

## SCHEDULE 2 – THE SERVICES

### A. Service Specifications

<b>Service Specification No.</b>	D05/S/a
<b>Service</b>	Stereotactic Radiosurgery and Stereotactic Radiotherapy (Intracranial) (All Ages)
<b>Commissioner Lead</b>	Kim Fell
<b>Provider Lead</b>	
<b>Period</b>	7 years
<b>Date of Review</b>	

#### 1. Population Needs

##### 1.1 National/local context and evidence base

Stereotactic radiosurgery (SRS) and stereotactic radiotherapy (SRT) are methods of delivering doses of precisely targeted cranial radiotherapy treatment. For the purposes of this specification SRS is a highly conformal radiotherapy treatment to a precisely delineated target volume. SRS is delivered using stereotactic localisation techniques. SRS is delivered in 1 fraction. A multidisciplinary team of neurosurgeons, neuro-oncologists and neuro-radiologists will be involved in SRS case selection, treatment planning and delivery.

SRT is a highly conformal hypo-fractionated radiotherapy treatment to a precisely delineated target volume, delivered using stereotactic localisation techniques. For the purposes of this specification SRT is delivered in 2 to 5 fractions only. A multidisciplinary team of neurosurgeons, neuro-oncologists and neuro-radiologists will be involved in SRT case selection, treatment planning and delivery.

Patients of all ages may benefit from SRS/SRT. The treatment is usually carried out with the patient awake and therefore the patient needs to be compliant. Young children and non-compliant adults can be treated using general anaesthesia, but only within the SRS/SRT providers designated to deliver paediatric SRS/SRT services.

Stereotactic Radiosurgery and Stereotactic Radiotherapy can be provided using one of several technologies. This service specification covers SRS/SRT whether delivered by Gamma Knife, Cyberknife or any other high specification modified linear accelerator-based technology (LINAC). Providers involved in the provision of these services must also have access to technologies with up-to-date dose planning and treatment planning systems.

This specification applies to services delivering SRS/SRT for the treatment of cranial indications and which will identify the activity using Office of Population Censuses and Surveys (OPCS) code A10.7 (stereotactic radiosurgery to tissue of brain) in combination with the appropriate International statistical classification of diseases and related health problems (ICD-10) diagnostic code.

There is evidence to support the use of stereotactic radiosurgery for a wide range of cranial indications including arteriovenous malformations, acoustic neuroma, meningioma, pituitary adenoma, ocular melanoma, trigeminal neuralgia and selected sub-groups of patients with cerebral metastases.

The prevalence of these conditions varies from less than one per 100,000 population to up to 30 per 100,000 though not all cases will be suitable for treatment with stereotactic radiosurgery. For example, it is estimated that the prevalence of patients with cerebral metastases suitable for treatment

with SRS is between 3 and 4 per 100,000.

**The evidence base for the service specification is drawn from**

- The clinical and cost effectiveness of stereotactic radiosurgery and fractionated stereotactic radiotherapy for arteriovenous malformations: an evidence based review , Pennant, Bayliss, Routh, Moore, West Midlands Health Technology Collaboration, University of Birmingham, 31/3/10
- The clinical and cost-effectiveness of stereotactic radiosurgery and fractionated stereotactic radiotherapy for acoustic neuromas: an evidence based review, Greenheld, Fry-Smith, Routh, Moore, Unit of Public Health and Epidemiology, University of Birmingham, 1/4/10
- The clinical and cost-effectiveness of stereotactic radiosurgery and fractionated stereotactic radiotherapy for pituitary adenomas: an evidence based review, Greenheld, Fry-Smith, Routh, Moore, Unit of Public Health and Epidemiology, University of Birmingham, 8/6/10
- The clinical and cost-effectiveness of stereotactic radiosurgery and fractionated stereotactic radiotherapy for trigeminal neuralgia: an evidence based review, Dretzke, Fry-Smith, Routh, Moore, Unit of Public Health and Epidemiology, University of Birmingham, 3/6/10
- Solberg TD, Medin PM, Mullins J, Li S. Quality assurance of immobilization and target localization systems for frameless stereotactic cranial and extracranial hypofractionated radiotherapy. *Int J Radiat Oncol Biol Phys.* 2008;71(1 Suppl):S131-5
- Palta JR, Liu C, Li JG. Current external beam radiation therapy quality assurance guidance: does it meet the challenges of emerging image- guided technologies? *Int J Radiat Oncol Biol Phys.* 2008;71(1 Suppl):S13-7
- Galvin JM, Bednarz G. Quality assurance procedures for stereotactic body radiation therapy. *Int J Radiat Oncol Biol Phys.* 2008;71(1 Suppl):S122-5
- Das IJ, Cheng CW, Watts RJ, Ahnesjö A, Gibbons J, Li XA, Lowenstein J, Mitra RK, Simon WE, Zhu TC; TG-106 of the Therapy Physics Committee of the AAPM. Accelerator beam data commissioning equipment and procedures: report of the TG-106 of the Therapy Physics Committee of the AAPM. *Med Phys.* 2008 Sep;35(9):4186-215
- The clinical and cost-effectiveness of stereotactic radiosurgery and fractionated stereotactic radiotherapy for trigeminal neuralgia: an evidence based review; A West Midlands Health Technology Assessment Collaboration Report Dretzke, Fry-Smith, Routh, Moore June 2010 Health Technology
- The clinical and cost-effectiveness of stereotactic radiosurgery and fractionated stereotactic radiotherapy for arteriovenous malformations: an evidence based review; A West Midlands Health Technology Assessment Collaboration Report Pennant, Bayliss, Routh, Moore March 2010
- The clinical and cost-effectiveness of stereotactic radiosurgery and fractionated stereotactic radiotherapy for cavernous haemangioma: an evidence based review; A West Midlands Health Technology Assessment Collaboration Report Bayliss, Routh, Moore June 2010
- The clinical and cost-effectiveness of stereotactic radiosurgery and fractionated stereotactic radiotherapy for acoustic neuroma: an evidence based review; A West Midlands Health Technology Assessment Collaboration Report Greenheld, Fry-Smith, Routh, Moore April 2010
- The clinical and cost-effectiveness of stereotactic radiosurgery and fractionated stereotactic radiotherapy for meningiomas: an evidence based review; A West Midlands Health Technology Assessment Collaboration Report Uthman, Fry-Smith, Routh, Moore September 2010
- The clinical and cost-effectiveness of stereotactic radiosurgery and fractionated stereotactic radiotherapy for ocular melanoma: an evidence based review; A West Midlands Health Technology Assessment Collaboration Report; Uthman, Fry-Smith, Routh, Moore September 2010
- The clinical and cost-effectiveness of stereotactic radiosurgery and fractionated stereotactic radiotherapy for pituitary adenomas: an evidence based review; A West Midlands Health Technology Assessment Collaboration Report; Greenheld, Fry-Smith, Routh, Moore June 2010
- Additional competence training in neurosurgical (Stereotactic) radiosurgery; Kemeny A, Reulen HJ, Cunha É Sa M, Trojanowski T; *Acta Neurochir (Wien).* 2012 May;154(5):941-5
- B01/S/a Radiotherapy NHS England
- B01/S/b Brachytherapy and Molecular Radiotherapy NHS England
- B17/S/a Cancer: Teenagers and Young Adults
- Joint Collegiate Clinical Oncology guidelines (published, 1999)
- Ionising Radiation (Medical Exposure) Regulations (IRMER) 2000.

## 2. Outcomes

### 2.1 NHS Outcomes Framework Domains & Indicators

The Commissioner and the Provider agree that for the first year of the contract (i.e. up to 31 March 2017), the consequences of breach listed shall not be applied by the Commissioner, however the Provider must provide the relevant data in order to measure the Quality Requirements ("QR"). Such data will then be used to revise the thresholds from 1 April 2017 onwards.

Quality Requirement	Threshold	Method of Measurement	Consequence of breach
<b>Domain 1: Preventing people dying prematurely</b>			
<p><b>Insert text</b> All SRS/SRT services should ensure mechanisms are in place for accurate data submission to the ongoing national neurosurgery audit programme and RTDS</p>	>90%	<p>% Collection and submission of the mandated national radiotherapy dataset (RTDS)</p> <p>% Collection of data to Neurosurgical National Audit Programme (NNAP)</p> <p>Compliance with the Quality Surveillance Programme for radiotherapy services</p>	<p>Provider to draft a QR remedial action plan and provide this to the Commissioner within 10 Operational Days of a request by the Commissioner setting out (i) how it will achieve compliance with the Quality Requirement; and (ii) the timescales for achieving such compliance. Such QR remedial action plan shall be agreed by the Commissioner, including any amendments that the Commissioner reasonably requires.</p> <p>Where the Provider breaches the QR remedial action plan, the Commissioner shall be entitled to issue an Exception Report in accordance with General Condition 9.20.</p>
Required activity levels are met	<p>&gt;100 Tier 1 / 2 cases per year per delivery team</p> <p>Number and type of patients treated at Tier 3 / Tier 4 per year</p> <p>Number of paediatric oncology patients treated per year</p>	NNAP/RTDS - Volumes of activity	Provider to draft a QR remedial action plan and provide this to the Commissioner within 10 Operational Days of a request by the Commissioner setting out (i) how it will achieve compliance with the Quality Requirement; and (ii) the timescales for achieving such compliance. Such QR remedial action plan shall be agreed by the Commissioner, including

