

## SCHEDULE 2 – THE SERVICES

### A. Service Specifications

<b>1. Service name</b>	Radiotherapy services (adults and children) Subspecialisation - Molecular Radiotherapy (all ages)
<b>2. Service specification number</b>	2322
<b>3. Date published</b>	September 2024
<b>4. Accountable Commissioner</b>	NHS England – Cancer National Programme of Care (NPOC) <a href="https://www.england.nhs.uk/our-work/our-approach-to-cancer/nhs-commissioning-cancer/">NHS commissioning » Cancer (england.nhs.uk)</a> <a href="mailto:england.npoc-cancer@nhs.net">england.npoc-cancer@nhs.net</a>

#### **5. Population and/or geography to be served**

##### **5.1 Population covered**

This specification (the ‘Specification’) covers people (all ages) who are within the commissioning responsibility of NHS England and who require Molecular Radiotherapy (MRT) Services (“the Service”).

MRT is the treatment of disease with unsealed radioactive substances, including Selective Internal Radiotherapy (SIRT). This specification does not include the use of ‘solid’ radiotherapy sources (such as seeds or wires) or external beam radiotherapy.

##### **5.2 Minimum population size**

The Service must serve a population sufficient to support a critical mass of infrastructure required to deliver the service and be configured to ensure workforce sustainability and maintain professional expertise. This requires sufficient volume of work for staff to maintain the necessary level of competence to deliver the [highest standards of care](#).

#### **6. Service aims and outcomes**

##### **6.1 Service aims**

The aim of the Service is to:

- Improve the outcomes from MRT and the experience of care by delivering best practice MRT treatments using appropriate technologies and holistic support in a safe culturally appropriate and inclusive way, enabling the diverse needs of service users to be met.
- Support disease specific multi-disciplinary teams to enable people requiring MRT to access high-quality care at the right time and in the right place and in a timely manner, giving regard to individual choice.
- Reduce variation in clinical practice through standardisation, audit and the adoption of best practice and dosimetry.

- Encourage the participation in clinical trials and research relating to conditions for which MRT is considered suitable.

## 6.2 Outcomes

### NHS Outcomes Framework Domains & Indicators

Domain 1	Preventing people from dying prematurely
Domain 2	Enhancing quality of life for people with long-term conditions
Domain 3	Helping people to recover from episodes of ill-health or following injury
Domain 4	Ensuring people have a positive experience of care
Domain 5	Treating and caring for people in safe environment and protecting them from avoidable harm

### Service defined outcomes/outputs

The quality of specialised services is monitored through Specialised Services Quality Dashboards (SSQDs), which normally comprise a range of quality outcomes (including clinical outcomes) and quality metrics which are supported by regular data collections. SSQDs are available on NHS England's website at: <https://www.england.nhs.uk/specialised-commissioning-document-library/>

Included in the range of metrics that support understanding of the quality of this service are:

Metric Reference Number	Domain	Rationale	Name of Metric /Description
MRT01a	1,2,4,5	To assess maintenance of professional expertise and workforce sustainability	The number of episodes (adults) of molecular radiotherapy that are carried out each year.
MRT01b	1,2,4,5	To assess maintenance of professional expertise and workforce sustainability	Number of MRT episodes administered to paediatric (0-15) service users that are carried out each year.

## 7. Service description

### 7.1 Service Model

The service model for MRT is set out in Table 1.

