Institute of Physics and Engineering in Medicine

Position Statement: The Impact of Extended Clinical Hours on a Radiotherapy Physics Service 2020 update

		Page
1	Executive Summary	3
2	Introduction	7
	2.1 The Development of 'Extended Hours' Clinical Services	7
3	Definition of a Safe Technical and Scientific Radiotherapy Service	17
4	Key components of a RT Physics Service	20
5	Implementing an Extended Hours Service	23
6	Manufacturers' Support for Extended Hours	35
7	Current Situation in UK	43
8	The Impact of Extended hours on different size centres	52
References		58
Appendices: A	Copy of Maintenance and QA Survey Proforma	61

The Institute of Physics and Engineering in Medicine

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We are a charity with around 5000 members from healthcare, research and industry. The majority of our members are medical physicists, biomedical engineers and clinical technologists employed within the National Health Service with some qualified to doctorate level.

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1 Executive Summary

This report reviews the arrangements for the management of Physics staff and Departmental equipment resources to enable optimal patient throughput given best practice safety standards and treatment techniques. It builds on the 2014 report [1] taking into account the reported evidence, guidance and technological capabilities now available.
This document upholds the view that 'all patients should expect to receive a high standard of modern treatment during the delivery of the prescribed course of radiotherapy which is not dependent on the time or day they attend' and that 'delays or cancellations of individual treatment fractions should be minimised'.

The following summary aims to present the key findings from the report in an accessible manner.

Treatment Planning Resources
A high standard of treatment requires:

- Competent staff across a range of specialties to prepare and validate the individualised treatment plan.
- That for complex radiotherapy planning cases all staff groups are represented at multi-disciplinary meetings.
- Adequate staff numbers to complete safety critical tasks in a timely manner. It is important that Medical Physics Expert (MPE) support is available to support the treatment planning and treatment processes.
- Clinical Scientist and Technologist staff to take responsibility for the Technical and Scientific aspects of treatment plan production and validation.
- Capacity to handle the increases in patient numbers being treated with IMRT (intensity modulated radiotherapy) and VMAT (volumetric modulated arc therapy), and requiring more patient specific QA, since the previous report in 2014 [1].

Servicing, QA, Efficiency and Safety

- A safe and resilient planning and treatment infrastructure must be in place to avoid delays to the start of radiotherapy and cancellations of individual fractions.
- All imaging and therapy equipment needs to function within predetermined geometric and radiation tolerances for safe radiotherapy planning and delivery.
- The integrity of software applications must be demonstrable and all the data transfer links robust, proven and ensured with programmes of planned maintenance, corrective maintenance and quality assurance.
- In a survey of UK Radiotherapy Centres during June 2019, 27% of centres revised their QA model since a similar survey in 2014 [1]. Over 80% of radiotherapy centres already operate extended days. This is considerably more than in 2014, and the majority of patient specific QA checks are carried out outside of the hours 9.00-17.00.
- Throughout the country, all Category 1 patients are being treated daily with over 70% of centres treating all patients every weekday and nearly 90% of centres treating some patients on Bank Holidays.
- Since the previous report in 2014 [1], the Radiotherapy Services Specification 2019 [2] has been published. The 9000 attendances per linac per year benchmark in this specification is a challenging aim, given that many centres are already working extended hours.

- While IPEM wishes to support NHSE in enabling high efficiency radiotherapy, it is important to prioritise patient safety and allow time for advanced image guided techniques.
- The 2019 Specification also requires that linacs be available for treatment 5 days out of 7. Major servicing schedules can last several days and are followed by QA to ensure patient safety; it is important therefore to prioritise safety standards while striving to achieve access goals.
- Operational Delivery Networks, as proposed in the 2019 Radiotherapy Services Specification [2], should initially focus on increasing patient throughput in centres where it is below the national average and identify barriers to improvement.
- There is under-provision of both service efficiency capacity, and decant bunkers which allow continuity of service when machines are being replaced. Centres that make use of service efficiency capacity indicate that such capacity is in use over 95% of the open hours of the Department. It is recommended that centres ensure continuity of service by having service efficiency capacity and decant bunkers in place.

Up-to-date Equipment and Software

- To ensure a modern infrastructure, regular up-grades to radiotherapy equipment and software are necessary. Trusts should support Departments in having a planned upgrade strategy in place.
- Software upgrades require time to implement and ensure correct operation for a safe service.

Best Practice Techniques

- The use of advanced techniques has increased since the 2014 report. These now include improved IGRT (image guided radiotherapy) techniques, SRS (stereotactic radiosurgery), SABR (stereotactic ablative body radiotherapy), adaptive radiotherapy and EPID (electronic portal imaging device) based dosimetry. Such techniques all require increased access to linacs to enable patient QA.
- IGRT, in particular, has increased dramatically since 2014 and is crucial to the delivery of advanced radiotherapy such as high-dose hypofractionated techniques requiring highly accurate position control. Adequate treatment and QA time must be allowed on a per patient basis to ensure the quality of treatment delivery.
- Access to the planning and treatment equipment is also required for service development, clinical trials and R&D. Sufficient staff are required to progress developments in addition to delivering the clinical service as stated in the IPEM recommendations [3].
- The requirements for networked arrangements for treatment delivery in the 2019 Services Specification [2] are recognised. However, there can be compatibility issues facing patient transfer once treatment has started. Patient transfer is easier if the treatment is both planned and delivered in the alternative centre. Longer term matching of linac beam characteristics together with easier inter-operability of equipment will help facilitate this, as will a strong IT infrastructure between operationally networked centres.
- It is also possible to transfer staff provided this does not leave either centre under-resourced, and training issues with different equipment are overcome. Some host/satellite centre arrangements provide a good model of how this can work. A further option is investment in additional staff employed on a network basis.

Service Resilience to Avoid Gaps and Delays in Treatment

- In both the 2014 and current surveys, it was found that the total time required to maintain and develop a safe and modern radiotherapy service equated to one linac year of activity (3000 hours p.a.) in an average department. Any plan to extend the clinical hours in a radiotherapy centre needs to identify when this time will be scheduled.
- One option is the use of Service Resilience Capacity, as outlined in the 2007 NRAG report [4]. Alternatively week-end, evening or night working could be considered.
- Manufacturers do not currently have the infrastructure to support significant extended hours working including service desk provision and out of hours maintenance, and favour a national commitment to such a service. A lead-in time of 2 – 3 years would be required to recruit and train the necessary personnel. An increase in the cost of maintenance of the order of 70% is anticipated to deliver such a service. This view has not changed since the 2014 report.
- Trusts should ensure there are sufficient trained local engineers to work with manufacturers' engineers and provide first line support in the event of unplanned maintenance.
- Trusts should ensure that IT departments provide adequate facilities to enable manufacturers to make full use of modern IT technology during maintenance and repair.
- When planning increased access to radiotherapy, consideration should be given to additional linac capacity in addition to that required for the planned clinical service. This would allow the infrastructure maintenance and service development to be completed during the working week. This may prove to be a more economically viable solution in the long term when manufacturers' costs are taken into consideration for any out of hours or weekend working.
- For centres considering PFI contracts, it is important to bear in mind extended hours working in advance of any contract being drawn up as such arrangements can severely restrict linac use outside the contractually agreed hours.