<p>There are agreed patient pathways in place for</p> <p>Neuro-oncology (tier 1) Skull base(tier2) Pituitary (tier2)</p> <p>Vascular (tier 3) Non tumour indications (tier 4)</p>	<p>100% of pathways submitted</p> <p>Statistical outlier</p>	<p>Pathways submitted for review</p> <p>Proportion of patients in whom the MDT outcome has been communicated to the referring consultant/MDT and the General Practitioner (GP) within 2 days.</p> <p>RTDS/NNAP: Proportion of patients with malignant disease for SRS that have clinical review within 1 week of the Neurosciences (Neuro-oncology) MDT meeting.</p> <p>RTDS/NNAP: Proportion of patients with malignant disease who had treatment with SRS delivered within 2 weeks of decision to treat (in clinic)</p> <p>RTDS/NNAP: Proportion of patents with benign disease treated within the current referral to treatment recommendations</p>	<p>any amendments that the Commissioner reasonably requires.</p> <p>Where the Provider breaches the QR remedial action plan, the Commissioner shall be entitled to issue an Exception Report in accordance with General Condition 9.20.</p>
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Metastases control	Statistical outlier	<p>NNAP/RTDS: number of tumours treated and volumes</p> <p>NNAP/RTDS: overall survival</p> <p>NNAP/RTDS: histology, systemic disease status</p>	<p>Provider to draft a QR remedial action plan and provide this to the Commissioner within 10 Operational Days of a request by the Commissioner setting out (i) how it will achieve compliance with the Quality Requirement; and (ii) the timescales for achieving such compliance. Such QR remedial action plan shall be agreed by the Commissioner, including any amendments that the Commissioner reasonably requires.</p> <p>Where the Provider breaches the QR remedial action plan, the Commissioner shall be entitled to issue an Exception Report in accordance with General Condition 9.20.</p>
Survival and Mortality	Statistical outlier	Death within 30 days of treatment	<p>Provider to draft a QR remedial action plan and provide this to the Commissioner within 10 Operational Days of a request by the Commissioner setting out (i) how it will achieve compliance with the Quality Requirement; and (ii) the timescales for achieving such compliance. Such QR remedial action plan shall be agreed by the Commissioner, including any amendments that the Commissioner reasonably requires.</p> <p>Where the Provider breaches the QR remedial action plan, the Commissioner shall be entitled to issue an Exception Report in accordance with General Condition 9.20.</p>

Survival and Mortality	Statistical outlier	NNAP: Proportion of patients treated with SRS/T with WHO performance status 2 or worse (Or KPS <70).	<p>Provider to draft a QR remedial action plan and provide this to the Commissioner within 10 Operational Days of a request by the Commissioner setting out (i) how it will achieve compliance with the Quality Requirement; and (ii) the timescales for achieving such compliance. Such QR remedial action plan shall be agreed by the Commissioner, including any amendments that the Commissioner reasonably requires.</p> <p>Where the Provider breaches the QR remedial action plan, the Commissioner shall be entitled to issue an Exception Report in accordance with General Condition 9.20.</p>
Survival and Mortality	Statistical outlier	NNAP: % of patients with delayed swelling causing symptoms or requiring treatment including radio-necrosis	<p>Provider to draft a QR remedial action plan and provide this to the Commissioner within 10 Operational Days of a request by the Commissioner setting out (i) how it will achieve compliance with the Quality Requirement; and (ii) the timescales for achieving such compliance. Such QR remedial action plan shall be agreed by the Commissioner, including any amendments that the Commissioner reasonably requires.</p> <p>Where the Provider breaches the QR remedial action plan, the Commissioner shall be entitled to issue an Exception Report in accordance with General Condition 9.20.</p>

Survival and Mortality	Statistical outlier	<p>NNAP: Percentage of patients that develop a permanent neurological deficit following treatment</p>	<p>Provider to draft a QR remedial action plan and provide this to the Commissioner within 10 Operational Days of a request by the Commissioner setting out (i) how it will achieve compliance with the Quality Requirement; and (ii) the timescales for achieving such compliance. Such QR remedial action plan shall be agreed by the Commissioner, including any amendments that the Commissioner reasonably requires.</p> <p>Where the Provider breaches the QR remedial action plan, the Commissioner shall be entitled to issue an Exception Report in accordance with General Condition 9.20.</p>
Survival and Mortality	Statistical outlier	<p>NNAP: Percentage of patients requiring re treatment or alternative treatment</p> <p>For tumours and vascular we need volume, method of treatment, dosage, etc, post treatment volumes with time</p>	<p>Provider to draft a QR remedial action plan and provide this to the Commissioner within 10 Operational Days of a request by the Commissioner setting out (i) how it will achieve compliance with the Quality Requirement; and (ii) the timescales for achieving such compliance. Such QR remedial action plan shall be agreed by the Commissioner, including any amendments that the Commissioner reasonably requires.</p> <p>Where the Provider breaches the QR remedial action plan, the Commissioner shall be entitled to issue an Exception Report in accordance with General Condition 9.20.</p>

Domain 2: Enhancing the quality of life of people with long-term conditions			
<p>AVM/cavernoma</p> <p>Obliteration of AVM</p>	<p>Statistical outlier</p>	<p>NNAP: Percentage of patients requiring re treatment or alternative treatment</p> <p>NNAP: % of patients with complete obliteration of AVM on 3 year angiogram</p> <p>NNAP: % of cases with re-bleeding after treatment</p>	<p>Provider to draft a QR remedial action plan and provide this to the Commissioner within 10 Operational Days of a request by the Commissioner setting out (i) how it will achieve compliance with the Quality Requirement; and (ii) the timescales for achieving such compliance. Such QR remedial action plan shall be agreed by the Commissioner, including any amendments that the Commissioner reasonably requires.</p> <p>Where the Provider breaches the QR remedial action plan, the Commissioner shall be entitled to issue an Exception Report in accordance with General Condition 9.20.</p>
<p>Pituitary adenoma control</p>	<p>Statistical outlier</p>	<p>NNAP: Pituitary function pre and post</p> <p>NNAP: % of patients with endocrine tumours with normalisation after treatment</p> <p>NNAP: visual field and visual acuity deficits pre and post treatment</p>	<p>Provider to draft a QR remedial action plan and provide this to the Commissioner within 10 Operational Days of a request by the Commissioner setting out (i) how it will achieve compliance with the Quality Requirement; and (ii) the timescales for achieving such compliance. Such QR remedial action plan shall be agreed by the Commissioner, including any amendments that the Commissioner reasonably requires.</p> <p>Where the Provider breaches the QR remedial action plan, the Commissioner shall be entitled to issue an Exception Report in</p>



			accordance with General Condition 9.20.
Improvement in facial pain in patients with trigeminal neuralgia	Statistical outlier	<p>NNAP: Patient reported reduction in level of pain compared to pre-treatment measurement within 1 year of treatment</p> <p>NNAP: % Requirement for ongoing medication</p> <p>NNAP: Incidence of numbness</p> <p>NNAP: Requirements for other treatments</p>	<p>Provider to draft a QR remedial action plan and provide this to the Commissioner within 10 Operational Days of a request by the Commissioner setting out (i) how it will achieve compliance with the Quality Requirement; and (ii) the timescales for achieving such compliance. Such QR remedial action plan shall be agreed by the Commissioner, including any amendments that the Commissioner reasonably requires.</p> <p>Where the Provider breaches the QR remedial action plan, the Commissioner shall be entitled to issue an Exception Report in accordance with General Condition 9.20.</p>
Quality of Life	Statistical outlier	<p>NNAP: QOL/PS before treatment and 6 and 12 months after treatment</p>	<p>Provider to draft a QR remedial action plan and provide this to the Commissioner within 10 Operational Days of a request by the Commissioner setting out (i) how it will achieve compliance with the Quality Requirement; and (ii) the timescales for achieving such compliance. Such QR remedial action plan shall be agreed by the Commissioner, including any amendments that the Commissioner reasonably requires.</p> <p>Where the Provider breaches the QR remedial action plan, the Commissioner shall be entitled to issue an Exception Report in</p>

			accordance with General Condition 9.20.
Meningioma control	Statistical outlier	<p>NNAP: Tumour control rate at 2 and 5 years</p> <p>NNAP: % of patients with requirement for other treatments</p>	<p>Provider to draft a QR remedial action plan and provide this to the Commissioner within 10 Operational Days of a request by the Commissioner setting out (i) how it will achieve compliance with the Quality Requirement; and (ii) the timescales for achieving such compliance. Such QR remedial action plan shall be agreed by the Commissioner, including any amendments that the Commissioner reasonably requires.</p> <p>Where the Provider breaches the QR remedial action plan, the Commissioner shall be entitled to issue an Exception Report in accordance with General Condition 9.20.</p>
Skull base tumour control	Statistical outlier	<p>NNAP: Cranial nerve deficits pre and post, including hearing and facial nerve function and numbness</p> <p>NNAP: Tumour control rate at 2 and 5 years</p>	<p>Provider to draft a QR remedial action plan and provide this to the Commissioner within 10 Operational Days of a request by the Commissioner setting out (i) how it will achieve compliance with the Quality Requirement; and (ii) the timescales for achieving such compliance. Such QR remedial action plan shall be agreed by the Commissioner, including any amendments that the Commissioner reasonably requires.</p> <p>Where the Provider breaches the QR remedial action plan, the Commissioner shall be entitled to issue an Exception Report in</p>

