by using the parts of those documents, using the documents for the technology other than the verified one, or modifying the information given in those documents in an unacceptable manner;
  - b) misuses the ETV logo, in particular by misleading the readers as to the technology endorsement or official approval or his product labelling;
  - c) did not notify the ETV Body of the changes impacting the technology verification conditions;
  - d) has made an untrue representation as to the legal title to the verified technology, included herein or in the application processing contract, or has breached the rights of third parties in any manner; or
  - e) puts at risk the reputation of the ETV Body.
  - f) the verified performance can no longer be considered valid due to deviations from the conditions, constraints or operational parameters defined in the SVP and confirmed during Phase 3 verification testing.
4. The Verification Statement shall be withdrawn by the ETV Body by removing it (and possibly the verification report) from the ETV Body website and by publication of the ETV Body's statement , including clear indication of the reasons for withdrawal.

## Article 16 - Other Post-verification Activities

1. Upon completing the ETV process, the Applicant undertakes to ensure and maintain contact with the ETV Body to keep the latter informed about the manner of use of the Verification Statement and his benefits therefrom – for 1 (*in words: one*) year after the receipt of the Verification Statement.
2. As part of post-verification activities, the Applicant undertakes to complete and return the survey questionnaires developed by the ETV Body to check the satisfaction of the Applicants as well as to participate in other ETV process-related feedback collection procedures.<sup>10</sup>
3. The Applicant may also take part in the promotion held by other entities participating in the Environmental Technology Verification (ETV) .

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<sup>10</sup>Other specific forms of collection of the information about the ETV procedure benefits can be described here.



## Article 17 - Complaints

1. The Applicant may file complaints of 2 types:
  - a) complaints about the verification of the technology covered hereby;
  - b) complaints about the authority or qualifications of the ETV Body.
2. All complaints shall be made in writing and they shall include:
  - a) full name of the complaining party;
  - b) address of residence or registered office of the complaining party, or possibly the mailing address;
  - c) a brief description of the factual or legal condition being the complaint basis;
  - d) concise claims as to the scope referred to in section 1 herein;
  - e) reasons;
  - f) date and venue of the complaint; and
  - g) a signature.
3. The complaint referred to in section 1.a herein shall be addressed to the ETV Body. The consideration of complaints is carried out in accordance with the procedure in force in the ETV Body.
4. The complaint referred to in section 1.b herein shall be addressed to the Polish Centre for Accreditation as the National Accreditation Body relevant for the surveillance of the ETV Body.

## Article 18 - Ownership of Products (Documents)

1. The Applicant shall retain the legal title to the verified technology and the documents delivered by him in accordance with the representation made in Article 3.6 hereof and the ETV Body shall not claim any rights thereto, without prejudice to the rights of the ETV Body to use such documents for the purposes of verification, assessment and reporting under this Contract.
2. For the case set out in Article 9.3 hereof – when a contract has to be concluded with the test body – the Applicant undertakes to obtain the legal title to the documents produced by including the relevant provisions in the contracts concluded. At the same time, the ETV Body shall be authorised to use them as needed to carry out the ETV process, including for the purposes of verification, quality control, assessment and reporting in accordance with this Contract.
3. Where, for the purposes of ETV proceedings, the Applicant submits to the ETV Body documents that constitute works within the meaning of Article 1(1) of the Act of 4 February 1994 on Copyright and Related Rights (Journal of Laws of 2006, No. 90, item 631, as amended – hereinafter referred to as the “Copyright Act”) and, on the basis thereof, the ETV Body creates a derivative work as referred to in Article 2(1) of the Copyright Act – the Applicant shall then grant the ETV Body permission to manage and use the derivative works pursuant to Article 2(2) of the Copyright Act.



4. The proprietary copyrights to the documents produced by the ETV Body in the course of the ETV process and having the features of the works as defined in Article 1.1 of the Copyright Law shall rest with the ETV Body.
5. Transfer to the Applicant of the ownership of a copy under section 6 herein shall not constitute a transfer of proprietary copyrights.
6. Hereunder the Applicant shall become the owner of a copy of:
  - a) the Verification Report – transferred under Article 12.2.a hereof; and
  - b) the Verification Statement – transferred under Article 12.2.b hereof.
7. For the proprietary copyrights, subject to the conditions and limitations of use defined in Article 13, the ETV Body shall extend to the Applicant a free non-exclusive licence to use the documents referred to in section 6 herein in the following fields of exploitation:
  - a) fixing and reproduction of works using the printing, reprographics, magnetic fixing and digital technology;
  - b) entry into the computer memory;
  - c) dissemination on the internet;
  - d) dissemination in printed materials, including leaflets and promotional materials;
  - e) introduction to trade; and
  - f) letting for use or rental of copies.
8. The licence referred to in section 7 herein shall be an open worldwide licence.
9. The Applicant shall not change the works without the consent of the ETV Body, including any modification that could affect the integrity, meaning or interpretation of the verified results.
10. Since the SVP in its entirety shall be ownership of the ETV Body, neither the ownership of a copy of the SVP nor the related copyrights shall be transferred to the Applicant, except to the extent necessary for the Applicant to comply with its obligations under this Contract and to perform testing in accordance with the SVP. Further, the ETV Body shall not extend to the Applicant the licence to use the SVP.