Planning an Extended Hours Service

- Three models of extended clinical hours of service have been considered:
    - An extended hours week day clinical service, which would enable infrastructure support work, such as software upgrades, to be undertaken at the weekend provided there are adequate staffing levels for safe working practices.
    - A six day clinical service where some infrastructure support could be completed on a Sunday; extended periods of servicing would require access on either a Saturday or Monday.
    - Seven day clinical working where all infrastructure support work would be scheduled during the clinical working week.
- A 5 day working period within a seven day week is considered in accordance with the 2019 Specification [2]. Two non-patient treatment days could be scheduled during the working week allowing easier access for the manufacturers.
- The case mix, capacity and response time should be defined for the clinical service, and the service level components required should be based on that planned clinical service
- The mix of staff during the hours of clinical treatment delivery is dependent on the equipment which is clinically available, and the techniques being delivered.
- The IPEM staffing level guidance [3] is based on an 8 hour day and states that 'additional resources would be required to account for extended working hours'. For an out of hours service departments will need to be staffed above these minimum levels.

- Extending the clinical working hours of a centre will also require adequate numbers of Medical Physics Experts to ensure a safe radiotherapy service.
- Additional staffing will ultimately require the commissioning and full additional funding of training places on a national basis.
- A risk assessment of any proposed model for an extended hours clinical service will ensure safe delivery with no compromise to the outcome of treatment. This should take into account equipment failure and the resolution of problems with individual treatment delivery.

2. Introduction

This report addresses the managerial, technical and scientific issues involved in providing extended clinical hours working and proposes a framework for development of an extended working hours initiative. It has been written by an Institute of Physics and Engineering in Medicine (IPEM) working party comprising a number of Heads of Radiotherapy Physics and representation from the IPEM Radiotherapy Professional Standards Group (RT-PSG). This is a revision of the document first published by IPEM in 2014 and aims to look at the changes in practice since that time, and the implications for extended hours working.

2.1 The Development of 'Extended Hours' Clinical Services

2.1.1 Background to 2014 Guidance

The previous guidance from IPEM (*The Impact of Extended Clinical Hours on a Radiotherapy Physics Service, 2014)* [1] made reference to the NRAG Report which contained key recommendations for Radiotherapy Services in England [4]. This made a number of assumptions and recommendations for radiotherapy departments including:

- Departments were to operate 239 days per year using a standard 5 day week, closing for only 3 bank holidays and allowing no more than 19 days for QA/servicing a year for each linac during normal working hours.
- The majority of the clinical service would be delivered over a 5 day week and maintenance and quality assurance (QA) would take place during the clinical week. Some QA would take place during weekday evenings (not included in the above 19 days).
- Departments would have a service efficiency machine (usually retained in a decant bunker following replacement with a newer machine) providing capacity to deal with unexpected peaks in workload or linac breakdown without increasing waiting times for patients. In addition to a service efficiency machine, radiotherapy departments operate at an average 87% capacity to allow for peaks in demand, testing of techniques & staff training.
- Linacs would work on average 9.2 hours per day with a minority running for an extended day (e.g. 11.5 hours). Apart from some palliative radiotherapy being undertaken on a Saturday there was no stated intention to significantly increase the length of the working week.
- Following the NRAG Report, NATCANSAT (National Clinical Analysis and Specialised Applications Team) established the collection of the Radiotherapy Dataset, recording clinical activity at radiotherapy centres on a national basis. This did not include the time required for non-patient activity.

In 2011 the National Audit office report 'Managing high value capital equipment in the NHS in England' [5] highlighted the NRAG report recommendation of 'extended hours for some units' but recognised the "*uncertainty about the willingness of patients to attend for treatment outside traditional opening times*"

It also highlighted the need to establish a replacement programme for 'Big Ticket Item' equipment such as linear accelerators, and included a review of the clinical hours of use of such items of equipment. It concluded with examples of how trusts had evaluated the configuration of their services and have taken steps to improve their efficiency of machine use, e.g. by achieving the right skill mix to support throughput, assessing the flexibility of working patterns and opening hours, strong engagement with

finance teams, using the right data to measure performance and assessing design and flow to support the patient pathway.

Following this, the radiotherapy community undertook a Radiotherapy Patient Access Survey during 2012 [6]. The survey concluded that patients would be willing to attend for radiotherapy outside the previously accepted clinical hours of 9 am-6pm, at weekends and Bank Holidays. Consequently, extending the hours of the clinical service was also seen to improve patient choice.

A further requirement for out-of-hours non-clinical linac time arose following the government's provision of the Radiotherapy Innovation Fund in 2013, as the volume of patient-specific QA increased dramatically.

Many radiotherapy centres also extended their hours of clinical service, often for limited periods of time, to avoid breaches of the Cancer Waiting Time targets (NHSE), manage high levels of clinical demand and to minimise delays in patients' treatment as recommended in the Royal College of Radiologists (RCR) report 'The Timely Delivery of Radical Radiotherapy: Standards and Guidelines for the Management of Unscheduled Treatment Interruptions' [7][8].

The 2014 Cancer Research UK (CRUK) document 'Vision for Radiotherapy 2014-2024' [9] made reference to the need for extended hours working to improve the efficient use of existing machine capacity. It also cautioned that the benefits of 7 day working need to be set against affordability in terms of staffing costs and the need for additional workforce capacity.

2.1.2 2014-2018

Since the 2014 guidance was issued there have been a number of significant changes in the radiotherapy commissioning, techniques, financial and equipment landscape. Specifically, the **2013/14 NHS Standard Contract for Radiotherapy (B01/S/a)** [10] contained a number of recommendations. It was available from late 2013 but became widely adopted following the formation of NHS England in 2014. It recommends that:

- **Linear Accelerators** were to be in operation for a maximum of 10 years with replacement in a timely manner.
- An **additional 13% capacity** be available to meet fluctuations in demand and technical development requirements, and was seen as essential to meet waiting times targets.

While these advances, which were to benefit patients and improve outcomes, were welcomed, centres that did not have access to additional service capacity in recent years have found that this has led to more maintenance and QA being done out of hours, and a reduction in capacity for accommodating peaks in patient activity. Section **7.6 of this report reports that since the 2014 report** [1]**, 27% of centres surveyed had** revised their model and have sought to maximise clinical time using a number of different approaches including moving QA out of clinical hours or to later in the day and adopting modular QA using a few hours per day on a linac every day of the week.

- **The radiotherapy service was to be available for 239 days per year** including 5 of the 8 bank holidays. Where sufficient patients showed a preference for extended days or weekends, this was to be provided with the appropriate support services available to ensure equitable services for patients outside normal hours.
  This move required support from Medical Physics in terms of both machine run-up and also MPE (Medical Physics Expert) availability.

- The NRIG recommendations regarding the percentage of patients treated with IMRT were upheld. The requirement was that **inverse planned IMRT should be standard for a minimum of 24% of radical patients** and that the number of patients receiving level 2 imaging with radical IMRT should be increased.
  Since then the Radiotherapy Board have recommended that the proportion of radical patients that receive inverse planned IMRT be increased [11]. While the recommended increases were site specific, and vary between departments depending on case-mix, it was expected that IMRT will be provided for at least 50% of radical cases within 5 years, and for leading centres within 3 years. Such increases added to the demand for patient-specific-checks and increased uptake of software based methods, all requiring physics commissioning.

