

Innovative Facility for Isotope GENeration with Efficient Ion Accelerator

T4.1 Develop Lab conditions (radiation protection) needed for producing isotopes

Thanasis Zacharakis, BIOKOSMOS SA

Medical Physicist/Radiation Protection Officer

Kick-off meeting 3-4 April 2025 Thessaloniki, Greece



This project has received funding from the European Union's Horizon Europe Framework Programme for Research and Innovation under grant agreement no 101186921.



T4.1 Develop Lab conditions (radiation protection) needed for producing isotopes

Extensive handling of unsealed radionuclides, produced via conventional methods or the novel linear accelerator developed in WP3, necessitates the construction of new laboratories in Greece, Slovenia, and Cyprus, along with staff training. These facilities will allow for the development and handling of novel radioisotope targets for patient use, ensuring adequate radiation protection within national legal frameworks. Measures include local shielding, washing facilities, and waste disposal, with personnel and contamination monitoring agreements with local authorities. Methodologies will be established through inter-laboratory comparisons, following the ALARA and ALARP principles to minimize radiation exposure while considering economic factors.



T4.1 Develop Lab conditions (radiation protection) needed for producing isotopes

- Ensure adequate radiation protection for extensive handling of unsealed radionuclides
- Provide equipment requirments
- Provide safety protocols
- Provide waste management and disposal instructions
- Staff training



Start Date:		1	Task Leader:	Task Leader:		BIOKOSMOS SA		
End Date:		42	Task Contribu	Task Contributors:		E. Halevas, A. Zacharakis, A. Lazopoulos, Ch. Tsoukalas, M. Kaplanis, Ch. Kanteler		
Del.	Deliverab	le Title		Lead Part	ner	Diss. Level	Due On	
D4.1	Report for building a	the specifications for or radio-isotope lab	signing and BIOKOSMOS SA		S SA	Sensitive	15 month	
Мх	Milestone Title			Lead Partner		Mean of verification	Due On	



> The radiation protection design will be based on the following:

- the National and the European legislation for radiation protection (dose limits)
- the optimization principle of ALARA (As Low As Reasonably Achievable) according to which we are defining the dose constraints for all the practices with ionizing radiation
- international recommendations (NCRP reports, IAEA reports)

Classification of the controlled and non controlled areas

Description of the kind of radiation (neutrons, γ radiation) for shielding design and calculations



- The facility design will be based on the radiation protection requirements
- The facility will be divided in two big areas: the controlled areas and the noncontrolled areas



- Cleanroom: a radiopharmaceutical synthesis laboratory
- Quality Control room: a fully equipped laboratory with all the prerequisite analytical devices for the quality control of the radioisotopes
- Shielded radioactive waste storage areas
- Washing facility
- Raw materials storehouse



- HVAC system (Heating, Ventilation, Air Conditioning) maintains the required air quality for the cleanroom. Cleanrooms must be supplied with 100% fresh air in order to comply with radiation protection regulations (no recirculation of air is permitted in radiation protection controlled areas)
- Structural and supporting components of the building and of the controlled areas must also comply with the radiation protection requirements: floors, walls, ceilings, doors, windows and surfaces of the benches must be non absorbent, easy to clean and resistant to contamination (microbial and radioactive)
- Pressure cascades: the design of pressure cascades will be based on radiation protection requirements



T4.1 Methodology – Non Controlled areas

- Personnel offices
- Public areas



T4.1 Methodology - Cleanroom



Pharmaceutically classified shielded hot cells in which the synthesis modules and the dispenser modules will be installed



T4.1 Methodology – Quality control lab





Fully equipped laboratory for the quality control of the radioisotopes





T4.1 Methodology – Radiation detectors

A full network of γ radiation detectors and neutron detectors which will be pc controlled, giving dose rate values in real time





T4.1 Methodology – Radiation detectors

Hand and foot contamination (HFC) monitors





T4.1 Methodology – Radiation detectors

Portable radiation detectors

Personal dosimeters









- The personnel before entering the controlled areas must wear specific clothing depending on the room and the practice (gloves, shoe covers, glasses, head covers, whole body suit etc.)
- The personnel before entering the controlled areas must have personal dosimeters (TLD and digital dosimeters of direct reading) and portable radiation detectors
- The personnel after leaving the controlled areas, must be monitored in a HFC monitor for possible contamination



- All practices with ionizing radiation must be described and the Radiation Protection Officer (RPO) must give written instructions to the personnel
- Specific instructions must be given to the personnel in case of an accident inside the facility.
- In any case the RPO must be informed immediately
- Detailed records must be kept with all the radioactive wastes which are created inside the facility
- Liquid wastes: Must be stored in shielded tanks before the disposal
- Solid wastes: Must be stored in the shielded waste storage room



•	Safety protocols	M1 – M3
•	Staff training protocols	M4 – M6
•	Waste management and disposal protocols	M7 – M9
•	Radiation protection measurements	M10 – M15
•	Equipment requirements	M14 – M15



T4.2 \rightarrow Identification of the produced isotopes

T3.5 \rightarrow Radiation protection requirements

General questions for clarification by all participating partners

- Production of radiopharmaceuticals...?
- Types of radiation biology testing (in vitro and/or in vivo)
- Biohazard (anticancer, toxic)



THANK YOU FOR YOUR ATTENTION