## **Article 19 - Rights and Duties of the ETV Body**

1. Hereunder the ETV Body shall perform this Contract in a proper and timely manner and in good faith; that is, it shall:
  - a. carry out the ETV process compliant to the requirements of ISO 14034 and in alignment with the THERESA PCP Phase 3 requirements where applicable;
  - b. perform its tasks with due professionalism, competence and impartiality;
  - c. provide the Applicant with the ETV procedure-related explanations;
  - d. provide ETV-related technical advice, provided it does not breach its impartiality or independence;
  - e. identify the partiality or dependence risks on an ongoing basis;





- f. perform formal and technical review of the Application;
  - g. co-operate with the Applicant when reviewing the Application hereunder;
  - h. develop an acknowledgement protocol under ~~Article 6.21~~ Article 5.21 hereof;
  - i. co-operate with the Applicant when verifying the technology hereunder;
  - j. assess and validate in a reliable manner ~~all the test data gathered~~ all test data used for verification in accordance with this Contract;
  - k. develop a SVP, a verification report and a Verification Statement – for the duly performed Contract;
  - l. transfer the ownership of the copies of documents referred to in Article 18.6 hereof onto the Applicant;
  - m. develop the acknowledgement protocols under Article 7.7 and Article 12.3 hereof;
  - n. duly secure the documents gathered for the purposes hereof and provide third parties therewith only on the terms and conditions hereof and under the applicable procedures;
  - o. review complaints under Article 17 hereof.
2. Hereunder the ETV Body shall have the right to:
- a. obtain exhaustive information and data from the Applicant as deemed necessary for the formal review of the Application;
  - b. share the documents gathered under Article 7.7 hereof , in accordance with confidentiality and data use provisions of this Contract;;
  - c. terminate the Contract under Article 25.4 hereof
  - d. assess the proposed technology in a voluntary manner, outside of any pressure, including economic pressure, following the professional reliability and integrity rules, including in the context of mandatory verification under the THERESA PCP, without prejudice to the independence of the assessment;;
  - e. assess and validate the existing data under Article 8 hereof , solely for the purpose of supporting the performance claim and development of the SVP, and not for verification;
  - f. perform the control activities under Article 10 hereof;
  - g. approve or refuse to approve the documents received from the Applicant or the test bodies , including test data not compliant with Phase 3 verification requirements;
  - h. refuse to suspend the ETV process under Article 6.4 hereof;
  - i. obtain feedback from the Applicant upon Contract completion under Article 16 hereof;
  - j. withdraw the Verification Statement under Article 15 hereof , including where the conditions of Phase 3 verification testing are no longer met;
  - k. terminate the Contract under Article 25.4 hereof.

## Article 20 - Rights and Duties of the Applicant





1. Hereunder the Applicant shall perform this Contract in a proper and timely manner and in good faith; in particular it shall:
  - a. follow the procedures and instructions of the ETV Body including those defined in the SVP and related to Phase 3 verification testing;
  - b. complete on its own the part of the Application set out in Article 5.2.a hereof;
  - c. submit the Application and the requested documents to the ETV Body under Article 6 hereof;
  - d. co-operate with the ETV Body during the review of the Application and during the verification of the technology hereunder;
  - e. notify the ETV Body of any circumstances which may cause occurrence of a conflict of interest with the latter or tarnish its impartiality or independence;
  - f. comply with the dates/timelines given herein;
  - g. deliver an adequate number of equipment units, amount material or access to the technology necessary to perform verification, including ensuring availability, installation, commissioning and operation of the pilot system under Phase 3 conditions;
  - h. conclude contracts with test bodies in the circumstances set out in Article 9.3 hereof;
  - i. enable the ETV Body to perform the control activities referred to in Article 10 hereof, including access to all data, systems and locations necessary to verify compliance with Phase 3 verification testing requirements;
  - j. report any and all changes pertaining to the verified technology– under Article 14 hereof;
  - k. participate in the post-verification activities – under Article 16 hereof;
  - l. ensure that the pilot system reaches and maintains stable operation prior to and during Phase 3 verification testing, and that all test data used for verification are generated in accordance with the SVP.
2. In particular, hereunder the Applicant shall not:
  - a. exert any pressure on or place the ETV Body or the persons used by it under any coercion;
  - b. refuse to sign the acknowledgement protocol when he cannot demonstrate its defects preventing acceptance of the work performed;
  - c. breach the terms of use of the verification report, the Verification Statement or ETV logo under Article 13 hereof , including misrepresentation of the verified performance beyond the conditions of Phase 3 verification testing; or
  - d. refuse to participate in the post-verification activities set out in Article 16 hereof.
3. Hereunder the Applicant shall have the right to:
  - a. receive from the ETV Body any and all information about the ETV process;
  - b. request explanations from the ETV Body, should the Application be rejected as set out in Article 5.17.b hereof;



- c. request explanations from the ETV Body under the circumstances given in Article 12.7 hereof;
- d. deliver the data confirming operation of the verified technology, provided that such data shall not be used for verification unless generated in accordance with Phase 3 verification testing requirements;
- e. select the test body under the circumstances given in Article 9.2 hereof;
- f. obtain assistance from the ETV Body as to the selection of the test body under the circumstances given in Article 9.2 hereof;
- g. review and provide comments to the documents developed , without prejudice to the independence of the ETV Body in defining the final content of such documents;
- h. receive the documents under Article 18.6 hereof;
- i. resolve to publish the verification report under Article 12 hereof , subject to the conditions and limitations defined in this Contract;
- j. submit a request for withdrawal of the Verification Statement under Article 15.1.a hereof;
- k. file a complaint under Article 17; and
- l. terminate the Contract under Article 25.6 hereof.