#### **Table1: The Clinical Model**

<b>Level 1 – single administration MRT in pill or capsule for benign disease.</b>	MRT treatments offered by Level 1 Services are of lower complexity. This includes single administration MRT in pill or capsule form for benign disease in an outpatient setting. Service provision will be linked to relevant disease-specific multi-disciplinary teams, with access to essential equipment facilities to store, document and measure delivered doses of radiopharmaceuticals.
<b>Level 2 -intravenous administration for cancer</b>	More complex treatments for localised or metastatic cancers. Including oral or intravenous MRT. It is expected that Level 2 services will also have the capability to deliver Level 1 services. Service provision will be anchored around multi-disciplinary teams and cancer pathways and require integration of nuclear medicine and oncology, to essential equipment facilities to store, document and measure delivered doses of radiopharmaceuticals.
<b>Level 3 – selective internal radiation therapy (SIRT)</b>	The delivery of SIRT is anchored around the specialist hepato-pancreatic biliary multi-disciplinary team and requires integration of nuclear medicine, oncology, interventional radiology, with access to radiopharmacy. SIRT is normally given in a day case setting. It is expected that Level 3 services will also have the capability to deliver Level 2 services.
<b>Paediatric MRT (0-15, up to 16<sup>th</sup> Birthday)</b>	MRT administered to paediatric service users. To deliver paediatric MRT, the Service will also need to be a Level 2 Service.

### **Core requirements of a Level 1 Service**

The Provider will deliver the Service in centres with appropriate levels of expertise relevant to the treatments being administered and must ensure that the Service:

- Operates within a clinically safe environment ensuring safe practice and adequate levels of staffing and equipment to deal effectively with medical emergencies.
- Ensures that unsealed radioactive sources are handled in safe designated areas that meet statutory requirements.
- Provides good care within a stringent clinical governance framework.
- Ensures adequate precautionary measures to comply with relevant legislation and to ensure that radiation risks are minimised for staff, other workers, relatives, carers, and the general public.
- Has the capability to undertake dosimetry in accordance with regulatory and licencing requirements. Where this is not available on sites, arrangements underpinned by agreed protocols must be put in place with other MRT services where required dosimetry can be undertaken.

The Service must ensure that:

- MRT is administered by an Administration of Radioactive Substances Advisory Committee (ARSAC) Licensed Practitioner or by another appropriately trained and

Entitled healthcare professional (HCP) (doctor, nurse, radiographer, scientist, or technologist).

- All medicines and radiopharmaceutical products are managed safely and securely, in accordance with defined local radiological rules, NHS Resolution and relevant consents and law. Legislation and Regulations that must be complied with are, as follows:
  - Environmental Permitting Regulations (EPR) 2016 (as amended).
  - Medicines Act 1968 (as amended).
  - Ionising Radiation (Medical Exposure) Regulations 2017 ("IR(ME)R") (as amended).
  - The Carriage of Dangerous Goods and Use of Transportable Pressure Equipment Regulations 2009 (as amended).
  - Agreement Concerning the International Carriage of Dangerous Goods by Road (ADR) 2023.
  - The Ionising Radiations Regulations 2017 (as amended).
- There are contingency plans in place to deal with following circumstances:
  - Adverse reactions.
  - Extravasation.
  - Clinical issues not related to MRT.
  - Medical emergencies, i.e., a deteriorating service user.
  - Re-admission to a healthcare establishment.
  - Reasonably foreseeable accidents involving radioactive materials.

The Provider must work in close alignment with the appropriate referring specialist multi-disciplinary teams (MDTs) and have agreed and documented protocols and associated clinical and referral pathways detailing that the Service can only be accessed by tertiary referral from an appropriate specialist MDT. The Service must:

- Develop local protocols to facilitate close collaboration and clear communication pathways between members of the MRT team and the referring specialists.
- Ensure that regular reviews are conducted to ensure that protocols remain up to date, and that staffing levels and skills mix are appropriate for the annual caseload.
- Ensure that the shared care between the referring specialist and clinician responsible for administering the MRT are underpinned by written protocols that specify the responsibilities of individual specialists involved in the delivery of treatment, aftercare, and follow-up.
- Ensure that service users receive both written and verbal information about the procedure prior to therapy and are advised about minimising radiation exposure and contamination after discharge.
- Ensure that service users receive clear and verbal information about their care and management between MRT administrations and after discharge from the MRT service.
- Implement new technologies that are recommended by the National Institute for Health and Care Excellence (NICE) and give due regard to national clinical guidelines and guidance (Section 7.9).