			accordance with General Condition 9.20.
<b>Domain 3: Helping people to recover from episodes of ill-health or following injury</b>			
Dependence on steroids	Statistical outlier	NNAP: % requirement for steroids post SRS	<p>Provider to draft a QR remedial action plan and provide this to the Commissioner within 10 Operational Days of a request by the Commissioner setting out (i) how it will achieve compliance with the Quality Requirement; and (ii) the timescales for achieving such compliance. Such QR remedial action plan shall be agreed by the Commissioner, including any amendments that the Commissioner reasonably requires.</p> <p>Where the Provider breaches the QR remedial action plan, the Commissioner shall be entitled to issue an Exception Report in accordance with General Condition 9.20.</p>
<b>Domain 4: Ensuring that people have a positive experience of care</b>			
Patient satisfaction	>50%	% of patients completing the Family Friendly Test	<p>Provider to draft a QR remedial action plan and provide this to the Commissioner within 10 Operational Days of a request by the Commissioner setting out (i) how it will achieve compliance with the Quality Requirement; and (ii) the timescales for achieving such compliance. Such QR remedial action plan shall be agreed by the Commissioner, including any amendments that the Commissioner reasonably requires.</p> <p>Where the Provider breaches the QR</p>

			remedial action plan, the Commissioner shall be entitled to issue an Exception Report in accordance with General Condition 9.20.
Patient satisfaction	>90 % recommend  <5% do not	% of patients who recommend the service and % who do not recommend	<p>Provider to draft a QR remedial action plan and provide this to the Commissioner within 10 Operational Days of a request by the Commissioner setting out (i) how it will achieve compliance with the Quality Requirement; and (ii) the timescales for achieving such compliance. Such QR remedial action plan shall be agreed by the Commissioner, including any amendments that the Commissioner reasonably requires.</p> <p>Where the Provider breaches the QR remedial action plan, the Commissioner shall be entitled to issue an Exception Report in accordance with General Condition 9.20.</p>
Patient satisfaction		% patients recruited into trials	<p>Provider to draft a QR remedial action plan and provide this to the Commissioner within 10 Operational Days of a request by the Commissioner setting out (i) how it will achieve compliance with the Quality Requirement; and (ii) the timescales for achieving such compliance. Such QR remedial action plan shall be agreed by the Commissioner, including any amendments that the Commissioner reasonably requires.</p> <p>Where the Provider breaches the QR</p>

			remedial action plan, the Commissioner shall be entitled to issue an Exception Report in accordance with General Condition 9.20.
<b>Domain 5: Treating and caring for people in a safe environment and protecting them from avoidable harm</b>			
Providers will be expected to ensure that the consequent “whole body dose” should be kept to a minimum appropriate to the condition and patient group being treated.	100% TYA treated using lowest possible whole body dose	NNAP/RTDS: Number of TYA patients treated in the year.  Number of patients referred to an alternative centre by indication	Provider to draft a QR remedial action plan and provide this to the Commissioner within 10 Operational Days of a request by the Commissioner setting out (i) how it will achieve compliance with the Quality Requirement; and (ii) the timescales for achieving such compliance. Such QR remedial action plan shall be agreed by the Commissioner, including any amendments that the Commissioner reasonably requires.  Where the Provider breaches the QR remedial action plan, the Commissioner shall be entitled to issue an Exception Report in accordance with General Condition 9.20.
Accurate treatment, delivered in the context of a safety-conscious culture.  There is a departmental QA process in place	100%  100%  Statistical outlier	The Pre-assessment RT QA process has been completed  % of medical staff treating SRS/T assessed as part of the RTQA process  Number and percentage of adverse events, errors or near misses for the year and reports to IRMER	Provider to draft a QR remedial action plan and provide this to the Commissioner within 10 Operational Days of a request by the Commissioner setting out (i) how it will achieve compliance with the Quality Requirement; and (ii) the timescales for achieving such compliance. Such QR remedial action plan shall be agreed by the Commissioner, including any amendments that the Commissioner

	Statistical outlier	Number of complaints per year	reasonably requires.  Where the Provider breaches the QR remedial action plan, the Commissioner shall be entitled to issue an Exception Report in accordance with General Condition 9.20.
MDT membership and attendance	All core members present at >75% MDTMs  >95%	Breakdown of core members and attendance  % of patients discussed in appropriate MDT before SRS MDTm	Provider to draft a QR remedial action plan and provide this to the Commissioner within 10 Operational Days of a request by the Commissioner setting out (i) how it will achieve compliance with the Quality Requirement; and (ii) the timescales for achieving such compliance. Such QR remedial action plan shall be agreed by the Commissioner, including any amendments that the Commissioner reasonably requires.  Where the Provider breaches the QR remedial action plan, the Commissioner shall be entitled to issue an Exception Report in accordance with General Condition 9.20.

### Monitoring of activity and outcomes

The 62-day and 31-day national targets for the management of oncology treatments using SRS/SRT will be embedded within all SRS/SRT services – Domains 1, 2, 3, 4.

### 3. Scope

#### 3.1 Aims and objectives of SRS/SRT service

##### Aims and objectives of service

The clinical and service model aims to:

- Improve both life expectancy and quality of life for patients that meet the requirements of the national commissioning policy for Stereotactic Radiosurgery/Radiotherapy (SRS/SRT).
- Ensure patients have equitable access to high quality SRS/SRT treatment and care appropriate to the condition being treated.
- Ensure the quality and safety of SRS/SRT services

The Provider must deliver the following objectives to meet these aims:

- Make accurate diagnosis and assessment of the suitability and deliverability of SRS/SRT in the context of each patient's overall management plan;
- Provide safe services which comply with recommendations and regulations as detailed in section 3.2 of this document;
- Enable equitable access through compliance with national clinical commissioning policies;
- Work with network partners to ensure that all eligible patients, as set out within published national clinical commissioning policies, are identified and offered SRS/SRT treatment maximising case ascertainment.
- Provide timely access through compliance with national waiting times requirements.
- Contribute to the ongoing national neurosurgery audit programme.
- Provide high quality radiotherapy delivery as follows:
  - Providing accurate treatment, delivered in the context of a safety-conscious culture.
  - Taking an evidence based approach to treatment delivery, according to locally agreed protocols.
  - Ensuring strong clinical and operational governance arrangements
  - Ensuring that treatment is received in a timely manner for all patients with cancer who require radiotherapy (including urgent and palliative radiotherapy) as part of their treatment
  - Ensuring appropriate planning and treatment systems to ensure and verify geographical and dosimetric accuracy of treatment
  - Ensuring adequate radiotherapy capacity to meet the current demand and improve patients' experience.
  - Ensuring that the consequent "whole body dose" should be kept to a minimum appropriate to the condition and patient group being treated.
  - Minimising any long-term side effects of treatment.
  - Ensuring that the information included in the mandated national radiotherapy dataset (RTDS) must be collected and submitted according to national requirements.
  - Having robust mechanisms in place for monitoring treatment outcomes.
  - Participation in the NHS England Quality Surveillance Programme for radiotherapy and SRS/SRT national audits, plans to address any shortcomings should be produced and results acted upon.
  - Where any radiotherapy is used concurrently with other treatments (such as chemotherapy), it should be integrated appropriately and scheduled to meet patients' needs.
  - Radiotherapy is accessible to all patients with all clinical indications who require it regardless of gender, age, ethnicity, disability, religion or belief, sexual orientation or any other non-medical characteristics.
  - Patients should have access to clinical trials if eligible and should be discussed with them where appropriate.

This is set out in 'A Commissioning Framework for External Beam Radiotherapy Services' available on the National Cancer Action Team website (<http://www.ncat.nhs.uk/our-work/ensuring-better-treatment/radiotherapy>). This framework should be used to inform the detail within this specification

### **3.2 Service description/care pathway**

#### **3.2.1 Overview**

Historically, stereotactic radiosurgery has been developed and delivered as part of a neurosurgery dedicated Gamma Knife facility. This approach was established many years ago in order to concentrate expertise in a small number of centres in England and focused on the treatment of a very limited range of complex, rare and generally benign clinical conditions.

The expected increase in the number of patients' eligible for intracranial stereotactic radiosurgery and radiotherapy, particularly for cancer patients with cerebral metastases, is an area where designing a service model that provides a more locally accessible service for these patients is needed.

In recent years, manufacturers of radiotherapy equipment have developed machines capable of delivering precision-based stereotactic techniques able to deliver stereotactic treatment to either the body or the head. The increasing use of stereotactic treatment techniques within a radiotherapy service setting using high specification modified linear accelerators or Cyberknife now offers opportunities for more local provision for some patients.

A service that has developed the broader expertise in the use of stereotactic techniques in the treatment of both tumours within and outside of the brain has the potential to offer a clinically equivalent alternative to a dedicated stereotactic radiosurgery facility.

In drawing together the advances in technology, broader patient eligibility and concentration of expertise and service integration between neurosurgery and oncology, the service model balances the current and future needs of patients, including access, whilst achieving optimum clinical outcomes for patients.

### **3.2.2 Defining Complexity and Rarity**

A number of Improving Outcomes Guidance documents for rarer tumours describe a population based requirement to ensure that clinical teams treat a minimum volume of patients as a way of improving patient outcomes through competency. The total number of patients receiving SRS/SRT in 2014/15 was 2300. It is expected that up to 6200 patients per year will access this form of treatment based on the published NHS England clinical commissioning policies and policy statements.

