SUBMISSION FROM NHS ENGLAND IN RESPONSE TO THE STATEMENT OF ISSUES DATED 30 AUGUST 2013 ISSUED BY MONITOR IN RELATION TO THE COMPLAINT INTO THE COMMISSIONING OF RADIOSURGERY SERVICES BY THORNBURY RADIOSURGERY CENTRE LIMITED

1. Introduction

NHS England makes this submission in response to the Statement of Issues dated 30 August 2013 issued by Monitor in relation to the complaint into the commissioning of radiosurgery services by Thornbury Radiosurgery Centre Limited (**Thornbury**).

Monitor published its notice of investigation into the Complaint on 5 June 2013. In that notice, Monitor referred to its initiation of the investigation following a complaint from Thornbury regarding conduct and procurement practices of the North of England Specialised Commissioning Group (**NESCG**), and its successor NHS England, in relation to certain Gamma Knife services (a specialised radiosurgery service). Monitor's notice referred to consideration of any breach in relation to the National Health Service (Procurement, Patient Choice and Competition) (No.2) Regulations 2013 (**Regulations**), in relation to matters occurring after 1 April 2013 (when the Regulations came into force), and to consideration of whether, in respect of matters before that date, NESCG's conduct was consistent with the Principles and Rules for Co-operation and Competition (**PRCC**). The PRCC had the status of Department of Health policy, on which the Co-operation and Competition Panel (**CCP**), then a panel sponsored by the Department of Health and Monitor, advised the Department of Health and other stakeholders, on an advisory basis.

In the Statement of Issues, Monitor announced that it was continuing its investigation in relation to matters from 1 April 2013 and the Regulations. Concerning matters before that date, and their relationship with PRCC policy, Monitor stated that these were no longer the focus of its investigation, but that if any "broader lessons" might be learned from NESCG's conduct before April 2013, Monitor might comment on those.

By way of background, prior to 1 April 2013, primary care trusts (**PCTs**) were responsible for commissioning specialised services, on a resident population basis. This responsibility was discharged through PCTs working together on a collaborative basis, through Specialised Commissioning Groups (**SCGs**). There were 10 SCGs and these separate regional arrangements operated in different ways resulting in commissioning variation. With effect from 1 April 2013, NHS England is responsible for the commissioning of specialised services working to a single operating model. Key components of the single commissioner approach are national service specifications (including service standards and outcome measures) and

national clinical commissioning policies. There are single contracts with each service provider for all of the population across England.

NHS England notes that Thornbury's complaint, as summarised out in the Statement of Issues, contains helpful details about certain actions or decisions of NESCG and why those were considered by Thornbury not to be consistent with identified principles or rules of the PRCC, but is less specific in regard to the Regulations. Although NHS England is aware of some concerns that Thornbury has expressed to it, before responding in detail to the specific requirements of individual Regulations and the period in question, we would like to confirm with Monitor the particular actions or decisions which are being assessed under the Regulations, and will then respond in detail on those points. NHS England will use the present response to give an overview of some of the policy and factual background that is relevant to this case, and its approach to specialised commissioning, as it relates to Gamma Knife services.

2. Scope of investigation, and the PRCC

NHS England welcomes Monitor's decision not to focus on previous matters under the PRCC, and therefore does not look to comment on how the conduct or decision-making of previous commissioners, under previous commissioning structures (and before the Regulations came into force) may have aligned with the PRCC. However, regarding Monitor's statement that it may still comment on those earlier matters, NHS England observes that:

- The matters complained of by Thornbury extend back to 2008, and accordingly it may be difficult, almost six years later, to assess and draw lessons from the commissioning, policy, financial and provider landscape against which earlier decisions were taken.

- Similarly, the criteria by which the CCP decided whether to accept procurement disputes required an applicant to bring any complaint within a given timeframe. NHS England would not wish undue time or resource to be devoted to the consideration of matters in relation to the PRCC (some dating back to 2008) which might not have been accepted for review, on grounds of delay, while the PRCC were still applicable.

- The structure of specialised commissioning has now changed radically. One of the aims of centralising specialised commissioning to a single commissioner for all of England was precisely to enable a new system-wide and consistent approach to specialised service

provision. Accordingly, even if it could be assessed whether those earlier commissioning decisions were consistent with the PRCC, the connection between such commissioning decisions – whether by NESCG or other commissioners – can only be indirect, at most, to the current requirements and structures for commissioning specialised services.