## **Article 21 - Remuneration**

1. The ETV Body shall not be entitled to remuneration or reimbursement from the Applicant for the performance of the subject matter of this Contract, subject to sections 3 to 4 of this paragraph.
2. The ETV Body shall finance the costs of the remuneration for the implementation of this Contract from the funds allocated under the Horizon-HLTH-2024-CARE-14-01 project THERESA PCP. The total estimated cost for the remuneration for the performance of this contract is ..... EUR, as set out in Appendix No. 2 to this Contract.
3. Should the Contract be terminated under Article 25.6 hereof, the Applicant shall pay the ETV Body the remuneration for the work performed, provided that, as a result of the termination of the Contract, the cost of such work is not subject to funding from the funds granted to the ETV Body under the THERESA PCP project.
4. The remuneration referred to in section 3 is payable to the ETV Body within .... calendar days from the date of delivery of the invoice to the Applicant.
5. The cost of additional test data generation within the meaning of Article 9 bears the Applicant.

## **Article 22 - Liability**



1. The Applicant shall be fully liable for the veracity, reliability and completeness of the data, information and documents delivered to the ETV Body , including all data generated during Phase 3 verification testing.
2. The ETV Body shall not be liable for the errors resulting from the presentation of incomplete, untrue or falsified information or data, including any supporting data originating from Phase 2 or pre-testing activities.
3. The ETV Body shall not be liable for any damage resulting indirectly or directly from the improper test performance by the test body or analytical laboratory, including deficiencies in testing carried out during Phase 3 verification testing.
4. The Applicant shall be fully liable for the performance of rights in the intangible assets pertaining to the verified technology, in particular the copyrights, the neighbouring rights, invention rights or rights to trademarks or decorative patterns and due to company secret or others.
5. The ETV Body shall not be liable for the breach of the rights given in section 4 herein.
6. The ETV Body shall not be liable in the situation where the verified technology does not satisfy the requirements set by other states and it is not admitted for use abroad – under Article 13.2-3 hereof, including where such non-compliance results from limitations of verification performed under defined Phase 3 conditions.
7. For the case set out in Article 6.3 hereof, the ETV Body shall not be liable for deadline postponement or the resulting damage.
8. The ETV Body shall not be liable for any damage resulting from the Applicant acceding to the ETV procedures , including the consequences of verification being limited to Phase 3 verification testing conditions; it shall not be liable in particular for:
  - a) the withdrawal of the proposed technology from the market;
  - b) a delay in the market placement of the proposed technology;
  - c) the financial damage sustained by the Applicant;
  - d) the delays caused by improper performance of his duties by the Applicant;
  - e) the consequences of the technology verification;
  - f) the consequences of the verification results which have not been expected by the Applicant, including differences between Phase 2 supporting data and Phase 3 verification results;
  - g) the Applicant's obligations towards third parties pertaining to the verification of the technology.
9. The ETV Body shall not be liable for the failure to perform or improper performance hereof, should it lose the necessary authority, the accreditation referred to in Article 2.2 hereof included, during the term hereof. Be it the case, Article 25.3 hereof shall apply, provided that such loss is not attributable to fault or negligence of the ETV Body.
10. Should any third party address the ETV Body with any claims directly or indirectly pertaining hereto and occurred for the reasons the Applicant is liable



for, including those pertaining to untrue representations of the Applicant given in Article 3 hereof, and in particular as to the breach of the rights given in Article 4 hereof, the Applicant shall indemnify and hold harmless the ETV Body from any liability towards the third party or pay the claim costs borne by the ETV Body otherwise., including claims arising from the use or misuse of verification results beyond the conditions defined for Phase 3 verification testing.

## **Article 23 - Third Parties**

1. The ETV Body may perform its obligations hereunder with the use of third parties, other than the employees of the ETV Body, as external staff of the ETV Body in particular, whereto the Applicant consents hereby. The ETV Body undertakes to entrust the activities only to such parties that statutorily warrant due performance of duties and can comply with the standards of the ETV process.
2. The ETV Body shall conclude contracts with the parties referred to in section 1 herein, whereby the latter shall be required to comply with the effective laws and all the existing procedures, and the ETV process-related ones first and foremost, and to perform the activities commissioned with the top quality and in observance of the due diligence principles, impartiality and professional integrity and confidentiality rules.
3. The ETV Body shall be liable for the activities of the parties referred to in section 1 herein as for its own, except for activities related to test data generation performed by independent test bodies contracted by the Applicant in accordance with Article 9.

## **Article 24 - Force Majeure**

1. Save for Article 22 hereof, the Parties shall be liable for ensuring due diligence; in particular, they shall be exempted from the liability for failure to perform or improper performance hereof, provided the performance hereof was impacted by force majeure.
2. The Parties understand the term of force majeure as a sudden and external event that could not have been foreseen and that is beyond the control of the Parties but which permanently or temporarily precludes performance hereof or of a part hereof; an event that could not have been counteracted or prevented upon exercising due diligence and in particular:
  - a) calamities, fires, floods, draughts, earthquakes, hurricanes etc., for example;
  - b) power failure;
  - c) strikes of national coverage;
  - d) acts of state authorities, martial law or state of emergency, for example;
  - e) acts of war, acts of sabotage or terror; and



- f) blockages and embargos regardless of the legal condition.
- 3. In the event of force majeure, the affected Party shall forthwith but not later than within ..... calendar days after the force majeure date, notify the other Party in writing of its occurrence and projected impact thereof on the performance hereof and, if possible, shall present the unquestionable documents confirming its occurrence.