These are:

- D05/PS/a Clinical commissioning policy statement: Stereotactic radiosurgery/radiotherapy for ocular melanoma and pituitary adenoma
- D05/P/e Clinical commissioning policy: Stereotactic radiosurgery/radiotherapy for Meningioma
- D05/P/f Clinical commissioning policy: Stereotactic radiosurgery/radiotherapy for Glomus Tumours
- D05/P/g Clinical commissioning policy: Stereotactic radiosurgery/radiotherapy for Cavernous venous malformations
- D05/P/a Clinical commissioning policy: Stereotactic radiosurgery/radiotherapy for Vestibular Schwannoma and Other cranial nerve tumours
- D05/P/b Clinical commissioning policy: Stereotactic radiosurgery/radiotherapy for Trigeminal Neuralgia
- D05/P/c Clinical commissioning policy: Stereotactic radiosurgery/radiotherapy for Cerebral Arteriovenous Malformations
- D05/P/d Clinical commissioning policy: Stereotactic radiosurgery/radiotherapy for Cerebral metastases

A 4 tier clinical model (Table 1) has been developed and is based on established patient pathways and the complexity and rarity of the clinical indications that can be treated with SRS/SRT. The clinical model will be delivered through a service model consisting of:

- Services which deliver Tier 1 and Tier 2 activity for adults and TYA are based on existing neurosciences networks that have a population footprint of at least 2 million in order to deliver a minimum of 100 SRS/SRT cases per year, per delivery site and treatment platform;



- Where there are extremely remote geographical areas and a service is delivering Tier 1 and Tier 2 activity out of more than one geographical site, the Provider must evidence an agreement in place that clearly defines:
  - a) The cohort and number of patients to be treated at each delivery site and treatment platform.
  - b) The arrangements describing the fully functional MDT arrangements in place at both sites.
  - c) The arrangements to ensure that each delivery site and treatment platform delivers a minimum of 100 cases per year.
  - d) Joint clinical protocols.
  - e) Quarterly clinical audit and service review meetings to cover as a minimum: (i) performance and quality outcomes; (ii) casemix; (iii) audit of treatments; (iv) Protocols and policies; and (v) critical incidents and near misses.
  - f) The joint service will submit a single set of all required returns, such as contract and data monitoring and quality and performance.
  
- Where a Provider is delivering Tier 3 and Tier 4 activity (adults and children), because these clinical conditions are rare, these services will be based on a further grouping of neurosciences networks and are therefore considered to be 'supra-network'. In order to achieve and maintain expertise and critical mass, Providers selected to deliver Tier 3 and Tier 4 activity must also deliver Tier 1 and Tier 2 activity to the standards listed within this specification for Tier 1 and Tier 2 activity.
  
- A Provider that is commissioned to treat the very rare and complex paediatric neuro-oncology patients must also deliver Tier 1 and Tier 2 activity. Paediatric neuro-oncology patients will be treated by Providers that also host paediatric neuro-oncology MDTs.

**Table1: The Clinical Model**

Tier 1 activity (neuro-oncology)	Deemed to be of lower complexity and able to be carried out in most, larger co-located (same city or as part of a broader strategic alliance) neurosurgery & (neuro) clinical oncology units to ensure integrated working between the full team. This includes cerebral metastases and non-skull base meningiomas and follows the patient pathway for patients via a regional adult neuroscience (neuro-oncology) MDT and in conjunction with TYA MDTs and pathways
Tier 2 activity (skull-base & pituitary)	Includes tumours such as Vestibular Schwannoma, meningioma, etc requiring co-location with a full skull-base team and following the patient pathway via a regional (adult) skull-base MDT in a neurosurgical centre. Pituitary (adult) indications require full pituitary MDT. Together with tier one this should allow >100 procedures per year, per delivery site and treatment platform.
Tier 3 activity (Vascular)	Includes cases such as Cerebral Arteriovenous Malformations and cavernomas. Requiring co-location with

	a full vascular MDT and full imaging support services, such as Digital Subtraction Angiography
Tier 4 activity (other non-tumour indications)	Includes trigeminal neuralgia. Lower volume; best carried out in fewer centres, enabling appropriate staffing skill-mix, MDT support, co-located services and appropriate equipment. Requires co-location of relevant MDTs – functional, epilepsy, pain services

NB Any patients approved for IFR funding for any other indication including “lesioning” for movement disorders, epilepsy, and pain should be managed as part of Tier 4. It is likely that should any such new clinical commissioning policies be agreed by NHS England they are likely to be Tier 4 but consideration will be made for tumour cases to align with the clinical and MDT pathways described in Tier 1 & 2.

### 3.2.3 Clinical Pathway for Tier 1 and 2

Where the Provider is providing Tier 1 and Tier 2 SRS/SRT, they must host neuro-oncology, skull base and Pituitary MDTs (as defined in NICE IOG 2006).

The Provider will provide assessment services to determine the suitability of individual cases for SRS/SRT. The Provider will provide SRS/SRT to patients who, following assessment, are considered suitable by the relevant Brain and Central Nervous System (CNS) Multidisciplinary teams and in accordance with the NICE IOG (2006), other NICE guidelines and technology appraisals and national commissioning policies.

#### Composition of the SRS/SRT MDT

The Provider is responsible for ensuring that the specialist MDT meets on a weekly basis for multi-disciplinary discussion of each patient during planning and treatment phases of the care pathway. SRS/SRT MDT meetings may run alongside or in parallel with appropriate NICE IOG tumour MDTs (see tiers above) or may equally run separately so long as there is full representation of core members, including a neurosurgeon, an oncologist, a neuro-radiologist, SRS Radiographer and other members according to the indication.

#### Composition of the SRS/SRT Treatment and Planning Team

The Provider’s clinical treatment team for Stereotactic Radiosurgery / Stereotactic Radiotherapy will involve neurosurgeons and clinical (radiation) neuro- neuro-radiologists, medical physics, health technology staff, radiographers, clinical nurse specialists and administrative support.

#### Staff education and training to demonstrate competence

Expertise in intracranial stereotactic radiosurgery requires added competence for Neurosurgeons and Oncologists. The Provider must demonstrate appropriate specialist training in SRS/SRT beyond equipment-specific practical training and ensure sufficient throughput to maintain competence.

### 3.2.4 Eligibility criteria

The Provider must meet the following criteria:

A Neurosurgical centre – Must cover (at least) an estimated 2 million population in order to generate a minimum volume of greater than 100 SRS/SRT Tier 1 and 2 patients per year. Geographical access in remote parts of the country will be considered alongside this requirement especially to provide prompt and local treatment for patients with cerebral metastases wherever safely feasible.

The radiotherapy centre undertaking SRS/SRT should be aligned and integral to the neurosurgical centre within the same geographical area or city with combined MDTs, usually hosted at the neurosurgical centre to ensure integrated working between the full clinical treatment team (see above).

There should be robust provider networked arrangements in place between those radiotherapy

centres, linked to the same neuro-surgical centres, to ensure that appropriate patients meeting NHS England commissioning policies are referred appropriately to the SRS/SRT service within that geography. This will also enable the SRS / SRT service within this network to achieve around 2 million population (geographical coverage).

There should be explicit referral arrangements in place to the SRS MDT.

The Provider for SRS/SRT must ensure that at least 100 patients per year receive SRS/SRT at each treatment delivery site.

This reflects the requirement for services to be able to demonstrate compliance with the European recommendations on service structure in order to acquire and maintain the level of training and competence of practitioners to work in this treatment area.

The Provider(s) must meet the pre-assessment RT QA requirements.

The Provider must have a defined and dedicated experienced workforce in place.

Where a Provider takes a referral from outside of their own catchment population, the Provider should have processes in place to ensure that referrals for SRS/SRT have been through local MDTs and all other treatment options have been considered.

The Provider must ensure that the services provided are compliant with National Cancer Peer Review / Quality Surveillance Programme, and meet the requirements as described within the NHS England CNS Tumours service specification and the NHS England Radiotherapy Service Specification. All services treating Teenage and Young Adults should also meet the requirements as outlined within the Paediatric cancer and TYA service specifications.

### **3.3 Service description**

#### **3.3.1 Care pathways**

##### **3.3.1.1 Assessment and Referral**

The SRS/SRT service will accept referrals from consultant medical staff and appropriate specialist multi-disciplinary teams (MDTs) in line with eligibility and referral guidelines. Referrals must be discussed in an appropriate specialist CNS MDT prior to a referral being made to the SRS MDT and the SRS MDT accepting the patient for treatment.

**The SRS MDT will include**, as a minimum, a Neurosurgeon, a Clinical Oncologist specialising in Neuro-oncology and a Neuro-radiologist SRS Radiographer and other members according to the indication.

The Provider must have clear documented pathways for each condition treated that show:

- The process for ensuring that each patient is reviewed by an appropriate specialist MDT which make the decision about the most appropriate treatment
- The process for determining where the patient is treated
- Where in each care pathway the role of SRS/SRT Provider starts and finishes
- The process for ensuring that the pathway is seamless and has no avoidable delays; and
- The process and pathway for patient follow up after treatment.

For patients with brain metastases, the decision to refer to a Neurosciences Brain and Central Nervous System (CNS) (neuro-oncology) MDT will be made by (or in conjunction with) a disease-specialist MDT which must consider the role of active management of brain metastases with SRS or surgery within the patient's overall oncological management and prognosis.