**Where the Provider delivers services for oncology indications, that Provider must work closely with the local Cancer Alliance to ensure effective service planning and pathway integration of the Service.**

### **Core requirements of a Level 2 Service:**

The Service must meet the Level 1 service requirements and:

- Ensure that all relevant ARSAC licenses are in place for employers, practitioners, and sites.
- Operate as part of fully constituted cancer MDT(s), comprising, as a minimum, a surgeon, clinical oncologist, radiologists, interventional radiologists where appropriate, and other members, according to the clinical indication, that are integrated as core members of the specialist MDT.
- Schedule and integrate treatment appropriately to meet the needs of service users where MRT is used concurrently with other treatments (such as external beam radiotherapy or chemotherapy).
- Ensure that regular reviews are conducted to ensure that protocols remain up to date, and that staffing levels and skills mix are appropriate for the annual caseload.

### **Core requirements of a Level 3 Service**

The Service should be a specialist liver centre co-located (within the same city/town) with a radiotherapy service and host a specialist hepato-pancreatic biliary (HPB) MDT. The Service must also meet the Level 2 service requirements and:

- Through the specialist HPB MDT, ensure appropriate case selection and to ensure that service users are offered the full range of treatment options appropriate to their clinical circumstances.
- Service users must have access to a nurse with experience in SIRT able to co-ordinate care and provide individual expert advice and support for the whole SIRT pathway.
- Ensure that regular reviews are conducted to ensure that protocols remain up to date, and that staffing levels and skills mix are appropriate for the annual caseload.

### **Core requirements of a Paediatric Service**

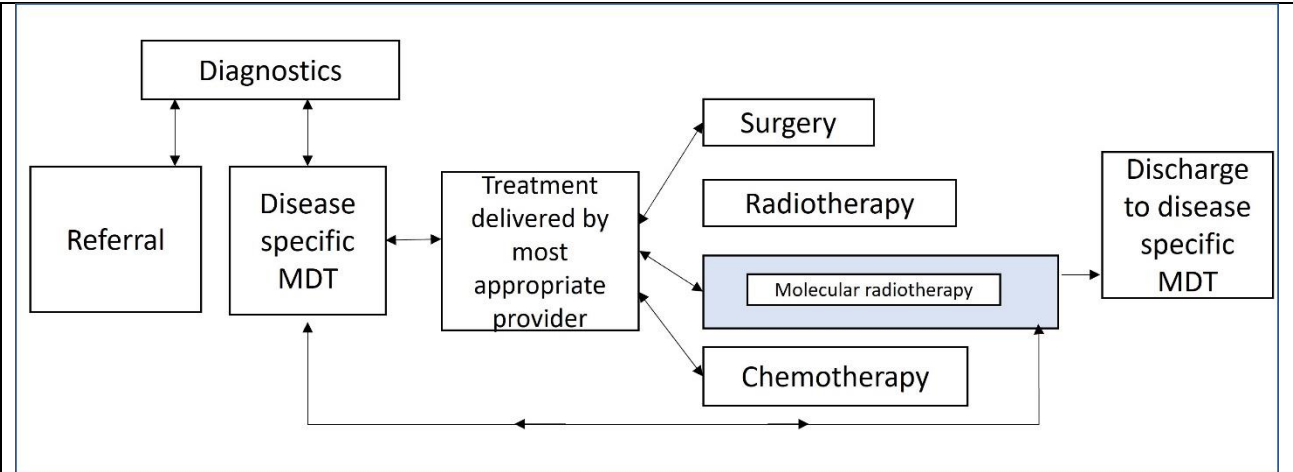
Paediatric MRT must only be delivered by a level 2 MRT provider at a designated paediatric centre working as part of a Children's Principal Treatment Centre and subspecialist paediatric cancer MDTs. The Service must:

- Have the appropriate MRT expertise, staffing and facilities for the treatment of children.
- Ensure that regular reviews are conducted to ensure that protocols remain up to date, and that staffing levels and skills mix are appropriate for the annual caseload.