However, NHS England has endeavoured to assist Monitor by supplying information relating to previous commissioning structures to the extent available, and will be interested to note any factors that Monitor might identify in relation to the previous system and the PRCC.

3. Status of contracting relationship with Thornbury

To give context to this matter, it may be helpful if NHS England summarises the status of its discussions with Thornbury on Gamma Knife services from 1 April 2013. The background to this is that in early 2013, at which time specialised commissioning for patients in the north of England was the responsibility of local SCGs, Thornbury already provided some Gamma Knife services to NHS patients under arrangements with Sheffield Teaching Hospitals NHS Trust (**STHT**), which ran the National Centre for Stereotactic Radiosurgery. Thornbury provided those services under the clinical governance, and using the multi-disciplinary team (**MDT**), of STHT.

In April, shortly after the commissioning of these services on a national basis became the responsibility of NHS England, NHS England and Thornbury were in communication about the possibility of Thornbury, in the new commissioning system, becoming a direct provider of these services, on its own account, under the NHS National Standard Contract. In May, following discussions with its regional specialised commissioning teams, NHS England informed Thornbury that, on the basis of its initial appraisal of current patient flows and capacity (including the fact that STHT had increased capacity at the National Centre for Stereotactic Radiosurgery), it had not identified a need to contract with Thornbury. However, following further analysis of referral patterns, NHS England wrote to Thornbury in early June stating that it would be appropriate for Thornbury to enter into an NHS National Standard Contract for Gamma Knife services.

During June, further discussions took place between NHS England and Thornbury, to address the details of how the MDT would work for Thornbury (which had previously had the benefit of the STHT MDT). These discussions focussed on whether the MDT members that met to discuss treatment options for an individual patient who was being considered for Gamma

Knife treatment should comprise the same clinicians that would have clinical responsibility for the planning and delivery of the actual treatment for that patient, and also whether all members of the MDT needed to be present in person (or could attend team meetings remotely).

These discussions continued in early July, and on 11 July (as noted in the Statement of Issues), NHS England informed Thornbury that, since Thornbury did not currently meet the MDT requirements that NHS England had as commissioner for these services, Thornbury should not accept direct referrals for those services until Thornbury had put in place MDT arrangements matching NHS England's commissioning requirements. In the same letter, NHS England invited Thornbury to put those MDT arrangements in place.

NHS England has statutory responsibilities to commission the services within its remit effectively, efficiently and economically, and to secure ongoing improvements in services and outcomes, including for clinical safety and patient experience. It appears to NHS England that, in respect of the MDT, there was a genuine difference of clinical opinion between NHS England and Thornbury on how an MDT for these services should operate. While this is an issue that NHS England hopes soon to resolve with Thornbury, NHS England does consider that its statutory commissioning duties oblige it to consider seriously such key matters of service delivery, and to act to assure itself as to the services it may commission.

4. Specialised services, plurality of provision, clinical safety, and clinical, financial and operational sustainability

Before turning to some general points in relation to the Regulations, NHS England wishes to make some observations about the commissioning context for specialised services.

It has long been recognised that specialised services are, by their very nature, different from "routine" or non-specialised services that might be widely provided by general acute hospitals. For example, the 2006 Carter Review, which introduced the concept of designation for specialist providers and made 32 separate recommendations about the reform of specialised commissioning at that time, commented that:

"*Specialised services commissioners have an additional role in preventing the proliferation of specialist centres to the point where there are too many centres, each treating too few patients, to provide a safe, high quality, value for money service.*[1]"

"*Designation of specialised service providers by SCGs would secure an appropriate concentration of clinical expertise and activity at designated centres, located to maximise geographical access. Designation would safeguard patient access to high quality, cost effective services and prevent unsafe and/or unplanned proliferation of services*."[2]

"*Commissioners should be able to choose how many providers to designate for each service so as to promote choice for patients but maintain sufficient critical mass in each provider to ensure clinical safety, quality and value for money*"[3]

The improvements in clinical outcomes for certain specialised services, connected with ensuring that specialised centres treat sufficient patient volumes and ensure critical mass, has been widely reported, for example, in relation to major trauma, vascular services, cancer (as for example the Cancer Improving Outcomes Guidance) and stroke services[4].