For patients being referred for indications other than brain metastases, the decision to offer SRS/SRT will be made by the appropriate sub-specialist MDT e.g. the base of skull MDT or pituitary MDT

##### **3.3.1.2 Treatment Planning**

Following discussion at an SRS MDT, the Provider shall ensure that patients accepted for SRS/SRT treatment will be seen by a clinician who is a core member of that MDT and who is able to deliver SRS treatment. This clinician will discuss with the patient their condition, their treatment options, the rationale for SRS/SRT treatment and will plan and supervise the treatment.

If patients are turned down for SRS/SRT treatment by the SRS MDT on clinical grounds, the Provider shall ensure that such decision will be conveyed to the patient by the referring specialist MDT, with the support of the SRS MDT.

Within 2 days of the definitive management plan being established, the diagnosis and management plan will be communicated to the referring consultant/MDT and the General Practitioner (GP).

For patients with malignant disease, the Provider shall ensure that clinical review should take place within 1 week of the Neurosciences (Neuro-oncology) MDT meeting and treatment with SRS should be delivered within 2 weeks of decision to treat (in clinic). This is in line with the Joint Collegiate Clinical Oncology guidelines (published, 1999).

The Provider shall ensure that patients will be provided with a full management plan. The plan will clearly indicate the overall management and the role of SRS/SRT. All patients will be provided with detailed condition specific information booklets and furnished with relevant website address during informal counselling. Patients will have access to a specialist nurse or keyworker throughout the referral and treatment process.

On agreement of a management plan which includes SRS/SRT treatment, the Provider must ensure that the patient's consent is formally documented.

The Provider must ensure that the patient's treatment will be carried out in line with clear, documented treatment protocols for the use of SRS/SRT in the agreed indications. Each Provider must have a fully funded, externally accredited quality management system in place (Towards Safer Radiotherapy).

Treatment protocols will ensure that target definition is performed by either a sub-specialised neurosurgeon and / or neuro-oncologist (clinical oncologist) with input from a neuro-radiologist before a treatment plan is created. The radiation dose and treatment plan will be approved or countersigned by an appropriately trained and accredited practitioner and all practices compliant with Ionising Radiation (Medical Exposure) Regulations (IRMER) 2000.

When treating Teenage and Young Adults requiring SRS/SRT for the treatment of benign disease providers should ensure that the treatment is planned to deliver the very lowest possible whole body radiation dose.

Where a Provider wishes to treat TYA patients with SRS/SRT, they must be part of an established Principle Treatment Centre in England and thus have direct access to the mandatory age specific support services and a TYA MDT.

A method which is independent of the planning computer and independent of the person producing the computer generated plan will be in place for checking the monitor unit calculation/treatment times (Towards Safer Radiotherapy).

The Provider must ensure that treatment of SRS/SRT forms part of the internal governance arrangements of the broader radiotherapy service. Any untoward incidents and near misses should be reported using the national reporting tool.

All treatments will be delivered by specialist therapeutic radiographers trained to operate SRS/SRT treatment platforms.

### **3.3.1.3 Discharge**

Providers shall ensure that patients will be either discharged back to the referring consultant/specialist MDT following treatment, or may sometimes be followed up by the SRS MDT.

Follow up recommendations will be detailed in a condition specific and patient specific manner to referring physicians with whom shared care is arranged. This applies particularly to patients for whom

transport may present difficulties. However, the ultimate follow up plan will then usually be the responsibility of the on-going clinical team and subject to alterations according to clinical needs including the management of late effects and survivorship.

Follow-up arrangements will depend on the clinical indication for SRS/SRT, patient's clinical features and local geography

### **3.3.2 Additional Standards for Providers of Tier 3 and Tier 4 Conditions**

#### **3.3.2.1 Service description/care pathway**

The Provider will provide assessment services to determine the suitability of individual cases for SRS/SRT. The service will provide SRS/SRT to patients who, following assessment, are considered suitable by the relevant Brain and Central Nervous System (CNS) Multidisciplinary teams and in accordance with national commissioning policies.

#### **Composition of the Neuro MDTs**

Robust linkages to each of the local neuro MDTs across the full number of associated services, within the supra-network geography must be in place to ensure appropriate referrals to the supra-network SRS MDT. The pathways to MDTs are described at Appendix A. For patients being referred for Tier 3 / 4 indications the decision to offer SRS/SRT will be made by the appropriate sub-specialist MDT e.g. the neuro-vascular MDT, before referral.

#### **SRS/SRT MDT**

The Provider must ensure that this specialist MDT meets on a regular basis for multi-disciplinary discussion of each patient during planning and treatment phases of the care pathway.

Meetings may run alongside or in parallel with appropriate neurosurgical MDTs (see tiers above) or may equally run separately so long as there is full representation of core members, including a neurosurgeon, neuro-oncologist, a neuro-radiologist, medical physics, SRS Radiographer and other members according to the indication.

For Tier 3 & Tier 4 work Providers will need to ensure that an SRS MDT contains clinicians who are specialists in the conditions being discussed (e.g. vascular neurosurgeon, functional neurosurgeon, pain surgeon, epilepsy surgeon, etc.) in addition to the SRS team and when appropriate specialist paediatric and TYA staff etc).

#### **Composition of the SRS/SRT Treatment and Planning Team**

The Provider's clinical treatment team for Stereotactic Radiosurgery / Stereotactic Radiotherapy will involve neurosurgeons and clinical (radiation) neuro-oncologists supported by paediatric oncologists (where appropriate) neuro-radiologists, medical physics, health technology staff, radiographers, clinical nurse specialists and administrative support.

Continuous staff education and training to demonstrate competence at Tier 3 and Tier 4 is essential.

Expertise in intracranial stereotactic radiosurgery requires added competence for Neurosurgeons and Oncologists. The Provider must demonstrate appropriate specialist training in SRS/SRT beyond equipment-specific practical training and ensure sufficient throughput to maintain competence.

There must be a defined and dedicated experienced workforce in place and all providers of Tier 3 and 4 services must have access to dedicated vascular services (level 3).

Providers of Tier 3 and Tier 4 services will be supra-network SRS/SRT centres and will treat Tiers 1-4, and Tiers 1&2 specifically as the "local" neurosurgical centre for that population using an integrated approach to the delivery of the service to include a single Neurosurgical / Radiotherapy team as part of the neurosurgical centre within the same geographical area or city with combined MDTs, usually hosted at the neurosurgical centre.

Supra-network centres taking referrals from outside of their own catchment population must have processes in place to ensure that referrals for SRS/SRT have been through local MDTs and all other

treatment options have been considered.

The Provider must ensure that there are robust provider network arrangements in place between those neurosurgical centres across the broader geography from which patients are referred for Tier 3 and Tier 4 services. This will ensure that appropriate patients meeting NHS England commissioning policies are referred to the SRS/SRT service within that geography. This will also enable the supra-network SRS/SRT service to achieve a critical mass of patient referrals to sustain the service (geographical coverage).

The Provider must ensure that there are explicit referral arrangements in place to the supra-network SRS MDT.

The Provider must meet the pre-assessment RT QA requirements.

The Provider must meet the requirements as described within the NHS England CNS Tumours service specification and the NHS England Radiotherapy Service Specification. Where a Provider is treating Teenage and Young Adults, they must meet the requirements as outlined within the TYA Service Specification.

### **3.3.2.2 Imaging**

The Provider must ensure that all services within the network will:

- a) Clearly define which imaging test or interventional procedure can be performed and reported at each site
- b) Have robust procedures in place for image transfer for review by a specialist radiologist, these will be supported by appropriate contractual and information governance arrangements
- c) Have robust arrangements in place for patient transfer if more complex imaging or intervention is required
- d) Ensure common standards, protocols and governance procedures exist throughout the broader network geography.
- e) Ensure all radiologists, and radiographers will have appropriate training, supervision and access to CPD
- f) Ensure all equipment is optimised for paediatric use and use specific paediatric software

Where a Provider wishes to treat TYA patients with SRS/SRT, they must be part of an established Principle Treatment Centre in England and thus have direct access to the mandatory age specific support services and a TYA MDT.

### **General Paediatric care**

When treating children, the Provider must additionally follow the standards and criteria outlined in the Specification for Children's Services (attached as Annex 1 to this specification)

### **3.3.3 Additional Standards for the Treatment of Complex Paediatric Neuro-Oncology tumours**

In the UK each year about 1600-1700 children under the age of 16 years are diagnosed with a primary cancer. Treatment outcome has been steadily improving over the last decades with 10 year survival of all newly diagnosed children with malignancies now reaching over 70% in the UK.

All patients are mandatorily treated in designated national children cancer centres. Following primary diagnosis patients are managed via local MDTs in accordance with nationally and internationally agreed guidelines unless treated in the context of an open clinical trial. Of all children diagnosed with a primary malignancy about 25-28% per year are presenting with a primary brain or spinal cord tumour. While radiotherapy is part of the primary management in around 30-35% of all tumours the proportion of children with primary brain and spinal cord tumours receiving RT is higher given that RT is frequently a fundamental part of the first line treatment strategy.

At present SRS/SRT is not part of any routine first line treatment strategy but may offer, in selected patients with recurrent disease, an effective therapeutic option in addition to or instead of either surgery and or chemotherapy following previous fractionated photon or proton radiotherapy (e.g.,

ependymoma, medulloblastoma, pilocytic astrocytoma etc.)