## **Article 25 - Duration and Termination**

1. Save for sections 3-6 herein, the Parties shall conclude this Contract for the period defined by the performance of the activities referred to in Appendix No. 3 hereof. However the expiry date of the Contract shall be the date of termination of the THERESA PCP project, including completion of Phase 3 verification testing and reporting activities.
2. The date set under Article 16.2 hereof shall be the expiry date hereof due to performance of the obligation.
3. The Contract shall be terminated automatically as of the date of loss of the authority required to perform the ETV procedures by the ETV Body.
4. The ETV Body may terminate the Contract without notice when:
  - a) the ETV Body suspects that the verified technology breaches third-party property rights, including intellectual property rights;
  - b) the Applicant takes action which may impact the independence or impartiality of the ETV Body or the persons used by it, in particular by exerting pressure or placing them under coercion;
  - c) the ETV Body is not notified of the circumstances which may cause occurrence of a conflict of interest or harm the impartiality or independence of the ETV Body;
  - d) there is no cooperation hereunder;
  - e) the arrangements made in Article 7.5 hereof are not performed;
  - f) the SVP has not been accepted by the Applicant under Article 7.8 hereof;
  - g) the Applicant failed to select the test body/ analytical laboratory, in accordance with the requirements of Article 9 and the SVP at the time set out in Appendix No. 3 hereto;
  - h) the Applicant failed to deliver the test plan, test report or other documents as may be indispensable for technology verification;
  - i) the Applicant delivered a flawed test plan, test report or other documents as may be indispensable for technology verification and has not rectified the same at the predefined time;
  - j) the test body/ analytical laboratory has not consented to the control activities performed by the ETV Body under Article 10 hereof;
  - k) the Applicant has not consented to reperforming the procedure under Article 9 hereof should the test body object to the control activities of the ETV Body;



- l) the Applicant has objected to the ETV Body controlling him when carrying out the tests as in-house ones;
  - m) the ETV Body has not received the information about the changes pertaining to the verified technology before the ETV process completion;
  - n) the ETV Body has received before the verification report development the information about technology changes which substantially impact its operation and require ETV process re-performance;
  - o) the ETV Body has been addressed with claims by third parties due to performance hereof, where such claims materially affect the feasibility or legality of continuing the verification process;
  - p) the verification report, Verification Statement or ETV logo has been used contradictory hereto;
  - q) the ETV Body has not consented to suspension of the process under Article 6.4 hereof and the procedure suspension request has not been withdrawn by the Applicant within .... calendar days and continuation of the process is not feasible within the THERESA PCP Phase 3 timeline,
  - r) the Applicant fails to ensure stable operation of the pilot system or fails to generate test data compliant with Phase 3 verification testing requirements as defined in the SVP.
5. As a result of termination of the Contract, the ETV Body is entitled to remuneration covering the documented costs borne by the ETV Body up to the date of termination, according to the rules stated in Article 21, proportionate to the work performed and consistent with the THERESA PCP funding conditions;
  6. The Applicant may terminate the Contract at any time, subject to the constraints and obligations arising from participation in the THERESA PCP project., provided he pays to the ETV Body the remuneration equal to the documented costs borne by the ETV Body and not covered by the amounts subject to funding from the funds granted to the ETV Body under the THERESA PCP project, with effect from the date of actual payment.

## **Article 26 - Confidentiality of the Verified Technology**

1. The ETV Body shall keep the verified technology confidential on the terms and conditions set out in the PN-EN ISO/IEC 17020 standard.
2. The ETV Body shall manage all the items of information received or produced during the ETV process with due diligence required by the law, standards and professional reliability rules.
3. The ETV Body shall require that all its employees and third parties entrusted with the verification activities abide by the confidentiality principles by making them sign the confidentiality declaration and ordering them to keep confidential all the items of information and data – during the performance of the activities and thereafter.



4. Save for sections 5 and 6 herein, all the items of information and data pertaining to the verified technology wherefore the Applicant did not consent to their provision into the public domain shall be treated as confidential until the said consent has been obtained.
5. Should the ETV Body be required to share information or data pertaining to the verified technology under the existing laws, or to perform the duty imposed thereon by the competent authorities, it shall notify the Applicant thereof in advance, unless contradictory to the law.
6. In keeping with Article 12.8 hereof, the ETV Body may share the documents produced to perform the ETV process with the eligible entities.

## Article 27 - Contact Details

1. The Parties shall contact one another in the following manner:

- 1) by phone:

- a. ETV Body: +48 32 254 60 31 ext. 264;
- b. Applicant: \_\_\_\_\_;

- 2) by electronic mail:

- a. ETV Body: etv@ietu.katowice.pl;
- b. Applicant: \_\_\_\_\_;

- 3) by fax:

- a. ETV Body: +48 32 254 17 17;
- b. Applicant: \_\_\_\_\_;

- 4) by regular mail:

- a. ETV Body:

**Instytut Ekologii Terenów Uprzemysłowionych (The Institute for Ecology  
of Industrial Areas)**

**ul. Kossutha 6**

**PL 40-844 Katowice, Polska (Poland)**

- b. Applicant:

.....  
.....  
.....  
.....

## Article 28 - Appendices

1. Appendices shall be a part and parcel hereof.
2. The following Appendices have been enclosed herewith:
  - Appendix No. 1: Proof of the legal title to the proposed technology
  - Appendix No. 2: Contract Cost Overview
  - Appendix No. 3: General Contract Schedule
  - Appendix No. 4: The template of the Application
  - Appendix No. 5: Table of Contents of the Test Plan and Test Report.