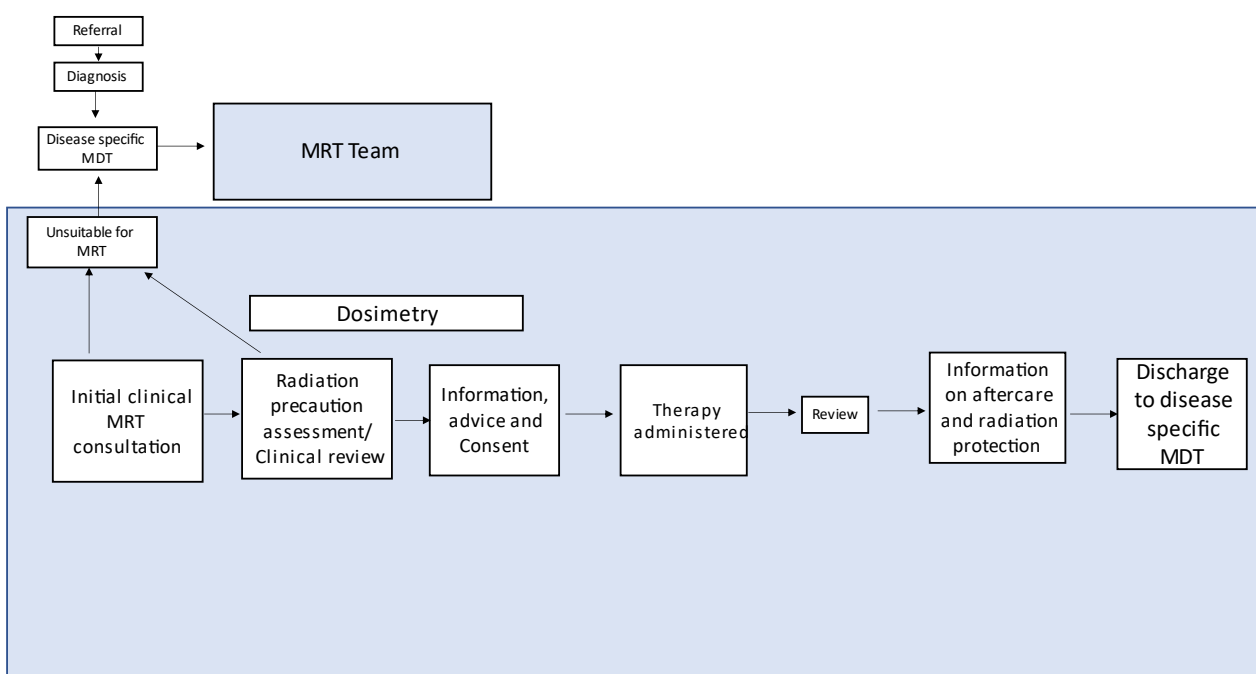
## **7.2 Pathways**

### Overall patient pathway

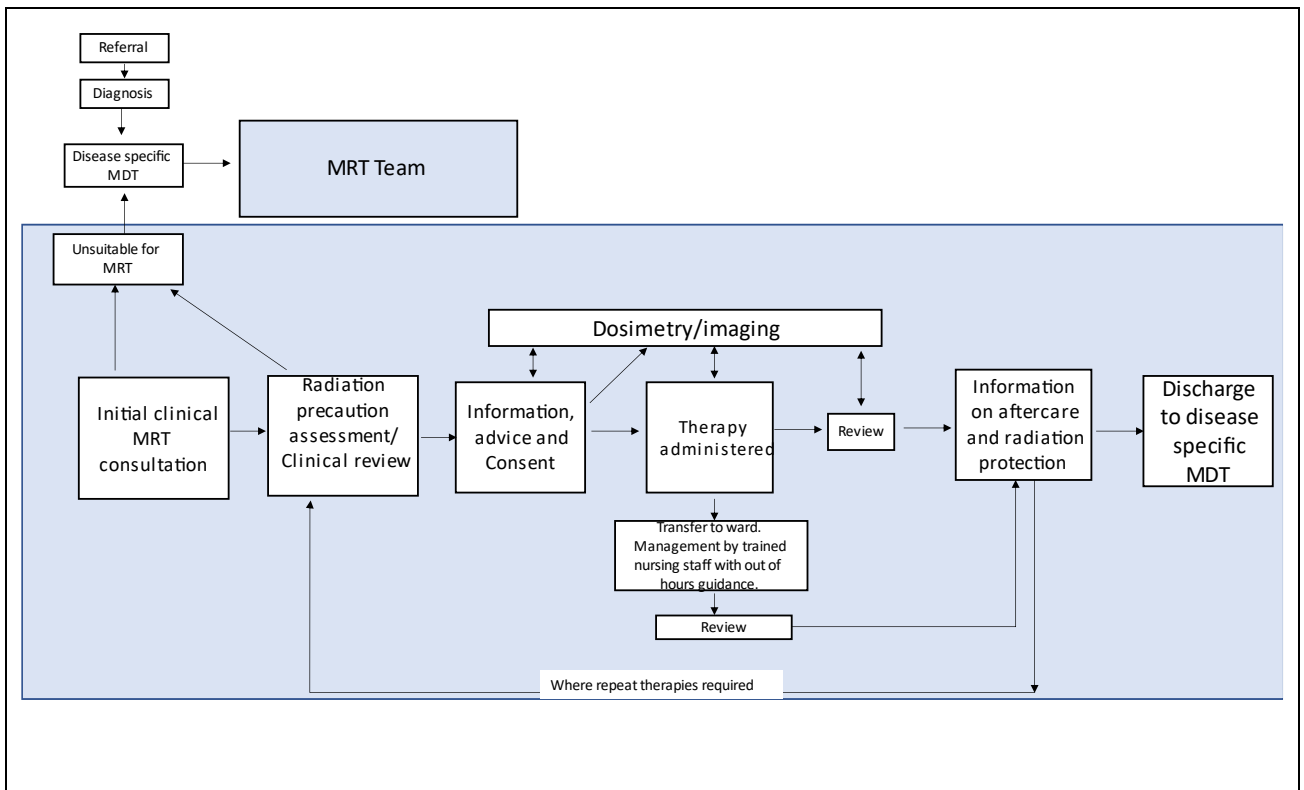
Level 1 and level 2 services



Specific patient pathway Level 1 services



Specific patient pathway Level 2,3 and paediatric services



### 7.3 Clinical Networks

There is a requirement for providers of this service to comply with the provisions of *Schedule 2F (Clinical Networks) of the NHS Standard Contract 2022/23 The Particulars*. This includes meeting the requirements of the *relevant* Specialised Services Clinical Network Specification.

All Providers will be required to participate in a networked model of care to enable services to be delivered as part of a co-ordinated, combined whole system approach.

Clinical Network	Link to 'published' network specification
Children's Cancer	<a href="https://www.england.nhs.uk/publications/1746-principal-treatment-centres-service-specification/">1746-principal-treatment-centres-service-specification-.pdf (england.nhs.uk)</a>
Teenage and Young Adult's Cancer	<a href="https://www.nhs.uk/healthcare-professionals/clinical-networks/teenage-and-young-adult-cancer-clinical-network-specification/">NHS England » Teenage and young adult cancer clinical network specification</a>
Radiotherapy	<a href="https://www.nhs.uk/healthcare-professionals/clinical-networks/operational-delivery-networks-external-beam-radiotherapy-services-adults/">Operational-Delivery-Networks-External-Beam-Radiotherapy-Services-adults</a>

### 7.4 Essential Staff Groups

The Provider must ensure that the service has sufficient appropriately trained staff to deliver a safe and effective MRT service that meets, regulatory and legislative requirements as well as activity. This includes the availability at all times of supervisory and specialist expertise as defined by regulatory requirements, set out in Section 7.1, including:

- A minimum of two ARSAC Licenced Practitioners.
- Radiation Protection Advisor.