The Regulations do not distinguish between the commissioning of specialised services and the commissioning of "routine" services, but NHS England would like to record that there are a number of important and legitimate considerations that commissioners of specialised services must take into account, and which are therefore relevant in any assessment of specialised commissioning under the Regulations. Those considerations include:

- primarily, and most importantly, ensuring clinical safety and where necessary overseeing the reconfiguration of specialised services where that might improve clinical outcomes;

- the fact that, for specialised services, there may be risks associated with greater plurality of providers, where this reduces critical mass below a level needed to secure optimum outcomes for the services in question;

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[1] Review of Commissioning Arrangements for Specialised Services, May 2006, An independent review requested by the Department of Health ("Carter Review"), chaired by Sir David Carter, at paragraph 114.
[2] ibid, paragraph 119
[3] ibid, paragraph 185
[4] see, for example, Hunter RM, Davie C, Rudd A, Thompson A, Walker H, Thomson N, Mountford J, Schwamm L, Deanfield J, Thompson K, and others: "Impact on Clinical and Cost Outcomes of a Centralized Approach to Acute Stroke Care in London: A Comparative Effectiveness Before and After Model", *PLoS One*, 2013 8(8):e70420. Epub 2013 Aug 1, concerning improved outcomes for stroke following the reconfiguration of services in London

- the fact that, where plurality of provision may need to be limited to ensure clinical outcomes, a reasonable geographic distribution of specialist centres is important to ensure fair service user access; and

- the fact that greater plurality may not necessarily offer best value for money (since the economic exercise of commissioning functions is a duty on NHS England).

Therefore, for specialised services, there are particular reasons why commissioners need to carefully balance any benefits that might result from increased plurality of providers and/or patient choice, and the specific benefits relevant to specialised services which may result from ensuring that the number of providers of any specialised service provides the optimum outcomes for that service.

5. The Regulations

As noted above, NHS England intends to respond separately following clarification of the particular actions or decisions at issue under the Regulations. However, NHS England would like to outline how it has approached the "overriding objectives" in Regulations to act with a view to securing the needs of service users, improving the quality of services and improving efficiency in the provision of the services. These align with other duties of NHS England outlined above.

Monitor's investigation into the current complaint was opened in early June 2013, some two months after the Regulations came into force and the responsibility for commissioning specialised services passed to NHS England. NHS England will therefore explain, in relation to Gamma Knife services, what steps it has already taken, and also what continuing or future actions it is carrying out or putting in place, to secure service user needs and improve service quality and efficiency. In the field of Gamma Knife and other stereotactic radiosurgery (**SRS**) and stereotactic radiotherapy (**SRT**) services, NHS England has already carried out a number of actions, including:

- putting in place a national Clinical Reference Group (**CRG**) covering stereotactic radiosurgery (**SRS**) and stereotactic radiotherapy (**SRT**), as well as other specialised services. NHS England has put in place CRGs (comprising clinicians, commissioners, public health experts, patients and carers) to:

- ensure the highest possible level of clinical expertise and stakeholder engagement in the development of service specifications and commissioning policies for specialised services;

- develop appropriate quality measures for specialised services, to assure provider performance and to facilitate consistent best practice on a national level;

- develop appropriate CQUIN metrics[5] for SRS; and

- collate and disseminate information on innovative approaches that might be suitable for more widespread application;

- developing an evidence-based service specification for SRS services[6], which specifies how NHS SRS services are to be delivered: it sets out services the required care pathways (assessment, treatment planning, delivery of treatment and discharge); applicable national standards (including NICE standards and relevant Royal College guidelines); key service outcomes and service indicators (i.e. KPIs); and additional specifications concerning the delivery of SRS to children;

- publishing commissioning policies for specialised commissioning generally[7];

- publishing commissioning policies for: stereotactic radiosurgery for vestibular schwannoma and other cranial nerve neuromas; stereotactic radiosurgery for trigeminal neuralgia; stereotactic radiosurgery for arteriovenous malformations; stereotactic radiosurgery/radiotherapy for cerebral metastases stereotactic radiosurgery/radiotherapy for meningioma; stereotactic radiosurgery/radiotherapy for glomus tumours; radiosurgery/radiotherapy for cavernous venous malformations; and stereotactic radiosurgery/radiotherapy for ocular melanoma and pituitary adenoma (interim statement)[8];