## Article 29 - Final Provisions

1. The headings of editorial units (sections) are of information nature only and have been applied for convenience of the Parties; neither they nor their sequence shall impact the interpretation hereof.
2. Should any of the provisions hereof be considered invalid, ineffective or unenforceable, in its entirety or in part, it shall not affect the validity, effectiveness or enforceability of the remainder hereof. Be it the case, the Parties shall substitute the invalid, ineffective or unenforceable, in its entirety or in part, provision with the provision of the universal laws.
3. This Contract shall be amended and supplemented in writing, otherwise null and void.
4. The Contract shall be governed by Polish law. *The Civil Code Act of 23 April 1964* (that is: Journal of Laws of 2014, item 121, as amended) and other applicable laws shall apply to all the matters not governed hereby.
5. In the event of any disputes between the Parties as to conclusion, interpretation, performance and legal consequences hereof, the Parties shall commence negotiations in good faith to resolve the dispute in an amicable manner. Should the Parties fail to resolve the dispute in an amicable manner within .... calendar days after the date of dispute occurrence the Parties shall refer it for resolution by the common court competent for the registered office of the ETV Body.
6. The Contract has been drawn up in two identical counterparts, one for either Party.

.....  
**ETV BODY**

.....  
**APPLICANT**





## Appendix No 2 Contract Costs Overview

**Application review - .....**

**Verification of an environmental technology - .....**

## Appendix No. 3 - General Contract Schedule

No.	Stage	Deadline
1.	conclusion on the eligibility of the proposed technology to verify its performance through ETV	Within the time limits set out under Article 5 of the Contract
2.	SVP development	Within ..... calendar days after the delivery of documents under Article 6.1 of the Contract.
3.	Review of the SVP by the Applicant	Within ..... calendar days after the SVP delivery to the Applicant.
4.	SVP acceptance under Article 7.8 of the Contract.	Within ..... calendar days after the last day of the deadline under item 2 herein – subject to Article 7.8.b of the Contract.
5.	Test performance – selection of the test body	Within ..... calendar days after the SVP acceptance by the Applicant.
6.	Test performance – testing	At the time agreed upon by the test body with the Applicant.
7.	Assessment and validation of test data data/confirmation of performance	Within ..... calendar days after the requisite data delivery to the ETV Body.
8.	Development of the verification report and Verification Statement	Within ..... calendar days after the assessment and verification of the gathered data.
9.	Review of the verification report and draft Verification Statement by the Applicant	Within ..... calendar days after delivery of the verification report and draft Verification Statement to the Applicant.
10.	Verification Statement registration and publication on the ETV Body website.	Within ..... calendar days after the date of review by the Applicant of the draft of the verification report and Verification Statement.
11.	Delivery of the Verification Statement with the number to the Applicant	Within ..... calendar days after the date of publication of draft Verification Statement on the website.



# Annex 10. ETV Application



## Application

### Environmental Technology Verification (ETV)

**Purpose:** This form intends to collect further information on the technology you would like to propose for verification after the first eligibility check. At this stage, all relevant information is exchanged between the applicant and the Verification Body in order to conclude a verification contract and allow for the preparation of the specific verification protocol. This Application is to be completed by the applicant and assessed by the Verification Body. The boxes for responses, in grey, may be extended. Additional information and documents may be attached, with references in the core text for clarity.

### Part A

Verification Body		Applicant	
Name:	<b>Environmental Technologies Verification Body, Institute for Ecology of Industrial Areas</b>	Name:	.....
Contact:	<b>Izabela Ratman-Kłosińska</b>	Contact:	.....
Address:	<b>ul. Kossutha 6 40-844 Katowice Poland</b>	Address:	.....
Telephone:	<b>+ 48 32 254 60 31 ext. 243</b>	Telephone:	.....
Telefax:	<b>+48 32 254 17 17</b>	Telefax:	.....
Email:	<b>etv@ietu.pl</b>	Email:	.....
Date Quick Scan:	.....		
Quick Scan Reference Number:	.....		

Application Reference Number: .....

Previous verification:



Previous verification performed: ☐ No ☐ Yes, date: .....

**Remarks out of Quick Scan to be considered (for Verification Body):**

## Part B

### Technology Description– technical documentation

The technical documentation shall make it possible to understand the technology, to define the performance claim and to assess the conformity of the technology design with the performance claim. It shall contain at least the following elements:

- Unique identifier of the technology, e.g. commercial name,
- a general description of the technology,
- conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc.
- descriptions and explanations necessary for the understanding of those drawings and schemes and operation of the technology,
- where relevant, standards or technical specifications applied in full or in part,
- results of design calculations made, examinations carried out, etc.

Technology

Description:

### Intended application of the technology

The application of the technology should be defined by describing the matrix and the purpose(s) of the technology. The matrix refers to the type of material for which the technology is intended e.g., soil, drinking water, ground water, cooling water, alkaline degreasing bath, effluent from domestic wastewater treatment plant etc.

The purpose(s) is a measurable property that is affected by the technology e.g, reduction of nitrate concentration, separation of volatile organic compounds, reduction of energy use (MW/kg), bacterial removal, monitoring of NO<sub>x</sub>, improvement of heating value etc. It is important that the purpose describes the claimed effect in quantitative terms, e.g. reduction of nitrate concentration in mg NO<sub>3</sub>/L.

