CHECKLIST 15. RADIOPHARMACY OPERATIONAL LEVEL 2

No.	Component	LC	Example of result / type of evidence
	Staffing		
15.1	Is there specific staff training and assessment of competency at operational level 2, including aseptic practice?		Check the training standard operating procedure (SOP) / check personnel files
15.2	Is there training provided for staff required to perform final checks on all products prepared before release for patient use?		Check personnel files
15.3	Before release of radiolabelled red blood cell (RBC) and white blood cell (WBC) labelling, is there confirmation of training?		Check the training SOP
	Facilities		
15.4	For operational level 2, are there regular checks on validated class II type B microbiological safety cabinets located in a dedicated room?		Check records
15.5	For negative pressure isolators, before preparation takes place, are gloves or gauntlets visually inspected and integrity tests carried out and recorded?		Check records / evaluation on-site
	Preparation protocols		
15.6	In practice, have all systems of work and documentation related to radiopharmaceutical preparation and processing been formally approved?		Check approved documentation
15.7	Do all products, kits and generators have product approval, marketing authorization or bear a product licence number?		Check records / check the purchase SOP

CHECKLIST 15. RADIOPHARMACY OPERATIONAL LEVEL 2 (cont.)

No.	Component	LC	Example of result / type of evidence
15.8	Is the preparation of Tc-99m radiopharmaceuticals from kits and generators carried out in a laminar airflow cabinet?		Evaluation on-site
15.9	Can each individual patient dose be traced to a specific generator and kit batch number?		Check records / evaluation of traceability
15.10	Under operational level 2b, do the written procedures for any autologous preparation, e.g. RBCs and WBCs, include clear instructions on safety, cleaning and decontamination?		Check SOPs / observation on-site
15.11	Are there written procedures for the preparation and dispensing of radiolabelled biologicals, e.g. monoclonal antibodies, peptides from approved kit formulations?		Check procedures / observation on-site
	Quality assurance / quality control (QC)		
15.12	Are there set QC criteria prior to release for preparation before patient use?		Check procedures
15.13	Is a record of approval/release made by an authorized person before a product is administered to a patient?		Check records
15.14	For operational level 2, is Mo-99 molybdenum breakthrough measurement performed on the first eluate of each Tc-99m generator and repeated when the generator is moved?		Check procedures / check records
15.15	Is aluminium ion breakthrough checked on the first eluate from a Tc-99m generator?		Check procedures / check records

CHECKLIST 15. RADIOPHARMACY OPERATIONAL LEVEL 2 (cont.)

No.	Component	LC	Example of result / type of evidence
15.16	Before patient use, are radiochemical purity tests performed on all new batches or newly delivered radiopharmaceutical kits?		Check procedures / check records
15.17	Is there routine microbiological monitoring of preparation and aseptic dispensing areas in the radiopharmacy?		Check procedures / check records
15.18	Are changes in the use of kits, diluents or vehicles, needles, syringes, swabs and sterile containers recorded?		Check procedures / check records
15.19	Are pH tests carried out regularly?		Check procedures / check records
15.20	Are rapid alternative methods employed for swift prospective QC, e.g. for the determination of the radiochemical purity of Tc-99m-HMPAO (hexamethylpropyleneamine oxime)?		Check procedures / check records

Note: LC: level of conformance (range 0–4). 0: absent or inappropriate; 1: planned or approximate; 2: partial conformance or partial implementation; 3: near full conformance or near full implementation; 4: full conformance or full implementation.