  Further trends were as follows:
- **Modern techniques and technologies** have increased the capability of linac based treatments.
  In the previous guidance, VMAT, FFF and SABR were discussed as new techniques. VMAT has since gained in popularity in accordance with its reduced delivery time and often superior dose distributions, while FFF beams with dose-rates up to 5 times higher than conventionally flattened beams are ideal for the delivery of large dose-per-fraction SABR plans.
  Other new technology included EPID based dosimetry which has enabled the assessment of the delivered treatment plan on a daily basis. Intrafraction imaging using kV x-rays was also available in 3D and 4D formats on some linacs, while other systems based on ultrasound imaging or electronic transponders are now available.
  The advances enabled by **MRI based treatment machine** initiatives have also been considerable [12]. While there were challenges for such systems, including the electron return effect and treatment planning in the presence of an imaging field, such systems allowed the verification of patient setup as well as the monitoring of internal motion within the treatment volume with updates typically of the order of 10 frames-per-second. Such combinations of technologies required increased QA and maintenance due to their added complexity compared with conventional linacs. It is envisaged that manufacturers will respond with suitable phantoms and devices.
  Such technologies have begun to enable an online **adaptive workflow** as an achievable aim. If these approaches become commonplace, and the online recalculation of treatment plans optimised for the daily setup becomes feasible, there may be an increased need for physics staff availability.

- **Hypofractionation** has been used in sites traditionally associated with a large number of fractions such as prostate. The initial CHHiP trial results [13] have led to speculation that it may be possible to use less fractions in a number of situations. While this released more time for physics use of the linacs, hypofractionation with a large dose-per fraction (e.g. SABR) raised the priority of the geometric accuracy in beam delivery and a streamlined and efficient adaptive pathway.
  Again, systems which improve the delivery and accuracy of radiotherapy have been welcomed. However, the complexity of radiotherapy has increased as more comprehensive systems have become available, all requiring additional QA and verification. While checking has been performed using increasingly automated and sophisticated software, there was still a need for some physical checks on the linacs themselves. This often required more to be done out-of-hours

by physics staff. A guide to QA checks, frequencies and action levels is available from IPEM (IPEM Report 81, second edition, IPEM 2018. [14])

- **Image guided radiotherapy (IGRT)** has been increasingly used in recent years.
  Although there have been no controlled clinical trials in this area, Johnson-Hart et al. [15] reasons that: *"because of the presumed benefit of IGRT, quantifying its efficacy in prospective clinical trials is problematic, given the difficulty in arguing equipoise between the two arms. In this context, retrospective observational studies may provide insight."*
  The theoretical basis and technology for IGRT is robust, and compelling clinical evidence for its efficacy is emerging from non-randomised studies. Dang et al. [16] reviewed the evidence for prostate and included a number of statistically significant studies showing a clear benefit for IGRT compared with non-IGRT for clinical endpoints in organs at risk, including dysfunctional rectal symptoms, rectal pain, urgency and diarrhoea. Zelefsky [17] also compared IGRT, using fiducial markers and non-IGRT, finding a significant reduction of $\geq$ grade 2 genitourinary toxicity rate of 10% vs 20%.
  In lung, Kilburn et al. [18] undertook a retrospective comparison of locally advanced lung cancer patients treated with and without IGRT. The IGRT cohort had an improved two year local failure-free survival of 80% vs. 64% (p=0.013).
  Johnson-Hart et al. [15] evaluated the link between residual IGRT shifts and patient outcomes in lung cancer. Residual shifts represent displacements which are less than the action level for an IGRT determined movement. This showed a statistically significant association between shifts in the direction of the heart and overall survival. This provided evidence of the importance of using strict IGRT protocols for organs-at-risk.
  Finally Surface Guided Radiotherapy (SGRT) using optical imaging is being increasingly recognised as contributing to reproducible patient positioning in some clinical situations [19].

- **New Guidance re: Unscheduled Treatment Interruptions**
  It is important to limit unscheduled gaps in radiotherapy for some patients due to tumour cell repopulation during the course of the treatment.
  The RCR guidance, 'The Timely Delivery of Radiotherapy: Guidelines for the Management of Unscheduled Gaps in Treatment 2019', [8] has recently been updated and makes a number of recommendations eg
    - **Category 1 & 2 patients**
      Treatment duration must not be extended by more than **2 days** over the original prescription
    - **Category 3 patients**
      Prolonged interruptions, which may occur because of intercurrent illness, may require compensation, particularly if longer than 7 days.

  While these issues are largely a matter for the Consultant Oncologist, the 2 day limit for the Category 1 and 2 patients adds to the demand for uninterrupted service provision.

- **Independent monitor unit checks for IMRT/VMAT** plans are a standard requirement and IPEM Report 81 [14] has a section on independent dose calculations. However, with an increasing proportion of IMRT for radical patients as well as a trend towards modulated therapies, including SABR, being used for palliative situations [20][21], departments undertaking a high proportion of

patient specific checks using physical dosimetry have needed to make use of out-of-hours working. The majority of PSQA measurements take place prior to 9:00 or post 17:00.
The alternative has been to use software based systems. Independent dose algorithm based checking systems which use DICOM, linac log files and EPID dosimetry for this purpose, together with metrics for assessing plan complexity and data transfer checks [22], [23]. A number of commercially available products for these situations have become available.

- **Training issues** have led to workforce shortages in Radiotherapy physics (IPEM 2016 [24]). The guidance strongly recommended that adequate numbers of physics staff be available at all times and this approach has been reiterated in '*Recommendations for the Provision of a Physics Service to Radiotherapy'* [3] which states that "*Additional resources would be required to account for extended working hours and/or weekend working for treatment, planned preventative maintenance, repair or quality assurance work."* Flexible alternatives, in the form of skill mix using other staff groups in some situations, are included in the above staffing recommendations. While the majority of Clinical Scientist trainees pass through the Scientific Training Programme (STP) scheme of the National School for Healthcare Science, some departments have offered on-the-job access to Route 2 training. This is a portfolio-of-evidence based scheme for those normally with a relevant higher degree. Approximately 15% of trainees passing the ACS assessment in Radiotherapy Physics in recent years were from the Route 2 pathway. It normally takes at least 4 years to gain sufficient experience. It is essential that STP remains a fully funded scheme. Shortfalls in training of clinical technologists under the Practitioner Training Programme (PTP) have led to the introduction of apprentice models to train clinical technologists and linac engineers. The lack of a viable PTP training scheme for dosimetrists has led to the increased recruitment of radiographers to these posts, where therapy radiography is itself a shortage profession [25,26]

2.1.3 2019 Radiotherapy Services Specification

Following a period of public engagement which included early proposals followed by a public consultation in December 2017, NHSE published a new Radiotherapy Services Specification in January 2019 [2] .

This was split into documents covering (a) the core services to be delivered by each radiotherapy centre within England and (b) the defined network of radiotherapy departments including staff and equipment.

