CHECKLIST 16. RADIOPHARMACY OPERATIONAL LEVEL 3

No.	Component	LC	Example of result / type of evidence
	Staffing and training		
16.1	Is the radiopharmacy operational level 3 unit operated under the direction of a person with appropriate training as defined by local or national regulations?		Registered pharmacist, scientist or qualified personnel. Check the training standard operating procedure (SOP) / check personnel files
16.2	Is there specific staff training and assessment of competency at operational level 3, including understanding of contamination risk, pharmaceutical formulation, quality control (QC), validation and aseptic practice?		Check the training SOP / check personnel files
16.3	Are there appropriately trained staff members (minimum of three) for compounding of diagnostics, therapies or cold kits, or for subdispensing commercial kits and validation/release of the final product?		Check the training SOP / check personnel files
16.4	Are there independent QC staff (to those involved with production) sufficiently trained to perform final checks, batch release on all products prepared before release for patient use?		Check the training SOP / check personnel files
	Facilities		
16.5	Are there clean rooms with anteroom facilities fitted with high efficiency particulate air filters to give United States Pharmacopeia / European Union (EU) standards for use, class D for use with isolators and class C with laminar airflow (LAF) cabinet?		Check records / evaluation on-site

CHECKLIST 16. RADIOPHARMACY OPERATIONAL LEVEL 3 (cont.)

No.	Component	LC	Example of result / type of evidence
16.6	Is there a heating, ventilation and air-conditioning (HVAC) system installed and commissioned professionally? Is the HVAC under service contract?		Check records / evaluation on-site
16.7	Are these facilities and all critical equipment regularly monitored and under control (i.e. regular radiation, airflow rates, particle counts and microbial contamination monitored and documented), including micropipettes, refrigerator control and glove leak tests for isolators and hot cells?		Check records / evaluation on-site
16.8	Are there documented calibrator checks and calibration assays of each radionuclide (single photon emission computed tomography / positron emission tomography (PET) / therapeutic) with standardized sealed source or National Physical Laboratory standards (including checks on geometry, container type, etc.)? Are daily calibrator checks performed using long lived radionuclides to include the range of radioisotopes for patients?		Check records / evaluation on-site
16.9	Are weighing scales maintained contamination free and appropriate for the range of powders weighed? Are records of cleaning, routine calibration and maintenance kept?		Check records / evaluation on-site
16.10	Does terminal sterilization or dispensing take place under International Organization for Standardization standard 5, class 100 or EU grade A conditions? Are these followed by controls such as microbiological plates, broth and filter integrity tests?		Check records / evaluation on-site

CHECKLIST 16. RADIOPHARMACY OPERATIONAL LEVEL 3 (cont.)

No.	Component	LC	Example of result / type of evidence
	Operational protocols		
16.11	In practice, have all systems of work and documentation related to radiopharmaceutical preparation and processing been formally approved and controlled?		Check records
16.12	Is there a system for material management, including control and appropriate checks on all raw materials (chemicals or gas), used? If applicable, are only ingredients and reagents of pharmacopeia grade and all glassware or all components/plastics with CE mark (or equivalent) used?		Check records / evaluation on-site
16.13	Are material storage conditions specified and controlled (e.g. storage in fridge/freezer/desiccator at room temperature) and does each item have a QC traceable tag?		Check records / evaluation on-site
16.14	Are the production environmental conditions compliant for production, and is the preparation of each stage of radiopharmaceutical compounding, kit production, tracer manufacturing and generator elution carried out in an LAF cabinet or under appropriate conditions to reduce risks and bioburden?		Check records / evaluation on-site
16.15	Is each step checked and cross-checked on the working document in real time, i.e. at the time of completion of that task?		Check records / evaluation on-site

CHECKLIST 16. RADIOPHARMACY OPERATIONAL LEVEL 3 (cont.)

No.	Component	LC	Example of result / type of evidence
16.16	Can each individual patient dose and/or batch number be traced back by an operational documentation system to the starting material, equipment used, operators, specific generator and/or kit, QC processes and final release?		Check records / evaluation on-site
16.17	Are there written procedures with clear instructions on safety, cleaning, line clearance and decontamination for prevention of any cross-contamination?		Check procedure, records / evaluation on-site
16.18	Are all critical checks (including visual), changes and amendments during the process of preparation of individual radiopharmaceuticals, kits, PET modules and therapies formally controlled, approved, timed and dated?		Check records / change control documentation / evaluation on-site
16.19	Does the production document specify a nationally approved label that includes approved name, radiation dose, clear instructions for storage, licence number and precautions? Are copies of labels retained and is the total number of labels reconciled before final QC release of the batch?		Check records / evaluation on-site
16.20	Is there an independent production manager to check before batch handover to the quality controller for checking and final release to the patient?		Check records / evaluation on-site
	Quality assurance (QA) / QC		
16.21	Are there controlled and approved written procedures for QA/QC, based on pharmacopoeia methods (or equivalent validated methods)?		Check procedure, records / evaluation on-site

CHECKLIST 16. RADIOPHARMACY OPERATIONAL LEVEL 3 (cont.)

No.	Component	LC	Example of result / type of evidence
16.22	Does the quality controller independently check environmental compliance, material, documentation, equipment, operator, cleaning, etc.?		Check procedure, records / evaluation on-site
16.23	Does the quality controller independently perform all required physical checks, e.g. sample, batch size, in-process checks, radioactivity, chemicals, weights, high performance liquid chromatography, colloid, osmolality, residual solvent, pH, product appearance, labels?		Check procedure, records / evaluation on-site
16.24	Is there routine microbiological monitoring of the preparation area and the aseptic dispensing station in the radiopharmacy? Does the quality controller independently perform all required microbiological assessments, filter integrity tests, endotoxins, plate controls, end of broth, contact plates, sterility tests, etc.?		Check procedure, records / evaluation on-site
16.25	Is radionuclidic purity assessment undertaken, e.g. multichannel analysis, half-life, before patient use, including parent radionuclides from a generator, and especially for therapies?		Check procedure, records / evaluation on-site
16.26	Have all critical assessments been performed and any changes been approved by a nationally licensed individual before final patient release?		Check procedure, records / evaluation on-site
16.27	Is there a quality management system (QMS) for packing and safe transportation requirements in accordance with national and IAEA guidelines?		Check procedure, records / evaluation on-site

CHECKLIST 16. RADIOPHARMACY OPERATIONAL LEVEL 3 (cont.)

No.	Component	LC	Example of result / type of evidence
16.28	Is there timely faxing of the product release document / certificate of analysis to end users and follow-up of any deficiencies, complaints and feedback? Is there annual testing of the product recall procedure to ensure radiopharmaceuticals/PET/therapies are not administered to patients before receipt of the product release document?		Check procedure, records / evaluation on-site
16.29	Is there an annual programme of self-assessment and audit of the QMS at radiopharmacy operational level 3?		Check procedure, records / evaluation on-site
16.30	Are there proper United Nations waste disposal practices, including separate lead shielding for radioactive waste, waste container for solvents and biological waste?		Check procedure, records / evaluation 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.