- Radiation Protection Supervisor.
- Medical Physics Expert.
- Radioactive Waste Advisor.
- Radiographers/ clinical technologists (or technologists) (diagnostic and therapeutic), physicists / clinical scientists and/or oncologists/other clinical specialists as appropriate.
- Surgeons, where required.
- Nuclear medicine physicians/Nuclear medicine radiologist.
- Radiologists.

**Where delivering Level 3 Services, the Provider must also ensure that the Service has access to:**

- A minimum of two interventional radiology operators.
- A minimum of two ARSAC Licenced Practitioners able to deliver SIRT.
- A SIRT nurse co-ordinator.

**Where delivering Paediatric MRT, the Provider must also ensure that the Service has access to:**

- Paediatric clinical oncologists.
- Therapeutic radiographers with special expertise in paediatrics.
- Play specialists.

**7.5 Essential equipment and/or facilities**

All sites must have access to equipment and facilities sufficient to meet the requirements of ARSAC licensing for the MRT procedures undertaken. This will include, but is not limited to:

- Radiation monitors.
- Spill kits.
- Radiation protection services.
- Uptake rooms, shielded toilets and waiting areas.
- Designated outpatient facilities with shielded rooms and shielded toilets where appropriate.
- Essential equipment facilities to store, document and measure delivered doses of radiopharmaceuticals. Diagnostic imaging.

**Additional requirements for services delivering Level 2 activity:**

- Full resuscitation equipment including oxygen and suction.
- Designated inpatient facilities with shielded rooms and shielded toilets where appropriate.

**Additional requirements for services delivering Level 3 activity:**

- Interventional Radiology with capacity to support at least 10-20 cases per annum.
- Daycase accommodation, with access to overnight inpatient facilities for those service users that require it.
- Interventional radiology suite must be equipped with cone-beam CT.



**Additional requirements for delivering paediatric MRT:**

- Age-appropriate facilities for associated imaging under general anaesthetic, where required.
- Age-appropriate accommodation.
- Paediatric anaesthetic service.
- On-site paediatric resuscitation.

**7.6 Inter-dependant Service Components – Links with other NHS services**

<b>Interdependent Service</b>	<b>Relevant Service Specification/Standards</b>	<b>Proximity to service</b> (not applicable/co-located/same town/city)
PET-CT	PET-CT Service Specification [this is undergoing stakeholder testing; a link will be added when finalised]	Not applicable
Children’s Cancer Services	Children’s cancer services: Principal treatment centres service specification- <a href="https://www.england.nhs.uk/publications/1746-principal-treatment-centres-service-specification-pdf">1746-principal-treatment-centres-service-specification-.pdf (england.nhs.uk)</a>	Same town/city – if delivering paediatric MRT
Paediatric Anaesthesia	Guidelines for the Provision of Paediatric Anaesthesia Services 2020. <a href="https://www.rcoa.ac.uk/gpas-2020-10-paediatrics">GPAS-2020-10-PAEDIATRICALS.pdf (rcoa.ac.uk)</a>	Collocated – if delivering paediatric MRT
Teenage and Young Adult Cancer Services	Specialist cancer services for children and young people: teenage and young adults principal treatment centre services <a href="https://www.nhs.uk/healthcareprofessionals/specialist-cancer-services-for-children-and-young-people-teenage-and-young-adults-principal-treatment-centre-services">NHS England » Specialist cancer services for children and young people: teenage and young adults principal treatment centre services</a>  <a href="https://www.nhs.uk/healthcareprofessionals/specialist-cancer-services-for-children-and-young-people-teenage-and-young-adults-designated-hospitals">NHS England » Specialist cancer services for children and young people: teenage and young adults designated hospitals</a>	Not applicable
Paediatric Endocrinology	E03/S/e - Paediatric Medicine: Endocrinology & Diabetes. <a href="#">Paediatric Medicine: Endocrinology and Diabetes</a>	Same town/city
Dosimetry services		Not applicable