One of the key aims of the revised specification for the radiotherapy network is to:

- *"Reduce variation in equipment utilisation in England through changing operating arrangements, clinical practice and equipment replacement; an average 15% increase in equipment utilisation for England as a whole is expected over the next 3 year period aligned to the equipment modernisation programme."*

The Specification has a number of requirements relevant to the provision of a radiotherapy physics service including the following, on page 5 of the core specification:

"Continually review the working arrangements of the service with the aim to improve equipment utilisation rates to meet the national benchmark of 9,000 attendances per year as a service average by ensuring that:

- *Each machine is available to treat patients <u>at least</u> 5 days per week;*
- *That servicing and planned preventative maintenance, quality assurance checks and other key activities (including capacity to accommodate machine breakdowns) do not disrupt Service User's treatments and should be undertaken on any of the other days of the week; and*
- *Ensure there are contingency plans and arrangements for the management of Service Users during periods of staff shortage and machine maintenance and breakdown which should be in place and form part of the Network workforce sustainability strategy."*

2.1.4 IPEM View

The IPEM wishes to work as closely as possible with NHSE in providing efficient radiotherapy driven by the latest evidence based protocols. It is however important to uphold standards of quality and safety while striving for the stated aims given in the 2019 Specification. The above requirements will be discussed and recommendations regarding implementation will be given.

- **9000 Attendances per year per linac Benchmark**

The national benchmark is clearly framed as a service aim to be attained by reviewing and adjusting the working arrangements of the service going forward. This aligns with the expected "*average 15% increase in equipment utilisation… over the next 3 year period"* to give an improvement of 5% per year.

Throughput will be influenced by the number of fractions per hour, the working hours of the department, and the time required for servicing and QA, as well as the case mix. Practically, the options for increasing throughput include increasing the fractions delivered per hour, or extending the treatment hours. The length of the linac timeslot used to treat the patient is typically 15 minutes but shorter and longer times are in use [27]. The timeslot can be reduced by having the patient change outside the room and taking discussions with patients to a separate room.

However, the RTDS data shows **only one department** currently works at the benchmark level (figure 1) with details given in chapter 8 of this report. The centre is concerned that there is little time to allow patients to share valid concerns regarding acute toxicities and other issues. There has also been a major increase in the amount of image guided radiotherapy in recent years which has added considerably to the time taken per fraction. This importance of IGRT is supported by a growing evidenced base as discussed in 2.1.2.

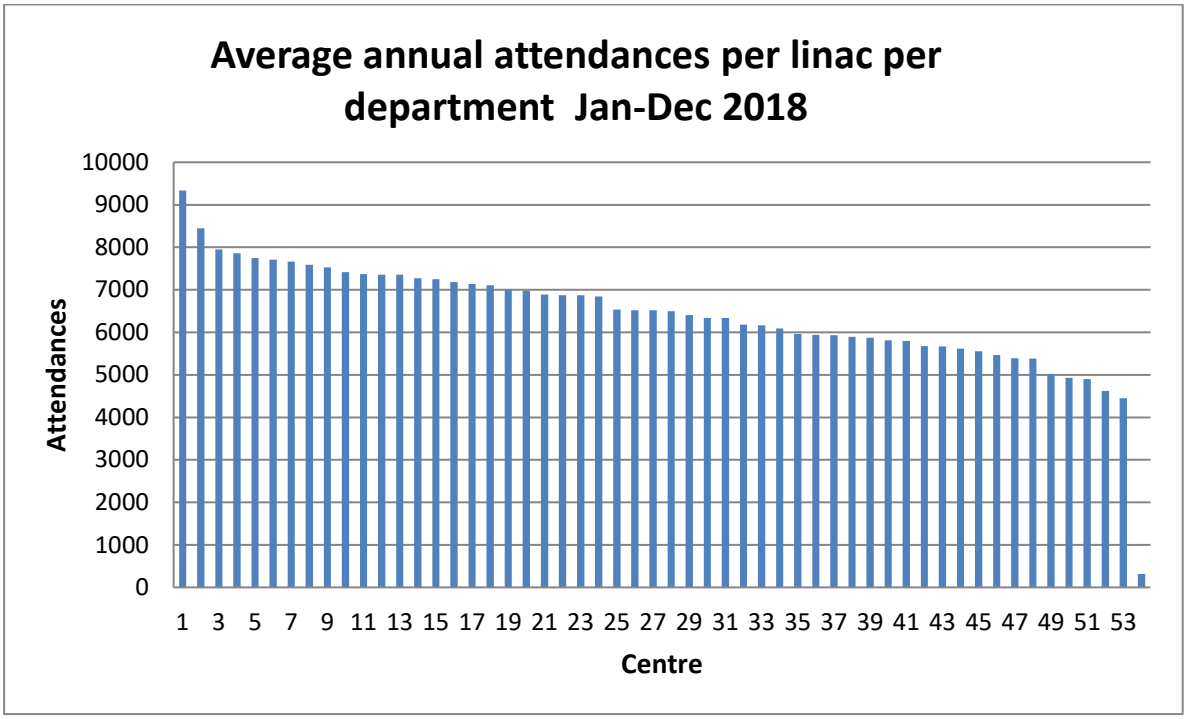

Figure 1 The average annual number of attendances (fractions) per linac per department Jan- Dec 2018

A large number of centres are achieving the national average of ~6500 attendances per year and it is more realistic and achievable to support those centres attaining less than this figure in increasing their throughput to thus increase the national average. Some more remote centres may also experience difficulties in increasing their throughput due to access issues.
Advanced complex radiotherapy which is image guided and adapted to daily changes in patient anatomy will require longer timeslots. Adaptive clinical trials such as RAIDER [28] and HYBRID [29] usually involve imaging followed by selection of the "*plan of the day*", both of which require extra time. It is likely that future techniques will involve plan recalculation and checking, again requiring additional time, until a more automated process is available. Sparing toxicity to the heart in breast radiotherapy by use of deep inspiration breath-hold (DIBH) [30] also requires longer timeslots. As breast patients generally account for approximately 25% of radical workload, full uptake of DIBH will have a significant effect on the length of the working day. Similarly, increased use of internal mammary chain (IMC) irradiation will increase the demand for treatment time.

One efficiency, discussed above, could be to migrate all static field IMRT plans to VMAT resulting in time savings of a few minutes per patient, though most UK centres already deliver greater than 50% of their modulated treatments using VMAT [11]. The complication of this approach is that most planning systems take considerably longer to optimise VMAT plans due to the additional degrees of freedom afforded by the rotational approach. Also, for centres undertaking patient specific QA (PSQA) for every patient, this may lead to a large number of additional checks. These can be reduced by using a sampling and/or software based approach to independently check MUs and distributions. Flattening filter free (FFF) beams also offer a shorter beam delivery, ideal for large dose-per-fraction treatments. To this end it may be useful for departments to review the proportion of plans generated for the techniques which are faster to deliver.

- **Each machine is available to treat patients at least 5 days per week**
  This is clearly intended to support the above benchmark target. However, it is not compatible with the latest servicing schedules from some manufacturers. Similarly, the Specification does not give any context for this statement and nor does it give any qualification to assist centres which have already extended their working hours into the weekday evenings.

  Servicing can last up to 5 days and needs to be followed by QA. As this is a patient safety issue, it must be upheld. It is possible to break such services down into smaller blocks but again each needs to be followed by QA, as required under IRMER [31].