**NB Any IFR approved cases for any of the indications listed above should be managed by the designated paediatric neuro-oncology SRS service.**

Patients should be considered for SRS/SRT in case of locally recurrent disease or selected cases with oligometastatic disease where a reasonable expectation exists that improved local control may meaningful extend progression-free or symptom-free survival.

Given the extreme rarity of these scenarios where SRS/SRT would be meaningful, and clinically justifiable patients with malignant tumours in the paediatric age group should be managed in a limited number of centres. However, paediatric patients with either NF2 associated tumours or AVMs will remain within the current framework of commissioned services for adults as here the technical expertise of the supra-network SRS MDT is perceived to be of higher importance than the specific primary paediatric tumour site expertise.

Centres wishing to offer SRS/SRT for patients in the paediatric age group are expected to form part of one of the currently accredited CCLG radiotherapy services in England and thus having direct access to the mandatory age specific support services. In order to assure the necessary tumour site specific expertise (brain and spine) the paediatric SRS/SRT service should be aligned with a large established tertiary paediatric neuro-oncology MDT. This is to ensure that there is the right oncological expertise available for the appropriate patient selection.

Where a Provider wishes to treat TYA patients with SRS/SRT, they must be part of an established Principle Treatment Centre in England and thus have direct access to the mandatory age specific support services and a TYA MDT.

### **3.4 Population covered**

The service outlined in this specification is for patients ordinarily resident in England\*; or otherwise the commissioning responsibility of the NHS in England (as defined in Who Pays?: Establishing the responsible commissioner and other Department of Health guidance relating to patients entitled to NHS care or exempt from charges).

\*Note: for the purposes of commissioning health services this excludes patients who, whilst resident in England are registered with a GP Practice in Wales, but includes patients resident in Wales who are registered with a GP Practice in England.

Specifically this service is for all patients of all ages requiring SRS/SRT as determined by the appropriate clinical specialists and in accordance with the national commissioning policy.

### **3.5 Any acceptance and exclusion criteria**

- The Provider will accept referrals from appropriate specialist MDTs in line with eligibility and referral guidelines. Patients will generally be under the care of an oncologist and/or neurosurgeon.
- Children will only be treated at a centre that has the necessary facilities for treating paediatric cases and that is compliant with the document 'Improving outcomes in children and young people with cancer – August 2005'. Typically this will require appropriate overnight accommodation and paediatric anaesthetic capabilities.

### **3.6 Interdependencies with other services**

- The Provider will ensure close working relationships with the local Neurosciences Brain and CNS, CNS Cancer Network and other tumour site specific MDTs including Paediatric and TYA MDTs as appropriate to the needs of individual patients.
- For the treatment of Arteriovenous Malformations the service must have access to angiography services and be able to transport patients safely from these services to the SRS/SRT treatment area.

- There is significant commonality between the standards and requirements for providing External Beam Radiotherapy and SRS/SRT. The Provider must ensure compliance with the relevant parts of the NHS England External Beam Radiotherapy service specification.

#### 4. Applicable Service Standards

##### 4.1 Applicable national standards e.g. NICE, Royal College

National Standards include:

- Service guidance for improving outcomes for people with brain and other central nervous system tumours – June 2006 (<http://guidance.nice.org.uk/csgbraincns>)
- NICE Interventional Procedure Guidance – Trigeminal Neuralgia (<http://guidance.nice.org.uk/IPG85>)

Other guidance documents include:

- Radiotherapy dose-fractionation” available at <http://www.rcr.ac.uk/publications.aspx?PageID=149&PublicationID=229>
- International RadioSurgery Association AVM Guidelines: <http://www.irsa.org/AVM%20Guideline.pdf>
- International RadioSurgery Association Vestibular Schwannoma Guidelines: <http://www.irsa.org/AN%20Guideline.pdf>
- International RadioSurgery Association Pituitary Guidelines: <http://www.irsa.org/Pituitary%20Guideline.pdf>
- International RadioSurgery Association Brain Metastases Guidelines: <http://www.irsa.org/Metastatic%20Guideline.pdf>
- Physics Aspects of Quality Control in Radiotherapy, IPEM Report 81, Institute of Physics and Engineering in Medicine, York 1999
- Acceptance Testing and Commissioning of Linear Accelerators, Chapter 13: Commissioning for Stereotaxis, IPEM Report 94, Institute of Physics and Engineering in Medicine, York 2006
- Towards Safer Radiotherapy, Royal College of Radiologists, 2008
- Department of Health – You’re Welcome quality criteria: making health services young people friendly <http://www.dh.gov.uk/en/Publicationsandstatistics/>
- Department of Health – National Service Framework Children and Maternity. <http://www.webarchive.nationalarchives.gov.uk>
- [Joint Collegiate Clinical Oncology Guidelines, 1999.](#)

##### Core Standards

The Provider must demonstrate compliance with the recommendations of The Royal College of Radiologists, Society and College of Radiographers, Institute of Physics and Engineering in Medicine, National Patient Safety Agency, British Institute of Radiology document 'Towards Safer Radiotherapy.' London: The Royal College of Radiologists, 2008.

The service must demonstrate compliance with the Ionisation Radiation Medical Exposure) Regulations 2000The service must demonstrate compliance with Ionising Radiation Regulations (IRR99).

The Provider must demonstrate compliance with the Radioactive Substances Act (RSA93) if applicable.

The Provider must follow the Institute of Physics in Engineering Medicine 'Guidelines for the provision of a Physics Service for Radiotherapy' 2002.

The Provider’s specialist team will demonstrate an appropriate level of knowledge, training and



experience commensurate with the provision of a safe and effective service which, as a minimum, meets the theoretical and practical training requirements needed to meet the Ionising Radiation (Medical Exposure) Regulations (IR(ME)R 2000).

#### **5. Applicable quality requirements and CQUIN goals**

5.1 Applicable quality requirements (See Schedule 4 Parts A-D)

5.2 Applicable CQUIN goals (See Schedule 4 Part E)

These are in the process of being developed and will be inserted once agreed.

#### **6. Location of Provider Premises**

The Provider's Premises are located at:

[To be confirmed]

For the purposes of this specification, treatment may only be provided at the Provider's Premises (which shall be interpreted as "delivery sites" for the purposes of this specification), and solely using treatment platforms agreed with the Commissioner.

#### **7. Individual Service User Placement**

Not applicable.

### **ANNEX 1 TO SERVICE SPECIFICATION – Additional Section**

#### **PROVISION OF SERVICES TO CHILDREN**

##### **Aims and objectives of service**

This specification annex applies to all Providers that are providing children's services and outlines generic standards and outcomes that are fundamental to all services and must be complied with by the Provider.

The generic aspects of care:

The Care of Children in Hospital (HSC 1998/238) requires that:

- Children are admitted to hospital only if the care they require cannot be as well provided at home, in a day clinic or on a day basis in hospital.
- Children requiring admission to hospital are provided with a high standard of medical, nursing and therapeutic care to facilitate speedy recovery and minimize complications and mortality.
- Families with children have easy access to hospital facilities for children without needing to travel significantly further than to other similar amenities.
- Children are discharged from hospital as soon as socially and clinically appropriate and full support provided for subsequent home or day care.
- Good child health care is shared with parents/carers and they are closely involved in the care of their children at all times unless, exceptionally, this is not in the best interest of the child; Accommodation is provided for them to remain with their children overnight if they so wish.

##### **Service description/care pathway**

- All paediatric specialised services have a component of primary, secondary, tertiary and even quaternary elements.
- The efficient and effective delivery of services requires children to receive their care as close to home as possible dependent on the phase of their disease.
- Services should therefore be organised and delivered through “integrated pathways of care” (National Service Framework for children, young people and maternity services (Department of Health & Department for Education and Skills, London 2004)

### **Interdependencies with other services**

All services will comply with Commissioning Safe and Sustainable Specialised Paediatric Services: A Framework of Critical Inter-Dependencies – Department of Health

### **Imaging**

All services will be supported by a 3 tier imaging network (‘Delivering quality imaging services for children’ Department of Health 13732 March 2010). Within the network:

- It will be clearly defined which imaging test or interventional procedure can be performed and reported at each site
- Robust procedures will be in place for image transfer for review by a specialist radiologist, these will be supported by appropriate contractual and information governance arrangements
- Robust arrangements will be in place for patient transfer if more complex imaging or intervention is required
- Common standards, protocols and governance procedures will exist throughout the network.
- All radiologists, and radiographers will have appropriate training, supervision and access to CPD
- All equipment will be optimised for paediatric use and use specific paediatric software

### **Specialist Paediatric Anaesthesia**

Wherever and whenever children undergo anaesthesia and surgery, their particular needs must be recognised and they should be managed in separate facilities, and looked after by staff with appropriate experience and training.<sup>1</sup> All UK anaesthetists undergo training which provides them with the competencies to care for older babies and children with relatively straightforward surgical conditions and without major co-morbidity. However those working in specialist centres must have undergone additional (specialist) training<sup>2</sup> and should maintain the competencies so acquired<sup>3</sup> \*. These competencies include the care of very young/premature babies, the care of babies and children undergoing complex surgery and/or those with major/complex co-morbidity (including those already requiring intensive care support).

As well as providing an essential co-dependent service for surgery, specialist anaesthesia and sedation services may be required to facilitate radiological procedures and interventions (for example MRI scans and percutaneous nephrostomy) and medical interventions (for example joint injection and intrathecal chemotherapy), and for assistance with vascular access in babies and children with complex needs such as intravenous feeding.