<p>Where SIRT is delivered by the MRT provider:</p> <p>Specialist Cancer Services (adults) Sub-heading: Hepato-Pancreatic Biliary (HPB) – Primary liver, secondary liver, perihilar biliary tract and gallbladder cancers.</p>	<p><b>TO BE ADDED – FOLLOWING APPROVAL OF THE DRAFT HPB – LIVER SPEC</b></p>	<p>Co-located – same provider.</p>
<p>Where SIRT is delivered by the MRT provider:</p> <p>Adult External Beam Radiotherapy Services Delivered as Part of a Radiotherapy Network</p>	<p><a href="#">Adult External Beam Radiotherapy Services Delivered as Part of a Radiotherapy Network</a></p>	<p>Same town/city</p>

### 7.7 Additional requirements

Not applicable.

### 7.8 Commissioned providers

The list of commissioned providers for the services covered by this specification are as follows: **[ADD LINK TO THE COMMISSIONED PROVIDER LIST ONCE AVAILABLE]**

### 7.9 Links to other key documents

Please refer to the [Prescribed Specialised Services Manual](#) for information on how the services covered by this specification are commissioned and contracted for.

Please refer to the [Identification Rules](#) tool for information on how the activity associated with the service is identified and paid for.

Please refer to the relevant Clinical Reference Group [webpages](#) for NHS England Commissioning Policies which define access to a service for a particular group of service users. The specific clinical policies that relate to the services covered by this service specification include:

- Selective internal radiation therapy for chemotherapy refractory intolerant metastatic colorectal cancer

### Relevant Professional Guidance

ARSAC notes for guidance: good clinical practice in nuclear medicine ([ARSAC notes for guidance: good clinical practice in nuclear medicine - GOV.UK \(www.gov.uk\)](https://www.gov.uk/guidance/good-clinical-practice-in-nuclear-medicine))

RCR molecular radiotherapy – guidance for clinicians ([Molecular radiotherapy: guidance for clinicians: report from the Intercollegiate Standing Committee on Nuclear Medicine | The Royal College of Radiologists \(rcr.ac.uk\)](https://www.rcr.ac.uk/molecular-radiotherapy-guidance-for-clinicians))

- Guidance on medical physics expert support for nuclear medicine (<https://www.birpublications.org/doi/full/10.1259/bjr.20211393>)