  We consider it more appropriate for there to have been an indication of the number of hours that would be considered the aim for the working of radiotherapy Departments. This would then allow individual departments to extend their working hours in ways that are most appropriate locally and in conjunction with the considerations laid out in this report.

  The two non-treatment days in the Specification are not limited to the weekend, and if week days are used for manufacturer servicing this will reduce costs compared with weekend servicing (see chapter 6).

- **Servicing and PPM, QA and capacity to accommodate machine breakdown do not disrupt treatments, and should be undertaken on any of the other days of the week.**
  We recommend that these important functions are not seen as something separate from the directly patient facing service as they facilitate and enable the complex radiotherapy that provides good clinical outcomes. **Service resilience capacity**, strongly recommended in earlier guidance, is needed in order to provide this. This can take the form of weekday servicing with treatment at the weekend, or extending the service into weekday evenings. Some centres use the beginning of the day for QA on, for example, one machine per week, or work an extended day for this.
  Other options for providing additional RT service time include:

    - The above "*high throughput, shorter day*", using shorter treatment slots approach. This extends clinical hours via an evening shift in a servicing or breakdown situation provided that is not a regular occurrence. Using all available machines for extended working 7 days a week leaves no contingency.
    - Service resilience capacity can be built into treatment schedules, especially for larger centres with matched beams where capacity can be shared around a number of linacs without significantly reducing the average machine throughput.
    - The use of specific time for patients/QA/servicing etc. can be flexible and negotiated within agreed limits.
    - The two "*non-treatment days*" suggested in the Specification are unlikely to be fully utilised every week for every linac, so there is an option to use them provided there are sufficient staff to provide cover for the remainder of the week.
    - Downtime can also be reduced by truly **preventive** replacement of parts during a service (e.g. electron gun) at recommended lifetime rather than point of failure. This approach may incur higher costs but would result in less downtime.

- If the cost of implementing a plan for increased throughput increases the average cost per patient (considering all capital and revenue costs) then implementing such a plan may be contrary to the spirit of the service specification.

It is more difficult to provide additional capacity for unplanned (breakdown) maintenance situations, though evening working can contribute to this area.

- *"Ensure there are contingency plans and arrangements for the management of Service Users during periods of staff shortage and machine maintenance and breakdown as part of the Network sustainability strategy."*

  Network provided capacity contingency may be an option for longer term situations, however short term options involving **patient transfer** will often be limited by geography, transport and patient acceptability. Following the Oncology Centre fire in Bristol during 2018, a significant proportion of patients declined to travel to an alternative centre for treatment. There is also a clinical risk of mistreatment due to unfamiliarity between patients and staff in the alternative centre. These factors make it difficult to operate a Network based contingency arrangement in the short term, but it may be possible in situations where there is advance warning of reduced linac availability. This includes machine replacement or a period of prolonged staff shortage. Such situations will generally require the full transfer of the patient, including CT data if already available, to the alternative centre, so they can be planned and treated there using the appropriate beam data. Immobilisation equipment may need to be transferred or purchased to facilitate such arrangements. Linked or satellite centres will be better prepared for such events, with decisions regarding machine matching and common networked planning systems made well in advance. In this situation the combination of centres may be able to work as 'one big department', but it should be noted that alternative departments will generally already have a significant workload. For full patient transfer situations, it will be helpful to have network based contingency plans and rehearse these in advance. It will also be helpful to quality assure dose delivery in preparation for such events.

  Staff transfer may be possible for defined periods but, as above, most centres will not have 'spare' staff, especially if longer periods of cover are required over the extended working week. Phone support and video conferencing can be useful, particularly as a means of gaining MPE support as well as input into complex planning issues.

  This approach assumes the shared staff are trained in the use of the equipment and techniques of the destination centre. One option is to have **additional staff employed on a network basis** so they can be called upon at such times and rotate them through different departments to gain the experience they will need. This solution may be useful for equipment commissioning, particularly for small departments.

- *"Reduce variation in equipment utilisation in England through changing operating arrangements, clinical practice and equipment replacement."*

  The redistribution of equipment resource in some networks will need to be decided by the Operational Delivery Network on the basis of capacity and demand, as well as patient acceptability. Reducing capacity in a centre will limit its ability to provide contingency either for local breakdown or transfer of patients from another centre.

  The alternative of partnerships between centres for the treatment of specific sites may also be an option depending on clinician availability, capacity and patient travel preferences.

In the rest of this document, we will discuss how to achieve the spirit of this specification i.e. delivering a cost effective service, and minimising delays and disruptions to patients, while recognising that departments will be reviewing working arrangements with the aim of improving utilisation rates as required by the Specification. Chapter 5 will examine the practical advantages and disadvantages of the various ways of working.

Summary of Recommendations & Key Points :

- Adequate time should be available to allow for image guidance in situations where there is evidence or expectation of its efficacy. Increased throughput should not compromise quality.
- Departments should review their treatment planning and delivery techniques to optimise throughput.
- It is essential that fully funded training schemes exist for both clinical scientists and technologists.
- Operational Delivery Networks should initially focus on increasing throughput in centres where it is below the national average, identifying barriers to improvement.
- Adequate time for servicing and QA should be prioritised so that patients can be safely treated.
- **Service resilience capacity** should be identified so that treatments, which may be adversely affected by prolongation, are not interrupted.
- Departments should review their servicing arrangements with the aim of providing a cost-effective and safe model that does not disrupt patient treatments.
- Operational Delivery Networks should work with Centres to formulate realistic contingency plans which identify the roles of local and network based contingency capacity.
- Operational Delivery Networks should explore the option of having additional staff employed on a network basis.
- Network based contingency plans for transfer of patients in emergency or high demand situations should be rehearsed or a regular basis.
- Operational Delivery Networks should formulate long term plans for equipment deployment and capacity based on capacity, demand and evidence based trends in radiotherapy utilisation. This will include reviewing the need for compatible equipment to facilitate contingency treatment capacity.

3. Definition of a Safe Technical and Scientific Radiotherapy Service

All patients receiving radiotherapy should receive a high standard of treatment during the delivery of the prescribed course while minimising delays or cancellations of individual treatment fractions. This requires a safe and resilient environment whatever time or day the patient attends for treatment.

3.1 Infrastructure

To ensure a safe clinical radiotherapy service the essential infrastructure must be established and maintained.

All imaging and therapy equipment must function within predetermined geometric and radiation limits for safe radiotherapy planning and delivery [14]. This includes pre-treatment as well as on-treatment verification imaging devices and therapy equipment. Trained staff with adequate time are key to the infrastructure required to do this. Staffing includes engineers, scientists, dosimetrists and technologists to undertake maintenance, repair and quality assurance, determine the outcome of assessments and initiate remedial actions. A Medical Physics Expert (MPE) is required to ensure the accurate calibration of all treatment equipment (IPEM recommendations for the Provision of a Physics Service to Radiotherapy [3]) and Medical and Dental Guidance Notes (MDGN) [[32], IPEM Report 81, appendix A [14]. The time required for equipment maintenance, repair, QA (both machine and patient-specific) and upgrades must be included in clinical service resource calculations.