Matrix: .....

Purpose: .....

Technical conditions: .....

### Initial performance claim

The specifications included in the initial performance claim shall relate to the technology itself and shall be quantitatively verifiable through tests. The initial performance claim shall state the conditions under which the specifications are applicable and mention any relevant assumption(s) made. For further information on how to define a clear initial performance claim, please refer to the Guide for Proposers.

Initial performance claim:

.....  
.....  
.....

### Description of tests performed and existing test data

The tests performed on performance parameters shall be described with all necessary details, including the qualification of testing bodies, test methods used (with references to standards where appropriate), test plans and test reports. Consult the Verification Body if there are confidentiality issues related to the information on tests.

Are there available test results or other data to back-up the technology's performance?

☐ Yes

Description of test plan:

.....  
.....



Description of test methods, including reference if standard methods were used:  
.....  
.....

Description of existing test data:  
.....  
.....

Qualification of the test body for the relevant tests:

☐ ISO 17025      ☐ ISO 9001      ☐ none      ☐ other: .....

Qualification of analytical laboratory:

☐ ISO 17025      ☐ none      ☐ other: .....

☐ No

Is there a test plan available?    ☐ Yes      ☐ No      ☐ Unknown

Is there a test method available?    ☐ Yes      ☐ No      ☐ Unknown

Full ..... description:  
.....

## Part C

### Environmental added-value

Please provide as much information as possible on the positive and negative environmental aspects resulting from your technology. Firstly, please identify the technologies that constitute relevant alternative(s) to your technology since this may help to identify the environmental added-value of your technology. Then indicate the phases which are most relevant to your technology, in terms of environmental aspects. You may indicate that a particular phase is not relevant to assess the environmental aspects of your technology when:

- the technology will lead to environmental pressures/impacts that are not significantly different than those of the relevant alternative(s)
- those environmental pressures/impacts are negligible compared to those of the other phases
- the information cannot be obtained – please provide a short justification in this case. It is expected that for the manufacturing and use stages the applicant will normally possess relevant information, as designer and manufacturer of the technology.

For each of the identified phases, and especially for the manufacturing and use phases please indicate as much qualitative information as possible regarding each environmental parameter. When available, support the elements provided with quantitative information. You may present information based on a comparison with the relevant alternative, or you may present absolute values, if you are unable to compare the performance of your technology with the one of a relevant alternative(s).

Relevant alternatives (if available):  
.....  
.....

For the phases identified in the Quick Scan as different from the relevant alternative(s), please provide information as detailed as possible on the following environmental parameters:

Indicate relevant phase:  
.....  
.....

Emission of pollutants to air: .....

Identify or quantify air pollutants including those listed under the green-house gas emissions



Emission of pollutants to water:

.....  
*Identify or quantify water pollutants*

Emission of pollutants to soil: .....

*Identify or quantify soil pollutants*

Consumption of natural resources:

.....  
*Identify consumption of natural resources, especially rare raw material required for the process Energy and water consumption will be addressed in the two following points.*

Energy consumption: .....

*Identify energy consumption and energy sources (indicate use of non-renewable or renewable energy)*

Water consumption and related processes:

.....  
*Identify the consumption or the use of water but also the quality of the water used and the necessary treatment before and after use, the consumption or the use of water. This section includes process water, but also water used in bulk such as cooling water.*

Production of non-hazardous waste:

.....  
*Identify or quantify non- hazardous waste*

Production of hazardous waste:

.....  
*Identify or quantify hazardous waste*

**If relevant, additional information on the overall productivity of the technology should also be provided, namely:**

Production efficiency – productivity:

.....  
*Indicate any significant differences in productivity of the technology vs. the relevant alternative (e.g. for recycling: ratio of substance recycled vs. quantity of substance contained in the waste).*

Production efficiency – final quality:

.....  
*Indicate the differences in the quality of the final product vs. the relevant alternative (e.g. for recycling: the level of purity of the recovered substance).*

Conformity with applicable standards:

.....  
*Indicate the standards or equivalent technical references applicable to the technology and any certificate or test results showing conformity with these standards.*

Other information (extra information that might be useful for the assessment relating to e.g., economic, social and safety aspects):

.....  
*Provide additional information that could justify or complement the information provided for environmental criteria. For example, a technology might be proposed that has little or no environmental benefits in comparison to the existing commercially available alternatives but provides greater social, economic or safety benefits*

**Applicant:** .....

Name: .....

Date: .....



Signature: .....



## Part D

### Assessment of Application (for the Verification Body)

#### Assessment of the technology

- Performances parameters correctly described ☐ Yes ☐ No
- Innovative technology: ☐ Yes ☐ No
- Ready-to-market: ☐ Yes ☐ No
- Prototype in advanced stage of development: ☐ Yes ☐ No

#### Assessment of environmental aspects

Conclusions:

.....  
.....

#### Preliminary assessment of existing test data

- Tests performed on technology: ☐ Yes ☐ No  
Comments: .....
- Test body suitably qualified: ☐ Yes ☐ No  
Comments: .....
- Test plan available: ☐ Yes ☐ No  
Comments: .....
- Test plan suitable: ☐ Yes ☐ No  
Comments: .....
- Test method available (standards): ☐ Yes ☐ No  
Comments: .....
- Test methods described: ☐ Yes ☐ No  
Comments: .....
- Test methods suitable: ☐ Yes ☐ No  
Comments: .....
- Test methods reproducible: ☐ Yes ☐ No  
Comments: .....
- Test methods accurate: ☐ Yes ☐ No  
Comments: .....
- Test results available: ☐ Yes ☐ No  
Comments: .....
- Test results relevant to the performance claim: ☐ Yes ☐ No  
Comments: .....
- Test results can be used in the verification process: ☐ Yes ☐ No



Comments: .....