### Relevant NICE Guidance

- Thyroid cancer: assessment and management, National Institute of Health and Care Excellence (NICE) Guideline 230 (NG 230) (<https://www.nice.org.uk/guidance/ng230>)
- Thyroid disease: assessment and management NG 145 (<https://www.nice.org.uk/guidance/ng145>)
- Brain tumours (primary) and brain metastases in over 16s NG 99 ([Overview | Brain tumours \(primary\) and brain metastases in over 16s | Guidance | NICE](https://www.nice.org.uk/guidance/ng99))
- Colorectal cancer NG 151 ([Overview | Colorectal cancer | Guidance | NICE](https://www.nice.org.uk/guidance/ng151))
- Non-Hodgkin's lymphoma: diagnosis and management NG 52 ([Overview | Non-Hodgkin's lymphoma: diagnosis and management | Guidance | NICE](https://www.nice.org.uk/guidance/ng52))
- Lung cancer: diagnosis and management NG 122 ([Overview | Lung cancer: diagnosis and management | Guidance | NICE](https://www.nice.org.uk/guidance/ng122))
- Lutetium (177Lu) oxodotreotide for treating unresectable or metastatic neuroendocrine tumours NICE Technology Appraisal 539 (TA 539) ([Overview | Lutetium \(177Lu\) oxodotreotide for treating unresectable or metastatic neuroendocrine tumours | Guidance | NICE](https://www.nice.org.uk/guidance/ta539))
- Radium-223 dichloride for treating hormone-relapsed prostate cancer with bone metastases NICE TA 412 (<https://www.nice.org.uk/guidance/ta412/chapter/1-Recommendations>)
- Selective internal radiation therapies for treating hepatocellular carcinoma NICE TA 688 ([Overview | Selective internal radiation therapies for treating hepatocellular carcinoma | Guidance | NICE](https://www.nice.org.uk/guidance/ta688))

### Relevant National Clinical Guidance

- British Nuclear Medicine Society (BNMS), Clinical Guideline for Administration of Molecular Radiotherapy (<https://www.bnms.org.uk/page/BNMSClinicalGuidelines>)
- European Association of Nuclear Medicine (EANM) Guidelines for radioiodine therapy of differentiated thyroid cancer ([https://eanm.org/publications/guidelines/gl\\_radio\\_ther\\_259\\_883.pdf](https://eanm.org/publications/guidelines/gl_radio_ther_259_883.pdf))
- EANM Procedure guidelines for 131I-meta-iodobenzylguanidine (131I-mIBG) therapy ([EANM procedure guidelines for 131I-meta-iodobenzylguanidine \(131I-mIBG\) therapy](https://www.eanm.org/publications/guidelines/gl_131i_mibg_therapy.pdf))
- National Comprehensive Cancer Network (NCCN), Clinical practice guidelines in Oncology Neuroendocrine tumours ([http://www.nccn.org/professionals/physician\\_gls/pdf/neuroendocrine.pdf](http://www.nccn.org/professionals/physician_gls/pdf/neuroendocrine.pdf)) ([Guidelines for the management of gastroenteropancreatic neuroendocrine \(including carcinoid\) tumours \(NETs\) | Gut \(bmj.com\)](https://www.nccn.org/professionals/physician_gls/pdf/neuroendocrine.pdf))

- EANM Procedure guideline of radio-immunotherapy for B-cell lymphoma with 90Y radiolabelled ibritumomab tiuxetan ([https://www.eanm.org/publications/guidelines/gl\\_radio\\_ther\\_radioimmun.pdf](https://www.eanm.org/publications/guidelines/gl_radio_ther_radioimmun.pdf))  
([https://www.eanm.org/publications/guidelines/gl\\_radio\\_ther\\_radioimmun.pdf](https://www.eanm.org/publications/guidelines/gl_radio_ther_radioimmun.pdf))
- EANM procedure guideline for treatment of refractory metastatic bone pain ([https://www.eanm.org/publications/guidelines/gl\\_radio\\_treatment.pdf](https://www.eanm.org/publications/guidelines/gl_radio_treatment.pdf))
- EANM procedure guideline for 32P phosphate treatment of myeloproliferative diseases ([https://www.eanm.org/publications/guidelines/gl\\_radio\\_ther\\_32p.pdf](https://www.eanm.org/publications/guidelines/gl_radio_ther_32p.pdf))
- EANM procedure guideline for the treatment of liver cancer and liver metastases with intra-arterial radioactive compounds ([https://www.eanm.org/publications/guidelines/EANM\\_liver\\_treatment\\_guidelines\\_2012.pdf](https://www.eanm.org/publications/guidelines/EANM_liver_treatment_guidelines_2012.pdf))
- Management of thyroid cancer: United Kingdom National Multidisciplinary Guidelines (<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4873931/>)