[5] Commissioning for Quality and Innovation (CQUIN) is a framework that was first established as part of the 2009/10 NHS Operating Framework as an incentive scheme which forms part of the contract between a commissioner and a provider, containing indicators which address a range of clinical areas and issues and aimed at driving quality improvements. In 2013/14 there are no national CQUIN schemes for SRS. CQUINs, once developed, for the 2014/15 contracting round will be published by NHS England in 2014/15

[6] see http://www.england.nhs.uk/wp-content/uploads/2013/06/d05-stere-radiosurg-stere-radiother.pdf

[7] see http://www.england.nhs.uk/wp-content/uploads/2012/11/comm-int.pdf

[8] available at http://www.england.nhs.uk/resources/spec-comm-resources/npc-crg/group-d/d05/

- consulting, and responding to consultation, on the draft service specifications and commissioning policies for specialised services, including those referenced above for SRS[9]; and

- monitoring and assuring the performance of contracted providers of Gamma Knife services, through the mechanisms of the NHS National Standard Contract which require providers to report on a monthly basis on a number of clinical and operational metrics and other requirements;

In addition, NHS England has already put in place arrangements to further assess service user needs, activity volumes, provider capacity, geographic coverage and other matters for SRS/SRT at a national level, in order further to inform and develop NHS England's commissioning policies for these services. This national review is the first of a number of reviews of the 200 specialised services which NHS England now commissions, and aims to take full advantage of the new possibilities for a national strategy for specialised services now that these are no longer commissioned on a more-or-less local basis and for their constituent catchment populations by separate SCGs, but commissioned by NHS England as the sole commissioner for all service users in England.

The aims and deliverables of this review are, in relation to SRS and SRT:

- to establish a baseline of current contracted activity (demand) and current provider capacity;

- to establish a demand projection based on recently agreed policies for intracranial SRS/SRT, to inform analysis of required capacity, location of that capacity and type of capacity required (SRS/SRT).

- to form, with input from CRGs and Royal Colleges, a clinical consensus on minimum volumes per unit (since there is an important relationship for many specialised services between volumes treated and clinical outcomes, and also important considerations of clinical, financial and operational sustainability to take into account);

- to make recommendations for a national price for SRS/SRT for intracranial indications (currently, some elements only are covered by national tariffs);

[9] see http://www.england.nhs.uk/wp-content/uploads/2013/07/consult-ssscp-13-14-sum.pdf

- to review the provider landscape and potential market entrants;
- to develop a provider map with population/volume isochrones;
- to develop an agreed definition of innovative radiotherapy which is service-driven rather than product-driven and which meets the needs of the patient population in the most effective and efficient manner ensuring value for money;
- to assess and benchmark providers on a national basis to assure best practice and ensure consistency of service standards and delivery; and
- finally, to consolidate the findings into a national commissioning strategy for SRS/SRT for intracranial conditions for local area team implementation. The strategy will make recommendations for any changes in provision that are required to ensure alignment of demand and capacity that is consistent and equitable geographically.

The review will draw on expertise from relevant CRGs and NHS IQ (Improving Quality)[10]. The procurement implications of the commissioning strategy arrived at will be formed with the involvement of Monitor. Project milestones for the review are already in place.

This review aligns with broader work which NHS England is putting in place for all specialised services, and NHS England is grateful for the helpful discussions it has already had with Monitor about the development of a framework against which the operation of choice and competition can be assessed for all 200 specialised services and how the particular issues affecting specialised services affect these decisions; and in particular, for Monitor's agreement to certain prioritisation criteria and other implications related to this work.

NHS England recognises that the overriding objectives are not "one-off" requirements that, once met, can be ticked off and laid to one side: rather, these are objectives that will continually inform NHS England's approach to the commissioning of all specialised services, which will necessarily develop or change over time in response to changes in treatment, changes to the NHS health economy and changes within the provider landscape. NHS England further recognises that not all intended actions or structures to support SRS commissioning are yet completed (for example, NHS England is currently recruiting for Chair of the SRS CRG, and a number of documents or policies relating to SRS are yet to be

[10] http://www.nhsiq.nhs.uk/

completed). However, NHS England considers that the measures already taken demonstrate definite and substantial evidence of NHS England's commitment and actions, in the short time that has elapsed since NHS England became responsible for commissioning specialised services, to ensure that its commissioning of NHS SRS services is addressed fully to secure service user needs, and to improve the quality and efficiency of those services.

