CHECKLIST 13. ASSESSMENT OF THERAPY

No.	Component	LC	Example of result / type of evidence
	Clinical		
13.1	Was the decision to treat this patient based on national/international guidelines?		Check records / check SOPs / check related international guidelines
13.2	Was the appropriateness of this therapy based on a multidisciplinary evaluation and formally approved by the physician in charge of treatment?		Check patient records
13.3	Have other issues (patient condition, allergies, concurrent diseases, socioeconomic issues, etc.) possibly interfering with or contraindicating the radionuclide therapy been identified?		Check patient records / check SOPs
13.4	Were results of all relevant diagnostic procedures available?		Check records / observation on-site
13.5	Was information about previous treatments (including previous radionuclide therapy) available?		Check records
13.6	Was information about ongoing medical therapy available and checked for any potential interference with the current radionuclide therapy?		Check records
Technical procedure: Check if done according to the standard operating procedure (SOP)			
13.7	Has the patient been identified according to the SOP?		Check records / check SOPs
13.8	Was the correct radiopharmaceutical prescribed and was the activity based on the estimated dose to target and non-target tissues?		Check records / check SOPs
13.9	Was the activity measured before administration?		Check records

CHECKLIST 13. ASSESSMENT OF THERAPY (cont.)

No.	Component	LC	Example of result / type of evidence
13.10	Was the procedure to avoid misadministration of the radiopharmaceutical followed?		Check records / check SOPs
13.11	Was pregnancy/lactation excluded and understanding of information concerning subsequent contraception checked?		Check records
13.12	Was imaging performed, if appropriate, to check the biodistribution of the radiopharmaceutical?		Check records
Patient preparation: Check if done according to the SOP			
13.13	Has the patient been fully informed and has consent been obtained as described?		Check records / check SOPs / observation on-site
13.14	Were instructions concerning treatment related medical therapy (hormones, bisphosphonates, calcium, thyroid blocking medications, etc.) and any other preparations (hydration, fasting, etc.) given?		Check records / check SOPs / observation on-site
13.15	Was patient condition and/or treatment related interference with the procedure checked?		Check records / check SOPs
13.16	Were patients instructed on the necessity of avoiding pregnancy during and for a specified time after therapy? Was relevant counselling on lactation given?		Check records / check SOPs
13.17	For paediatric patients, were relatives/caregivers appropriately informed about radiation protection issues?		Check records / check SOPs
Quality assurance (QA) / quality control (QC): Check if done according to the SOP			
13.18	Patient preparation ascertained		Check records / observation on-site

CHECKLIST 13. ASSESSMENT OF THERAPY (cont.)

No.	Component	LC	Example of result / type of evidence
13.19	Documentation of QC of the radiopharmaceutical including in the case of external procurement		Check records / check SOPs
13.20	Filing of batch number, dosing and time of administration of any therapy related pharmaceutical		Check records
13.21	Handling and documentation of any incidents (spilling, extravasation at the injection site, vomiting, etc.) or adverse events (patient related or not)		Check records / check SOPs
13.22	Traceability of all patient related data, e.g. radiopharmaceutical, administered activity and injection site (if applicable), name of technologist and doctor in charge		Observation on-site / check all records showing traceability
	Reporting and follow-up		
13.23	Was a comprehensive treatment report issued and made available to all involved parties?		Check the report / check SOPs
13.24	Was the report drafted as specified in the relevant SOP?		Check the report / check SOPs
13.25	Was any feedback received after therapy properly documented and managed?		Check records / check SOPs

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.