Specialist acute pain services for babies and children are organised within existing departments of paediatric anaesthesia and include the provision of agreed (hospital wide) guidance for acute pain, the safe administration of complex analgesia regimes including epidural analgesia, and the daily input of specialist anaesthetists and acute pain nurses with expertise in paediatrics.

\*The Safe and Sustainable reviews of paediatric cardiac and neuro- sciences in England have noted the need for additional training and maintenance of competencies by specialist anaesthetists in both fields of practice.

### **References**

1. Guidelines for the Provision of Anaesthetic Services (GPAS) Paediatric anaesthetic services. Royal College of Anaesthetists (RCOA) 2010 [www.rcoa.ac.uk](http://www.rcoa.ac.uk)

2. Certificate of Completion of Training (CCT) in Anaesthesia 2010
3. CPD matrix level 3

### **Specialised Child and Adolescent Mental Health Services (CAMHS)**

The age profile of children and young people admitted to specialised CAMHS day/in-patient settings is different to the age profile for paediatric units in that it is predominantly adolescents who are admitted to specialised CAMHS in-patient settings, including over-16s. The average length of stay is longer for admissions to mental health units. Children and young people in specialised CAMHS day/in-patient settings generally participate in a structured programme of education and therapeutic activities during their admission.

Taking account of the differences in patient profiles the principles and standards set out in this specification apply with modifications to the recommendations regarding the following:

- Facilities and environment – essential Quality Network for In-patient CAMHS (QNIC) standards should apply (<http://www.rcpsych.ac.uk/quality/quality accreditationaudit/qnic1.aspx>)
- Staffing profiles and training - essential QNIC standards should apply.
- The child/ young person's family are allowed to visit at any time of day taking account of the child / young persons need to participate in therapeutic activities and education as well as any safeguarding concerns.
- Children and young people are offered appropriate education from the point of admission.
- Parents/carers are involved in the child/young persons care except where this is not in the best interests of the child / young person and in the case of young people who have the capacity to make their own decisions is subject to their consent.
- Parents/carers who wish to stay overnight are provided with accessible accommodation unless there are safeguarding concerns or this is not in the best interests of the child/ young person.

### **3. Applicable Service Standards**

#### **3.1 Applicable national standards e.g. NICE, Royal College**

Children and young people must receive care, treatment and support by staff registered by the Nursing and Midwifery Council on the parts of their register that permit a nurse to work with children (Outcome 14h Essential Standards of Quality and Safety, Care Quality Commission, London 2010)

- There must be at least two Registered Children's Nurses (RCNs) on duty 24 hours a day in all hospital children's departments and wards.
- There must be an Registered Children's Nurse available 24 hours a day to advise on the nursing of children in other departments (this post is included in the staff establishment of 2RCNs in total).

Accommodation, facilities and staffing must be appropriate to the needs of children and separate from those provided for adults. All facilities for children and young people must comply with the Hospital Build Notes HBN 23 Hospital Accommodation for Children and Young People NHS Estates, The Stationary Office 2004.

All staff who work with children and young people must be appropriately trained to provide care, treatment and support for children, including Children's Workforce Development Council Induction standards (Outcome 14b Essential Standards of Quality and Safety, Care Quality Commission, London 2010).

Each hospital who admits inpatients must have appropriate medical cover at all times taking account of guidance from relevant expert or professional bodies (National Minimum Standards for Providers of Independent Healthcare, Department of Health, London 2002). "Facing the Future" Standards, Royal College of Paediatrics and Child Health.

Staff must carry out sufficient levels of activity to maintain their competence in caring for children and young people, including in relation to specific anaesthetic and surgical procedures for children, taking

account of guidance from relevant expert or professional bodies (Outcome 14g Essential Standards of Quality and Safety, Care Quality Commission, London 2010).

Providers must have systems in place to gain and review consent from people who use services, and act on them (Outcome 2a Essential Standards of Quality and Safety, Care Quality Commission, London 2010). These must include specific arrangements for seeking valid consent from children while respecting their human rights and confidentiality and ensure that where the person using the service lacks capacity, best interest meetings are held with people who know and understand the person using the service. Staff should be able to show that they know how to take appropriate consent from children, young people and those with learning disabilities (Outcome 2b) (Seeking Consent: working with children Department of Health, London 2001).

Children and young people must only receive a service from a provider who takes steps to prevent abuse and does not tolerate any abusive practice should it occur (Outcome 7 Essential Standards of Quality and Safety, Care Quality Commission, London 2010 defines the standards and evidence required from providers in this regard). The Provider must minimise the risk and likelihood of abuse occurring by:

- Ensuring that staff and people who use services understand the aspects of the safeguarding processes that are relevant to them.
- Ensuring that staff understand the signs of abuse and raise this with the right person when those signs are noticed.
- Ensuring that people who use services are aware of how to raise concerns of abuse.
- Having effective means to monitor and review incidents, concerns and complaints that have the potential to become an abuse or safeguarding concern.
  
- Having effective means of receiving and acting upon feedback from people who use services and any other person.
- Taking action immediately to ensure that any abuse identified is stopped and suspected abuse is addressed by:
  - having clear procedures followed in practice, monitored and reviewed that take account of relevant legislation and guidance for the management of alleged abuse
  - separating the alleged abuser from the person who uses services and others who may be at risk or managing the risk by removing the opportunity for abuse to occur, where this is within the control of the provider
  - reporting the alleged abuse to the appropriate authority
  - reviewing the person's plan of care to ensure that they are properly supported following the alleged abuse incident.
- Using information from safeguarding concerns to identify non-compliance, or any risk of non-compliance, with the regulations and to decide what will be done to return to compliance.
- Working collaboratively with other services, teams, individuals and agencies in relation to all safeguarding matters and has safeguarding policies that link with local authority policies.
- Participates in local safeguarding children boards where required and understand their responsibilities and the responsibilities of others in line with the Children Act 2004.
- Having clear procedures followed in practice, monitored and reviewed in place about the use of restraint and safeguarding.  
Taking into account relevant guidance set out in the Care Quality Commission's Schedule of Applicable Publications
- Ensuring that those working with children must wait for a full CRB disclosure before starting work.
- Training and supervising staff in safeguarding to ensure they can demonstrate the competences listed in Outcome 7E of the Essential Standards of Quality and Safety, Care Quality Commission, London 2010

The Provider must ensure that all children and young people who use services must be:

- Fully informed of their care, treatment and support.
- Able to take part in decision making to the fullest extent that is possible.
- Asked if they agree for their parents or guardians to be involved in decisions they need to make.

(Outcome 4I Essential Standards of Quality and Safety, Care Quality Commission, London 2010)

#### 4. Key Service Outcomes

Evidence is increasing that implementation of the national Quality Criteria for Young

People Friendly Services (Department of Health, London 2011) have the potential to greatly improve patient experience, leading to better health outcomes for young people and increasing socially responsible life-long use of the NHS. Implementation is also expected to contribute to improvements in health inequalities and public health outcomes e.g. reduced teenage pregnancy and Sexually Transmitted Infections (STIs), and increased smoking cessation. All providers delivering services to young people should be implementing the good practice guidance which delivers compliance with the quality criteria.

Poorly planned transition from young people's to adult-oriented health services can be associated with increased risk of non adherence to treatment and loss to follow-up, which can have serious consequences. There are measurable adverse consequences in terms of morbidity and mortality as well as in social and educational outcomes. When children and young people who use paediatric services are moving to access adult services (for example, during transition for those with long term conditions), these should be organised so that:

- All those involved in the care, treatment and support cooperate with the planning and provision to ensure that the services provided continue to be appropriate to the age and needs of the person who uses services.

The National Minimum Standards for Providers of Independent Healthcare, (Department of Health, London 2002) require the following standards:

- **A16.1** Children are seen in a separate out-patient area, or where the hospital does not have a separate outpatient area for children, they are seen promptly.
- **A16.3** Toys and/or books suitable to the child's age are provided.
- **A16.8** There are segregated areas for the reception of children and adolescents into theatre and for recovery, to screen the children and adolescents from adult patients; the segregated areas contain all necessary equipment for the care of children.
- **A16.9** A parent is to be actively encouraged to stay at all times, with accommodation made available for the adult in the child's room or close by.
- **A16.10** The child's family is allowed to visit him/her at any time of the day, except where safeguarding procedures do not allow this
- **A16.13** When a child is in hospital for more than five days, play is managed and supervised by a qualified Hospital Play Specialist.
- **A16.14** Children are required to receive education when in hospital for more than five days; the Local Education Authority has an obligation to meet this need and are contacted if necessary.
- **A18.10** There are written procedures for the assessment of pain in children and the provision of appropriate control.

All hospital settings should meet the Standards for the Care of Critically Ill Children (Paediatric Intensive Care Society, London 2010).

There should be age specific arrangements for meeting Regulation 14 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010. These require:

- A choice of suitable and nutritious food and hydration, in sufficient quantities to meet service users' needs;
- Food and hydration that meet any reasonable requirements arising from a service user's religious or cultural background

- Support, where necessary, for the purposes of enabling service users to eat and drink sufficient amounts for their needs.
- For the purposes of this regulation, “food and hydration” includes, where applicable, parenteral nutrition and the administration of dietary supplements where prescribed.
- Providers must have access to facilities for infant feeding, including facilities to support breastfeeding (Outcome 5E, of the Essential Standards of Quality and Safety, Care Quality Commission, London 2010)

All paediatric patients should have access to appropriately trained paediatric trained dieticians, physiotherapists, occupational therapists, speech and language therapy, psychology, social work and CAMHS services within nationally defined access standards.