Specialist software applications are required for the preparation of complex data for radiotherapy during the planning process, including treatment planning systems as well as image fusion software, virtual simulation, auto-contouring and plan checking applications. Similarly during the preparation and delivery of radiotherapy, specialist applications are essential for the recording and verification of radiotherapy, and image guided radiotherapy. This may become more necessary as the technology becomes available for online adaptive radiotherapy, requiring rapid decision making based on daily imaging and positioning data. Innovations such as the MRI linac [12,33,34] employ novel technology combinations requiring new planning and checking approaches in order to verify that the desired dose distribution has been delivered [35,36].

Clinical Scientists with specialist knowledge and expertise are required to commission and maintain these applications and take full responsibility for the scientific aspects of the treatment planning process including setting up treatment protocols. Time is required when systems are non-clinical, for software upgrades, maintenance, and validation of the integrity of data transfer between the specialist software applications and the treatment units.

A robust IT infrastructure is essential for the preparation of complex data for radiotherapy and to ensure secure data transfer between the specialist software applications and the treatment units. Thus personnel and resources are required to maintain the IT infrastructure with time allowed for hardware replacement, end-to-end testing and disaster recovery validation. The tasks involved, especially at the interface between IT and specialised software controlling complex medical devices, are beyond the scope of a normal IT department. Therefore this resource is best provided by specialised staff either within Radiotherapy Physics or within a separate section of Medical Physics.

The delivery of a safe clinical radiotherapy service is only possible if time and resources are identified and available to maintain and deliver the infrastructure as outlined above. As such, the time and range of

specialist personnel, including IT staff, required to ensure this infrastructure is in place must be included in the clinical service resource calculations.

3.2 Individual Patient Resource

To ensure the delivery of a safe and high standard of radiotherapy, appropriate immobilisation must be available and treatment data that is customised and validated is essential. This will require the manufacture and fitting of the immobilisation aid followed by localisation imaging, outlining, treatment planning and treatment data validation, to ensure the appropriate data is available for treatment delivery and recording. A number of stages in the planning of a customised treatment are undertaken without direct contact with a patient and requires input from dosimetrists, oncologists, radiologists, clinical technologists, therapy radiographers and clinical scientists.

Customised immobilisation equipment is often required for a patient, so mould room services delivered by either radiographers or clinical technologists are an essential part of the clinical service. This service may also require input for non-standard situations from oncologists and Clinical Scientists. As a result, a range of staff are required to contribute to the design and construction of immobilisation devices, most of whom are not required to be present for treatment delivery, unless there is an issue with patient setup. Similarly, the staff required to prepare the patient data for treatment may have to be available for multi-disciplinary meetings, but are not normally required for first or subsequent treatments provided all the essential data are available.

When a problem arises during a course of treatment, there may be a requirement to access specialist expertise. This would include out of tolerance in-vivo dosimetry results or patient anatomical changes, possibly indicating a requirement for re-planning. These situations often require the advice of a clinical scientist or technologist to resolve the problems prior to the next treatment fraction and usually require the specialist to be available prior to the planned delivery of the next treatment fraction.

3.3 Summary of Recent Publications in the Literature

There has been very little published on the issue of extended days and weekend working. Most accounts of the use of weekend treatments have been in the context of emergency treatments [37],[38] or as a means of compensating for unscheduled breaks [39] rather than as a means of increasing the capacity of a department.

Thomas [40] modelled capacity and demand on linacs, and showed that, to keep waiting lists down, capacity must exceed mean demand by at least 10%. This, in combination with 3% for training etc., formed the basis of the 13% used by NRAG.

Two papers in Clinical Oncology by the same team from St Thomas' Hospital, London [41], [42] gave a comprehensive review of the situation in 2007, including results of a survey of patients, and a survey of practices in UK departments, based on questionnaire responses from 52 departments. Issues of servicing (in hours and out of hours) were discussed; the mean amount of time spent on servicing and QA (excluding daily checks) was 247.2hrs per machine (range 129.1-429.5) of which, on average, 35.2% (range 0-100%) was done out of hours, defined as before 09.00hrs or after 17.00hrs.

A survey of patients in British Columbia [43] also looked at patients' willingness to attend outside core hours, defined as 8:00 to 16:30 Monday-Friday. They concluded that 80-90% of capacity should be provided in core hours, and 10-20% outside core hours, 7:30-8:00 or 16:30-18:00 or weekends. In 2006,

Routsis et al. modelled different patterns of radiographer staffing for an extended day, and concluded that all gave fewer treatment hours per radiographer than a standard 7.5 hour day with breaks [44]. The longer the day, the smaller this effect became.

The NRAG Report [4] advised that only half the machines in a department should run an extended working day, and recommended a 5 day week, saying "*internationally radiotherapy practice is based on a 5 day working week and recommended fractions for radical treatment have been developed and proven over the years on this basis. Alterations in the working week to include Saturdays for radical treatment would therefore pose complex scheduling problems. Only a 7 day week would avoid this, but NRAG advised that this is unlikely to be feasible given the national and international shortage of specialist staff needed to run the service. It is also not clear that a 7 day service would be popular with patients or that it would be attractive to radiography or physics staff (once numbers have increased) - leading to further recruitment and retention difficulties. Where departments open on a Saturday, Sunday or bank holiday NRAG recommend that a full service should be operated – this does not mean that all linacs in a department need to be in operation. However, there should be appropriate support for patients available including reception staff and the ability to obtain refreshments. In addition to the therapeutic radiographers delivering the treatment, physics and medical staff would also need to be available to support treatment."*

Probst et al. [45] suggested a link between extended working days and staff 'burnout', which could result in radiographers leaving the profession. This may limit the ability of departments to expand radiotherapy capacity. Radiotherapy Clinical Scientists, Clinical Technologists and Therapy Radiographers both appear on the UK list of shortage occupations (Home Office 2016 [25]–under review [26]).

The joint document from IPEM, Society of Radiographers (SCR) and RCR published in 2013, "Guidance on the Management and Governance of Additional Radiotherapy Capacity", [46] mainly describes increases in capacity by provision of additional machines and satellite departments. However, mention is made of the "*pros and cons"* of servicing at evenings and weekends, noting that the former may not be an option if there is a long extended working day, and the latter, for a small staff group, the frequency that each member is required to be available may impact on staff morale. It recommends the use of Malthus [47] to predict demand for radiotherapy.

Summary of Recommendations & Key Points :

- **The provision of a safe radiotherapy service requires considerable scientific and technical input.**
- **Scientific and technical staff are required, at the levels recommended by IPEM** [3]**.**

4 The Key Components of a Radiotherapy Physics and Technical Radiotherapy Service

A safe, resilient and modern radiotherapy service requires on going non-clinical activities to maintain and develop the infrastructure. These activities are defined in the following section. They could be undertaken in parallel with the clinical service if resources permit or outside the hours of the clinical service. However they are not optional and require adequate resources and access to equipment to ensure they are delivered safely and to a high standard.

4.1 Non-Clinical Activities Required to Deliver a Safe Clinical Service

4.1.1 Planned Maintenance

For all radiotherapy equipment, the manufacturers specify a schedule of planned maintenance inspections (PM). Depending on the company and the department, these may either be carried out by the company or by in-house engineers. The schedule may also involve the periodic replacement of parts with a known lifetime.

