CHECKLIST 14. RADIOPHARMACY OPERATIONAL LEVEL 1

No.	Component	LC	Example of result / type of evidence
	Staffing		
14.1	Is the radiopharmacy unit operated under the direction of a person with appropriate training as defined by local or national regulations?		Check the job description and the personnel card of the person in charge
14.2	Are there written staff training manuals for all grades of staff?		Check the training standard operating procedure (SOP) / check personnel files
	Facilities		
14.3	Does the unit have appropriately furnished rooms (including adequate lighting, walls, floors, ceilings and ventilation) and a shielded dispensing station?		Evaluation on-site
14.4	For operational level 1b, is there a well ventilated area or a shielded dispensing station for radioiodine capsules?		Evaluation on-site
14.5	Is there a shielded and validated (annual check on airflow, safety and challenge testing) fume hood with suitable filters for handling radioiodine solutions?		Check records / evaluation on-site
	Purchase of materials		
14.6	Are there suitable protocols and trained staff for the purchase of approved or authorized radiopharmaceuticals?		Check purchase SOPs / check the job description and personnel files
14.7	Are all goods received checked and recorded against the order for correctness of delivery?		Check records / check purchase SOPs

CHECKLIST 14. RADIOPHARMACY OPERATIONAL LEVEL 1 (cont.)

No.	Component	LC	Example of result / type of evidence
	Dispensing protocols		
14.8	Under operational level 1a, are there written procedures for the aseptic dispensing and labelling of unit doses of ready to use radiopharmaceuticals?		Check SOPs
14.9	For operational level 1b, is a shielded dispensing station and/or a fume hood available?		Evaluation on-site
14.10	Is there a fume cupboard with suitable filters for volatile radioactive materials such as I-131 solutions?		Evaluation on-site
14.11	If only radioiodine capsules are handled, is the package opened in a well ventilated area?		Evaluation on-site
14.12	For operational level 1b, do the written procedures contain clear safety and monitoring instructions for dispensing radioiodine solutions or capsules?		Check SOPs
14.13	Can the audit and documentation for each radiopharmaceutical batch be traced from the prescription to the actual administration of individual patient doses?		Check records / evaluation of radiopharmaceutical traceability
	Quality assurance / quality control		
14.14	Are periodic quality checks on radiopharmaceuticals performed?		Check records / check SOPs
14.15	Is there a written procedure for dealing with products that do not meet the required standards and/or for which a complaint has been received?		Check procedures

CHECKLIST 14. RADIOPHARMACY OPERATIONAL LEVEL 1 (cont.)

No.	Component	LC	Example of result / type of evidence
	Waste		
14.16	Are there written procedures for the disposal of radioactive and non-radioactive waste specific to the radiopharmacy?		Check procedures / observation on-site

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.