### Conclusions on the Application:

.....  
.....

**Applicant:** .....

Name: .....

Date: .....

Signature:

**Verification Body:** .....

Name: .....

Date: .....

Signature:





# Annex 11. Quick Scan document



## Quick Scan

### Environmental Technology Verification (ETV)

**Purpose:** This form aims to collect sufficient information about the proposed technology in order to evaluate eligibility under the ETV and to provide early indication of the potential costs involved. The Applicant completes the Quick scan for assessment by the Verification Body. The boxes for responses, in grey, may be extended but responses should remain brief and no more than one half-page each.

### Part A

Verification Body		Applicant	
Name:	<b>Environmental Technologies Verification Body, Institute for Ecology of Industrial Areas</b>	Name:	
Contact person:	<b>Izabela Ratman-Kłosińska</b>	Contact person:	
Address:	<b>ul. Kossutha 6 40-844 Katowice Poland</b>	Address:	
Telephone:	<b>+ 48 32 254 60 31 ext. 243</b>	Number of employees:	
Telefax:	<b>+48 32 254 17 17</b>	Telephone:	
E-mail:	<b>etv@ietu.pl</b>	Telefax:	
		Email:	

Quick Scan date:



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Previous Quick Scan performed ☐ No ☐ Yes, date:

*Indicate if you have already submitted a quick-scan on the same or similar technology to be evaluated by this Verification Body*

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**Quick Scan Reference Number:**

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## Part B

### B.1 - Identification of the Technology

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Name of the Technology:

*NB : A technology can be a product, a process or a service*

Technology Area:

☐ Water Treatment and Monitoring

☐ Materials, Waste and Resources

☐ Energy Technologies

☐ Other:

Comments:

*If the technology could fit in more than one area, please signal this and insert a clarification in the comment section.*

### B.2 - General description of the Technology

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Introduction or context:

*Briefly explain the specific problem(s) or opportunities your technology wishes to address.*

Main purpose of the technology:

*How does this technology address the problems or opportunities?*



Relevant alternatives

*The 'relevant alternative' helps to determine the environmental added-value and innovation level through a qualitative comparison (quantitative if data is available). It should perform an identical or similar function as the technology under verification but it can correspond to different technologies working in sequence, e.g. in recycling, a material sorting procedure including dismantling can be an alternative to a crusher. It should be a current technology that is commercially available, it should be legal and accepted by end-users in the specific targeted market(s). It should also be effective in achieving a reasonably high level of protection of the environment.*

Principle used:

*Which are the scientific or technical principles and techniques used by this technology*

Which are the main claim(s) on the technology's performance that would need to be verified? (Preliminary elements for the performance claim)

*Consider as much as possible verifiable, quantifiable features, expressed in absolute (i.e. not comparative) terms. Please note that the initial performance claim is starting point for the verification and may evolve during the verification process*

Under which conditions is this performance(s) achieved?

*Detail the key operational parameters and limits in order for the technology to perform as described in the claim.*

Main technical standards, regulations or references applicable to this technology:

*Are there existing standards that cover (parts of) this technology? What are the main regulations relevant for this technology? Are you aware of any guidelines that would be useful for the verification of this technology?*



### B.3 - Market readiness

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Is the technology already on the market?

☐ No      ☐ Yes, number years:

If no, is there a prototype or a demonstration unit available?

☐ No      ☐ Yes      ☐ Pilot scale      ☐ Full-scale

When transforming the prototype/ demonstration unit into a marketable product, will any changes affect the technology's performance?

☐ No      reason:

☐ Yes      How substantial will the changes be?

Comments:

*A verification will check whether the technology matches the claimed performance. Ideally this verification should only be done once the product is finished, so as to reduce costs of new verifications with changes or upgrades to the technology.*

*The intention is to determine if the technology is ready to market: "is it available on the market or at least available at a stage where no substantial change affecting its performance will be implemented before introducing the technology on the market (e.g. full-scale or pilot scale with direct and clear scale-up instructions)".*

### B.4 - Innovation level

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Description of the innovation provided by the technology, in comparison with relevant alternatives on the market:

*Novelty presented by the technology in terms of design, raw materials involved, energy used, production process, use, recyclability or final disposal, when compared with the alternatives identified above*

### B.5 - Environmental added-value

Please provide a short overview of the major positive and negative environmental aspects of your technology in each of the four main life-cycle stages identified below:

*You are expected to provide as much information as possible, especially for the manufacturing and use phases. Qualitative or quantitative information may be given on emissions, waste streams, consumption or use of raw materials, energy and water. The information provided will help the Verification Body assess whether your technology would fit and benefit from an ETV. If you have no detailed information you are encouraged to provide any generic information you may have useful to the evaluation.*

*In some cases you may limit the amount of information, in particular when:*

- i) the technology will lead to environmental pressures/impacts that are not significantly different than those of the relevant alternative*
- ii) those environmental pressures/impacts are negligible compared to those of the other phases*
- iii) the information cannot be obtained – please provide a short justification in this case*



**Natural resources (raw materials, energy) extraction and transformation phase:**

Is this stage under your direct control? ☐ Yes ☐ No

Do you have information concerning environmental aspects for this stage? ☐ Yes ☐ No ☐ Partial

In terms of environmental impacts or environmental added value, are there significant differences in this stage between your technology and relevant alternatives?