6. Observations on dealings with Thornbury since 1 April 2013

As already noted, NHS England will respond in further detail following clarification of the actions and decisions at issue, but it may be helpful if NHS England explains what steps it has taken, from April, and why in NHS England's view a cautious approach was merited.

NHS England has, from 1 April 2013, attempted to engage with Thornbury in a fully transparent manner. The main issues that were discussed have been summarised above. As to why NHS England did not consider it appropriate, as of 1 April 2013, to enter into a contract with Thornbury for Gamma Knife services, it is relevant that in the previous NHS contract year (2012/13[11]), SCGs had in place a number of separate contracts for SRS Gamma Knife services with five providers. On 1 April 2013, NHS England became responsible for commissioning all 200 prescribed specialised services. NHS England therefore decided, for the beginning of the NHS contract year 2013/14, to continue to contract with those providers which, for the previous contract year, had provided Gamma Knife services to NHS commissioners under the NHS National Standard Contract. A number of factors are relevant to this cautious approach:

- there had not, hitherto, been any national assessment of demand for SRS services against national capacity, since commissioning decisions had previously been taken on a more local basis by different SCGs;

- there had not been an assessment of the need for Gamma Knife services at a national level as opposed to other SRS services (not only Gamma Knife but also possible alternative services based on other technologies such as linear accelerator-based technology) some of which are used for the same clinical conditions;

- in the case of Thornbury, even though it had previously provided NHS services as a subcontractor for STHT, those services fell within the clinical governance of STHT, and

[11] NHS contracts typically run with the NHS financial year, that is, 1 April to 31 March.

so it could not automatically be assumed that equivalent clinical governance arrangements would be in place for Thornbury as direct provider of services, but rather, that this required further consideration;

- there might reasonably be questions about whether there was an optimum number of service providers for these services and/or optimum geographic distribution, and whether greater plurality could automatically be assumed to be in the best interests of service users;

- the health service reforms and transition to 1 April 2013 represented a very considerable change in commissioning responsibilities for the NHS in England, and accordingly a degree of transitional stability might be important while these system changes were being implemented.

Taking all those factors into consideration, NHS England could not be sure that to award an additional contract for Gamma Knife services to Thornbury, from 1 April 2013, would necessarily be the right commissioning decision, but that further review of the situation was necessary. Therefore, it appeared to NHS England that beginning the 2013/14 contract year with providers already experienced in the delivery of Gamma Knife services under direct NHS contracts, while continuing to review the possibility of Thornbury also providing such direct services, was a proportionate and reasonable approach to procuring these services at this time.

Concerning NHS England's approach in investigating and assuring the MDT position that would be in place at Thornbury before moving to a contract, this caution was based on the need to fully understand and assess the case of a provider that had not, hitherto, been directly responsible for the clinical governance for NHS Gamma Knife services. NHS England did not simply decline any further possibilities for the 2013/14 contract year that Thornbury might directly provide NHS services, but has continued dialogue with Thornbury with a view to Thornbury entering into a contract during the 2013/14 contract year. In this case, NHS England's aim was to ensure, to the fullest extent possible, that the delivery of services matched what NHS England wished to commission. NHS England considers that it must retain the discretion not to immediately enter into a contract where there remain significant issues of service delivery, especially affecting a key clinical safety requirement of best practice on which further assurance may be required. NHS England has not used those

concerns as a reason to discontinue engagement, but is actively seeking a timely and effective solution.

7. Conclusion

This response contains some initial observations of NHS England to Monitor's Statement of Issues. As already noted, NHS England would welcome the opportunity to clarify the scope of the particular actions or decisions relevant to this investigation, as it relates to the Regulations, and looks forward to responding in appropriate detail to those points, and also to considering more broadly with Monitor how Monitor will be seeking to apply the Regulations in relation to specialised commissioning.

NHS England

16 September 2013