All children and young people should have access to a professional who can undertake an assessment using the Common Assessment Framework and access support from social care, housing, education and other agencies as appropriate

All registered providers must ensure safe use and management of medicines, by means of the making of appropriate arrangements for the obtaining, recording, handling, using, safe keeping, dispensing, safe administration and disposal of medicines (Outcome 9 Essential Standards of Quality and Safety, Care Quality Commission, London 2010). For children, these should include specific arrangements that:

- ensure the medicines given are appropriate and person-centred by taking account of their age, weight and any learning disability
- ensure that staff handling medicines have the competency and skills needed for children and young people’s medicines management
- ensure that wherever possible, age specific information is available for people about the medicines they are taking, including the risks, including information about the use of unlicensed medicine in paediatrics.

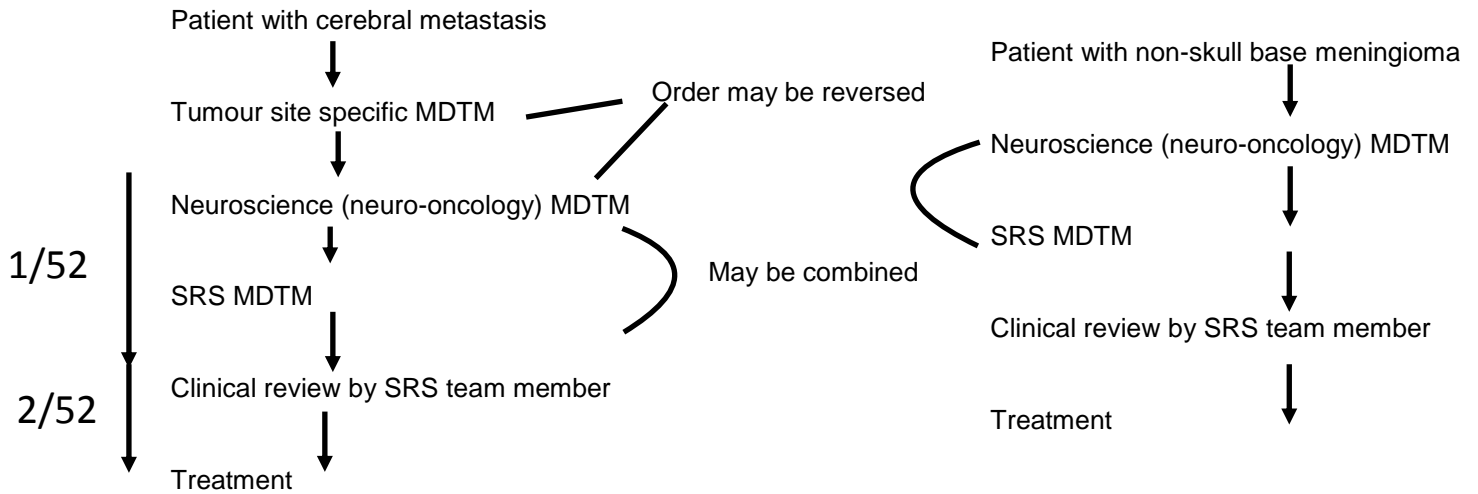
Many children with long term illnesses have a learning or physical disability. The Provider must ensure that:

- They are supported to have a health action plan
- Facilities meet the appropriate requirements of the Disability Discrimination Act 1995
- They meet the standards set out in Transition: getting it right for young people. Improving the transition of young people with long-term conditions from children’s to adult health services. Department of Health, 2006, London

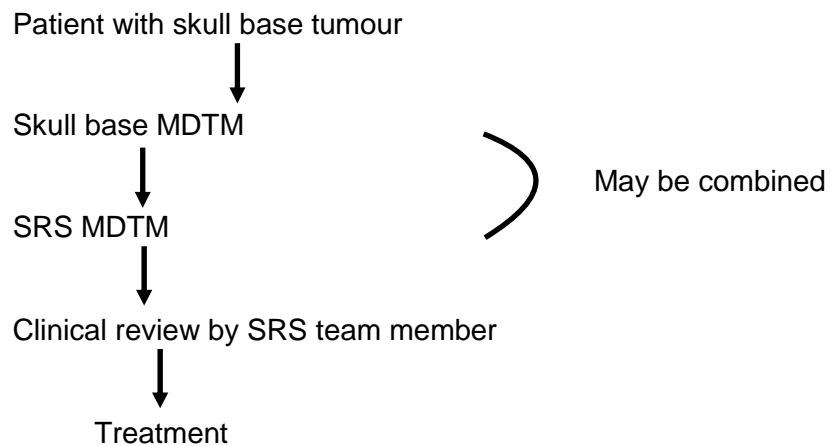
## Appendix A

## MDT PATHWAY ARRANGEMENTS

### Tier 1

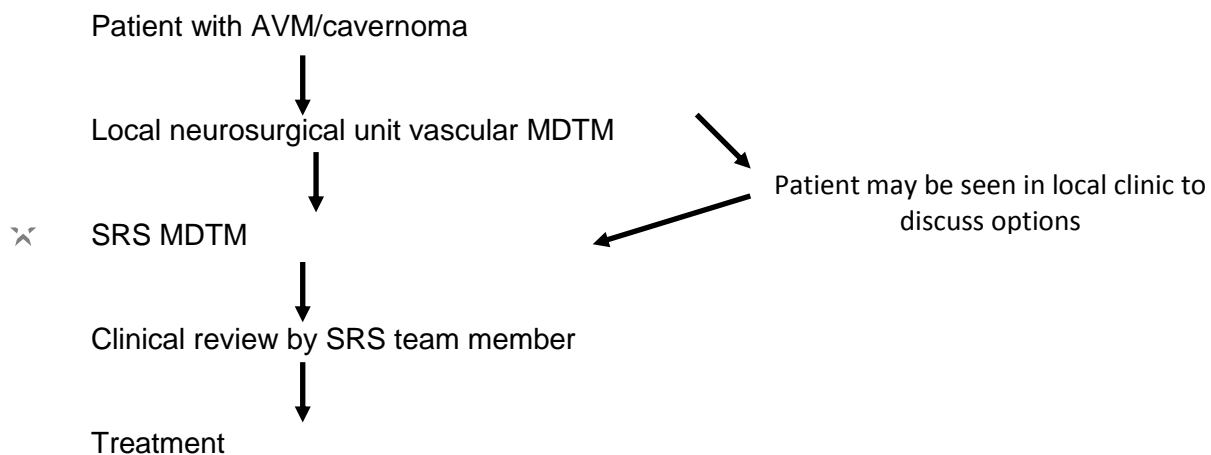


### Tier 2



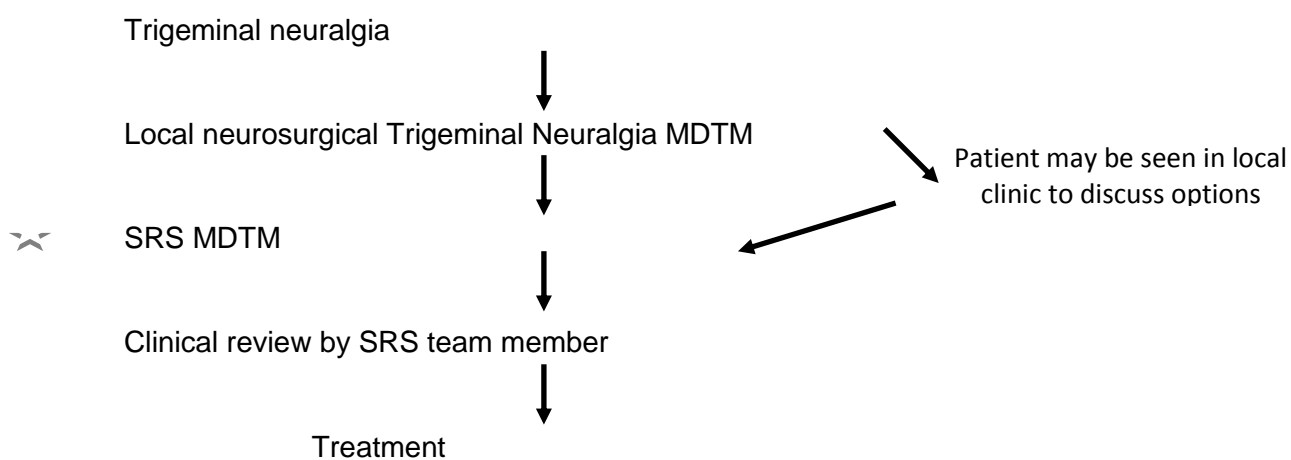
For patients with pituitary tumour, the same pathway but through pituitary MDTM

### TIER 3



✕ SRS MDTM must contain a vascular neurosurgeon as well as core members of SRS MDT

### Tier 4



✕ SRS MDTM must contain a trigeminal neuralgia neurosurgeon as well as core members of SRS MDT  
For other Tier 4 indications an appropriate specialised neurosurgeon must be present

Same model for ocular melanoma and IFR patients - epilepsy, rare tumours etc