4.1.2 Corrective Maintenance

When a QA measurement falls outside an agreed limit, work has to be carried out to return the parameter to within tolerance. Minor work will frequently be carried out within the QA schedule or scheduled to minimise disruption to the clinical service. More major work will generally count as an unplanned equipment repair.

4.1.3 Unplanned Equipment Repairs

When a machine breaks down, has a fault, which significantly impairs performance, or has a QA measurement outside a defined suspension limit, it has to be removed from clinical use until it is repaired. This work is generally unplanned, and so has the potential to disrupt patient treatments. In some cases, where an intermittent fault occurs, or a parameter is heading towards a limit, there is some choice available about when to do this work, so it may be counted as corrective maintenance by some departments; however, the shorter the notice, the more it is in effect unplanned. In a department working extended hours, unplanned repairs are very disruptive on patient schedules, and this can be alleviated if the department has built-in service resilience capacity.

4.1.4 Machine Quality Assurance; Regular and following Upgrades.

IPEM Report 81 (edition 2, 2018)[14] specifies a programme of regular checks to be carried out on radiotherapy equipment. There are daily checks that must be carried out before the machine is used each day, and more detailed checks carried out at intervals such as weekly, monthly, quarterly and annually. The rationale for the frequency of some checks is given in IPEM Report 81 [14]. The legal requirement for employers to establish a quality assurance programme is specified in Regulation 6 of IRMER 2017 [31] and each department has a QA system that specifies the quality control (QC) checks to be followed. In addition to these regular checks, there are extra checks that must be carried out after repairs and upgrades. The nature of these checks will depend on which components have been changed or repaired; for example the replacement of a transmission ionisation chamber would require additional dosimetry checks, as laid out in the guidance for definitive calibrations in the Medical and Dental

Guidance Notes (MDGN), which is also currently being revised [32]. Upgrades to computer hardware may additionally require checks on the functioning of software, as described below.

4.1.5 Software Quality Assurance

This applies to both routine QA and that required following software upgrades. Radiotherapy equipment is usually computer controlled. A computer system called a Radiotherapy Management System (RMS) links the systems in a department. RMS in use in the UK include Aria, from Varian, and Mosaiq, from Elekta. A failure of an RMS can prevent treatment on all machines in the department at the same time. There are also software systems specific to each individual piece of treatment or imaging equipment. Software within Treatment Planning Systems (TPS) is used to calculate the parameters required to deliver the required radiation dose distributions for individual patients. The QA system will include regular checks on the software systems.

Software upgrades are typically required at intervals of 1-2 years. Following an upgrade, a series of tests are required to assure that the software is running as expected. For an RMS upgrade, the upgrade typically takes 2 days, with a further 1-2 days required for QA tests. This can potentially close the radiotherapy service for four working days, especially where manufacturers are unable to support upgrades at weekends (see chapter 6).

4.1.6 Cross-Calibrations and Reference Dosimetry

The dose of radiation received by patients must be traceable to national primary standards. To ensure this, each department has access to one or more secondary standard dosimeters, which are calibrated at the National Physical Laboratory. Departments follow codes of practice published by IPEM to ensure consistency of reference dosimetry. These codes require that the field instruments used for routine measurement of dose are cross-calibrated annually by inter-comparison against a secondary standard. This can take 1-2 days per annum on a multi-energy machine. Where machines are not beam-matched, this needs to be repeated on each machine.

Inter-departmental audit involves Clinical Scientists from one centre performing measurements on equipment in another centre in order to validate the accuracy of reference dosimetry and related measurements. This is coordinated by regional audit groups of the IPEM RT-SIG inter-departmental audit sub-committee.

4.2 Clinical Activities

To ensure the delivery of safe and state of the art radiotherapy for individual patients, customised treatment data must be validated prior to treatment.

4.2.1 Patient-Specific QA for Complex Treatments.

Complex treatments are usually the more technologically advanced, which at the time of writing would be considered to include Intensity Modulated Radiotherapy (IMRT), including rotational delivery such as Helical TomoTherapy and Volumetric Arc Therapy (VMAT), Stereotactic Ablative Radiotherapy (SABR), Stereotactic Radiosurgery (SRS), Adaptive Radiotherapy and use of Flattening Filter Free (FFF) beams. However, other techniques are likely to be developed for which the same principles would apply.

It is widely accepted that patient-specific QA measurements are performed for IMRT and VMAT, except in certain circumstances described below. Patient-specific QA involves delivering the treatment plan to a

phantom, with measurements being performed with chambers, films, detector arrays or Electronic Portal Imaging devices (EPIDs) [14]. This QA involves time on the machines, and must be scheduled to be performed after the plan has been produced and before the patient starts treatment. These measurements can be reduced or dispensed with in some cases where at least 10 patients have been treated with the same treatment procedure (class solution) for similar body sites and where an independent check of monitor units/dose has been carried out for the treatment plan, as defined by NCAT 2011 [48]. For other complex non-IMRT treatments such as SABR and SRS patient-specific QA is also carried out, especially in cases where no reliable independent Monitor Unit (MU) check software exists or the treatment fluence is too modulated to rely on a single point MU check.

4.3 Clinical Service Development

Maintaining a modern radiotherapy service requires the continuous implementation of new radiotherapy techniques and procedures. Guidance can often be provided through clinical trials or national recommendations, but local validation is required before clinical implementation. This activity, which cannot be considered optional, will usually require access to the therapy equipment. This can be undertaken in parallel with the clinical service if resources permit or outside the hours of the clinical service. However, adequate resources must be available for safe implementation.

4.3.1 New Techniques

It is the nature of the work of a radiotherapy department that new radiotherapy techniques are continuously being developed and implemented. This work includes both new techniques and implementing a technique developed in another centre and requires access to therapy equipment by Clinical Scientists. This access is required to measure beam data specific to the new technique, to carry out relevant phantom measurements, and finally complete end-to-end tests of all the stages in the process to provide validation of the new technique before it is used clinically. Examples of recent developments in UK centres include rotational IMRT techniques, such as VMAT, the use of flattening-filter free beams (FFF), SABR and SRS.

4.3.2 Clinical Trials

Radiotherapy centres are encouraged to participate in single-centre and multi-centre clinical trials. For all National Institute of Health Research Clinical Research Network (NIHR CRN) Portfolio trials that include a radiotherapy component, centres are required to be credentialed by the Radiotherapy Trials Quality Assurance (RTTQA) team. The RTTQA was established to ensure that patients in all National Cancer Research Institute (NCRI) radiotherapy trials adhere to a trial protocol, and are treated according to nationally accepted standards. This is an integral part of radiotherapy clinical trials and serves to minimise variations thus ensuring clinical trial outcomes reflect differences in randomisation schedules rather than departures from the trial protocol. Credentialing is done by a mix of questionnaire, planning exercises and measurement visits. These visits depend on the trial being credentialed, but a typical IMRT credentialing visit may involve individual field measurements, combined field measurements and dose point measurements, which all require access to a linac.

4.3.3 Research and Development

In addition to the two areas above, a department may have a programme of research that requires other measurements to be carried out on linear accelerators. For example the department may be devising

new forms of dosimetry, new computer models for modelling dose deposition, or new methods of imaging the patient for IGRT.

