Annex no. 1 –Specification of the Equipment

„Specification of the Equipment - Shielded chamber with integrated filling equipment for working with radioactive materials“

Shielded chamber (Dispensing cell) with integrated filling equipment for working with radioactive materials should contain the following general parameters and components, which must at the same time meet all of the following specifications:

General parameters	• the Dispensing cell consists of an isolator and a shielding providing protection against the effects of ionizing radiation, including protection against occasional opening door during work with ionizing radiation, a handling pre-chamber for sterile insertion of input material and a chamber for radioactive waste RW • the interior of the insulator should be accessible from the front side after opening the shielded door; • the manipulating pre-chamber is located on the side will also be accessible from the front; • the chamber for RW is located under the isolator and is accessible from the front; • the ventilation of the isolator should complying air quality with Class "A" (grade according to cGMP) in the workspace of the chamber; in the workspace of the pre-chamber and the RW chamber, the ventilation system should complying air quality with Class "B", the external construction of the dispensing cell must, from the front, meet the requirements for class "C" and must ensure a tight connection to the already installed hot cells; • the dispensing cell must have access to the technological background from the back; • minimum shielding of the front side of the cell: equivalent to min. 75 mm Pb; • minimum shielding of the other walls of the cell: equivalent to min. 75 mm Pb; • the front side of the isolator must have a lead glass with a shielding equivalent of min. 75 mm Pb; • dispensing cell is equipped one (or two) tele-plier and two shielded openings gloves ports for manual handling. • maximum external dimensions of the chamber with the pre-chamber (width x depth x height): **1750 x 1300 x 2800 mm**;
Component	Specification
Isolator	• isolator workspace material: AISI 316L stainless steel with mirror-bright internal surface finish; • material of other steel structures: stainless steel AISI 304 or better; the surface requirements must meet the sanitation needs for class "C"; • the ventilation system must comply air with Class "A" with vertical laminar flow in the workspace; • the ventilation system must comply a negative pressure difference between isolator compared to the outdoor environment in the range of -100 Pa to - 250 Pa; • the ventilation system must have a HEPA filter H14 or better at the outlet • minimum dimensions of the workspace (width x depth x height): 700 x 700 x 600 mm;

	• The DELIVERY SYSTEM (DSk) must be adapted to the type of container used by the issuer (purchaser). The construction of the delivery system for the transport container should allow the issuer (purchaser) an eventual change of the type of container dimensions, given the circumstances, for example by removing the filler-the reductions for the defined packaging file may be issued by the issuer (purchaser) into the packaging file with bigger external dimensions.
	• Insulator equipment requirements:
	  • H2O2 input/output for isolator sanitation (ACV system)
	  • integrated H2O2 detector – measuring accuracy range 0-20ppm with resolution 0,1ppm;
	  • preparation for microbiological and particle monitoring;
	  o the exact location of the monitoring outlets will be mutually agreed upon between the supplier (contractor) and the customer (purchaser) during the production of the chamber
	  o microbiological monitoring - stainless steel pipe with ID min. 21.7 mm, ending in the insulator with a flange DN50.5 (Tri-Clamp connection) and in the rear part of the chamber ending with a ball valve with a flange DN50.5 (Tri-Clamp connection)
	  o particle monitoring - isokinetic probe installed in the isolator, ending in a ball valve from the back of the chamber
	  • min. 14 inlets for capillaries and technical gases;
	  • min. 12 inputs for cables up to 14 mm in diameter
	  • One (or two) dose calibrator for activity measuring, (1x dose calibrator with integrated lift; 1x dose calibrator with integrated balance). In case isolator will be equipped one dose calibrator: 1x dose calibrator with integrated lift and balance for "mother vial".
	  • the dose calibrator must have a metrological certificate of conformity (or type test of the device)
	  • The measuring range of the dose calibrator is for the isotope 18F → 0 to 400GBq
	  • the calibrator has the following predefined isotopes: 18F, 11C, 68Ga, 64Cu, 137Cs, the possibility of expansion by 2 isotopes
	  • adequate lighting of the work space (min. 500 Lux);
	  • UV lamp for sterilization.
	  • Integrated temperature sensor with feedback - ensuring the temperature in the isolator 23 ± 2 ° C
	  • Connection of the isolator with the RW chamber using an opening built- door into the bottom of the isolator

Shielded chamber for RW	• the material of the workspace of the RW chamber: stainless steel AISI 316L or better with mirror-bright internal surface finish; • material of other steel structures: stainless steel AISI 304 or better; the surface must meet the sanitation needs for Class "C"; • the ventilation system must comply air with Class "B" • the ventilation system must comply a negative pressure between isolator and RW chamber, must be under any working conditions in the isolator min. - 20 Pa • The ventilation system must have a HEPA filter H14 or better • minimum shielding of the RW chamber: equivalent to min. 75 mm Pb;
Pre-chamber	• Pre-chamber workspace material: AISI 316L stainless steel or better

	with mirror-bright internal surface finish;
	• material of other steel structures: stainless steel AISI 304 or better; the surface must meet the sanitation needs for Class "C";
	• the ventilation system must comply air with Class "B"
	• The ventilation system must ensure a pressure difference of +20 / -250 Pa in the workspace compared to the outdoor environment
	• the pressure difference between the isolator and the pre-chamber must be min. - 20 Pa under any operating conditions in the isolator;
	• The ventilation system must have a HEPA filter H14 or better at the output
	• minimum dimensions of the workspace (width x depth x height): 450 x 450 x 500 mm;
	• Pre-chamber equipment requirements:
	  • H2O2 input/output for chamber sanitation;
	  • preparation for particle monitoring;
	  • A cart for material transfer between the pre-chamber and the isolator
	  • the height of the loading surface of the cart is as low as possible above the working surface of the insulator.
	  • The loading area of the cart within reach of the manipulator and the operator's hand

Component	**Specification**
Dispensing unit	• Possibility dispensing of the product into open vials • the automatic process of removing aluminum seal and rubber stopper from the vial • The device contains a crimping head for closing the vials • Disposable dispensing KITs are used in the device • The device contains a barcode reader - vial ID (this function can be activated/deactivated in the settings) • Dispensing accuracy can be selected - gravimetrically or volumetrically • Automatic process of diluting the final product to a user-defined value of the declared volume activity • At the end of the dispensing process, the rinsing function of the dispensing kit • the device has an option to install "sterilization filter integrity test" (bubble point test) • dispensing accuracy - error is lower as10% • The minimum dispensing volume is 0.2 ml • Possibility to fully control the device in manual mode