☐ Yes ☐ No

Major positive and negative environmental aspects:

*Extraction, refining, processing, transformation and transport of natural resources including every aspect of all activities involved before the manufacture of the technology's equipment, sub-assemblies or products. By definition, this also includes all of the raw materials, the energy and water used and all waste or emissions released to the environment during these activities.*

**Manufacturing phase:**

Is this stage under your direct control? ☐ Yes ☐ No

Do you have information concerning environmental aspects for this stage? ☐ Yes ☐ No ☐ Partial

In terms of environmental impacts or environmental added value, are there significant differences in this stage between your technology and relevant alternatives?

☐ Yes ☐ No

Major positive and negative environmental aspects:

*Manufacturing of parts, components, machinery and of products including every aspect of the production of the technology. In general, it is expected that this will include the production of most if not all sub-assemblies. This also includes all of the water, energy and consumables used, together with all of the emissions and all of the products and wastes. This will generally occur on production sites under control of the applicant.*

**Use phase:**

Is this stage under your direct control? ☐ Yes ☐ No

Do you have information concerning environmental aspects for this stage? ☐ Yes ☐ No ☐ Partial

In terms of environmental impacts or environmental added value, are there significant differences in this stage between your technology and relevant alternatives?

☐ Yes ☐ No

Major positive and negative environmental aspects:

*Use and maintenance phase of a product, a process or a service including estimates of its use by the client/end-user refers to consumables, maintenance, and all raw materials, energy and water used for its functioning, as well as all the emissions, products and waste streams.*

**End of life phase:**

Is this stage under your direct control? ☐ Yes ☐ No

Do you have information concerning environmental aspects for this stage? ☐ Yes ☐ No ☐ Partial

In terms of environmental impacts or environmental added value, are there significant differences in this stage between your technology and relevant alternatives?

☐ Yes ☐ No

Major positive and negative environmental aspects:

*End of life of a technology including every aspect of all activities involved in the 'End of Life' of a product or an equipment, when it is discarded by the client/end-user, including its recycling, dismantling and/or disposal of all components. This also includes all of the water, energy and consumables used, together with all types of emissions, all of the products and wastes.*



## B.6 - Potential to meet user needs

Does the technology have the potential to meet user needs?

☐ Yes ☐ No

What specific user needs is the technology addressing? How does this technology meet the user needs?

*Does this technology address a need in the market? Are the advantages provided a real advantage to the user? If the technology is already on the market provide general information on its success in addressing user needs.*

## B.7 - Fulfilment of legal requirements

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What is the target market for this technology?

☐ EU ☐ Specific country/countries:

☐ Other:

Does the technology fulfil the legal requirements in the targeted market(s)?

☐ Yes ☐ No

Comments:

## B.8 - Intellectual Property Rights (IPR)

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Are you the sole and full owner of the technology? ☐ Yes ☐ No

If no, do you detain intellectual property or other rights on the technology?

☐ Yes

Description of the license or other contractual arrangement giving you the legal right to ask for the technology to be subject to a verification procedure:

☐ No

Are there any Intellectual Property issues in respect of this technology or any part or aspect of the technology that might prevent its development and/or which could result in any legal or other issues for the ETV?

☐ Yes ☐ No

Comments:

## B.9 – Existing test data

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Are there available test results or other data to back-up the technology's performance?

☐ Yes

☐ No

Comments:

*Please include in our comments, if a test plan was followed, if standard methods were used, if testing was done by accredited testing bodies, i.e. ISO 17025.*

*If test results are not available, please indicate if you have a test plan prepared and/or if there are test methods available, including standard methods.*

### Applicant:

Name:

Date:

Signature:



## Part C

### Assessment of Quick-Scan (for the Verification Body)

#### Conclusions of Quick Scan by the Verification Body

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Enough information is provided to conclude? ☐ Yes ☐ No

If no, indicate the information that needs to be provided:

If yes, is the technology recommended for ETV? ☐ Yes ☐ No

Why?

Technology in the scope of VB ? ☐ Yes ☐ No

Comments / remarks / recommendations:

Estimated cost range for a verification (excluding tests):

#### Applicant:

Name:

Date:

Signature:

#### Verification Body:

Name:

Date:

Signature:





# SIGNATURES

1. FUNDACION PUBLICA MIGUEL SERVET (FMS)

Signature(s)

Name(s):

Title(s):

Date



## 2. FUNDACION PUBLICA ANDALUZA PROGRESO Y SALUD M.P. (FPS)

Signature(s)

Name(s):

Title(s):

Date



### 3. SIHTASUTUS POHJA-EESTI REGIONAALHAIGLA (PERH)

Signature(s)

Name(s):

Title(s):

Date



#### 4. WOJEWODZKI SZPITAL SPECJALISTYCZNY W OLSZTYNIE (WSS)

Signature(s)

Name(s): Patrik Krauspe

Title(s): State Secretary

Date



5. ACADEMISCH ZIEKENHUIS MAASTRICHT (AZM)

Signature(s)

Name(s):

Title(s): -

Date



6. ZIEKENHUIS AAN DE STROOM (ZAS)

Signature(s)

Name(s):

Title(s):

Date



## 7. CONSORCI HOSPITALARI DE VIC (CHV)

Signature(s)

Name(s):

Title(s):

Date



# theresa