4.4 Infrastructure Maintenance

4.4.1 Buildings and Estate Maintenance

Estates departments will require access to treatment rooms, and to associated plant rooms, to carry out maintenance work. This cannot be carried out at the same time as treating patients.

4.4.2 IT Infrastructure Maintenance, e.g. Database Backups, Operational Upgrades

In addition to the software upgrades described in 4.1.5 above, there will be a requirement by the IT department for access to the system for IT infrastructure maintenance, for example to the routers and switches in the network infrastructure, upgrades to operating systems, and back-ups of data. Some of these tasks can be performed without affecting the service, whilst others will need to be scheduled to take place at times when the centre and hence equipment is not in clinical use.

Summary of Recommendations & Key Points

- All radiotherapy equipment needs a schedule of planned maintenance.
- Where a machine breaks down, or fails a QC test, unplanned repairs or corrective maintenance are required.
- Upgrades to hardware and software require time to be scheduled, both for the upgrade itself and for QA following the upgrade.
- Time must be scheduled for annual inter comparisons and periodic dosimetry audits.
- Patient specific QC measurements for complex treatments such as IMRT and SABR need to be scheduled to fit in with patient pathways.
- New techniques, clinical trial work and other R&D all require time on treatment equipment to be allocated.
- Infrastructure maintenance can also impact on machine availability.
- Close cooperation with Trust IT departments is essential to ensure that the IT infrastructure meets the Radiotherapy Department's requirements, is available as necessary, and provides sufficient redundancy to withstand incidents such as network failures or to provide disaster recovery.

5 Implementing an Extended Hours Service

Before implementing an extended hours radiotherapy service, it is important that key stakeholders are involved in discussions regarding the scope as well as the limitations and opportunities involved. In the

2014 version of this guidance, the survey of radiotherapy centres showed that the clinical service generally started around 8:30 and finished by 17:00, Monday to Friday. This 'normal hours' pattern of working has been acceptable amongst the majority of staff and has benefitted from the availability of support from manufacturers and other services within the hospital (portering, estates, IT etc). Many radiotherapy centres have been able to accommodate routine machine QA and maintenance within these hours. However increased levels of patient specific QA and other technical and scientific activities, as well as clinical pressure on linac time have moved a lot of these activities to the evening or weekend.

Financially it might appear to make sense to operate the radiotherapy equipment over a longer day to make the most of the capital investment. However, this simplistic view ignores the other aspects of the clinical service which are essential to sustain an effective high quality service. These include planned maintenance, quality assurance and developments in treatment techniques, which are as much a part of the clinical service as delivering radiotherapy to the patient, as outlined in chapter 4. Therefore, it is important to develop a model of the proposed extended service which meets clinical needs within available resources as well as allowing the service to be safely delivered and developed in line with current practice.

5.1 Models of Extended Hours Service

Models of extending the working hours of a radiotherapy service beyond normal hours can be summarised as follows:

Extended Week Day Working

In this scenario, the operating hours of the treatment machine are extended beyond 9 to 5 at the beginning and / or the end of the normal working day. Daily QA is performed early in the morning and treatment appointments offered beyond 5pm. The disadvantage of this model is that service development, which requires access to the machine, must be done either during the hours of clinical service, or at weekends. Similarly, routine machine maintenance and manufacturers' support must be accommodated when required. It is common in these scenarios that more complex treatments requiring constant or occasional input from more experienced or skilled staff are restricted to normal working hours. It is therefore imperative that the range of techniques delivered throughout is properly considered before operating hours are extended to ensure appropriate staff are available.

Six Day Working

In this scenario the working week is extended to include a Saturday or a Sunday. The issues surrounding time for scheduled maintenance and service development are similar to the Extended Week Day working situation but time for service development would be restricted to the seventh day or evenings. The risk of a lack of manufacturers' support is exacerbated by offering a full service on the weekends if local support staff are unavailable. Similarly, other support services, such as estates are also unlikely to be available without prior arrangement.

Seven Day Working

In this scenario, a full clinical service is offered every day of the week. This working pattern has benefits of increasing capacity and, by potentially enabling patients to start or finish on any day of the week, can maintain the lowest possible treatment duration removing the need, for example, to start on a Monday.

This may help reduce the time from referral for radiotherapy to treatment start. In this scenario, time for routine maintenance, quality assurance and service development must be carefully considered to ensure a robust and developing service. As with other scenarios, manufacturer and other service support may be problematic to attain and should be included in the considerations of the implications of such an arrangement. By operating the machines in such a demanding schedule, a significant amount of contingency is lost, which is required for emergency breakdown situations and machine and information system upgrades that may require several days of unavailability. In other scenarios, this can often be accommodated at the weekend. It should also be noted that the majority of patient set up issues occur on the first fraction. However, due to the availability of experienced staff, it may be appropriate for all but the simplest treatments to start within standard working hours.

A variation on this scenario is to offer 5 day working within a 7 day week, as required by the 2019 Radiotherapy Services Specification [2] and discussed above in chapter 2. Under this arrangement, most machines in the department will be working over the full 7 day week, but one or more linacs may be undergoing maintenance or QA for the other 2. The two non-patient days may be the Saturday/Sunday but could equally be scheduled for week days with treatment over the weekend. This arrangement does allow easier access to manufacturers, although there may be issues for machines which develop faults over the weekend.

In all these scenarios, attempts to remove the problem of lack of experienced staff out of hours by scheduling them to cover the start and finish of the day produce only a very short window when all members of a team will be present. This presents difficulties when introducing new techniques, since this relies heavily on communication between members of the team with different skills. This problem is increased even further if staff are rostered across a six or seven day week highlighting the need for robust staffing levels to be maintained [3].

Scenario	Description	Advantages	Issues
Extended Week Day Working	The clinical service extended to deliver radiotherapy beyond normal working hours at the beginning and / or the end of the day, Monday to Friday.	• Weekends would be available for emergencies and some palliative patients as outlined in the NRAG report [4]. • Weekends are available for software upgrades without service disruption	• Time for essential services required for clinical operation such as infrastructure maintenance, including PM and QA needs to be found within these hours or at the end of the day. • Availability of experienced / specialist staff outside of normal working hours. Restricted opportunities for service development and clinical upgrades. • Possible lack of manufacturer support outside normal working hours.
Six Day working	An additional treatment day is operated at the weekends	• May enable patient starts to be accommodated on two days per week to optimise treatment duration. • Some emergency contingency available on 7th day	• Time for essential services required for clinical operation such as infrastructure maintenance, including PM and QA needs to be found within these hours or at the end of the day. • Restricted opportunities for service development and clinical upgrades. • Possible lack of manufacturer support on 6th clinical day or 7th day if used for routine maintenance. • Availability of experienced / specialist staff outside of normal working hours. • Possible issues with software upgrades.

Seven Day Working	Treatment Delivered on all days	• Patient starts on any day of the week accommodated.	• Time for essential clinical services such as infrastructure maintenance, including PM and QA needs to be found within these hours or at the end of the day. • Restricted opportunities for service development clinical upgrades. • Lack of manufacturer support at the weekend unless maintenance & QA take place during the week. • Availability of experienced / specialist staff outside of normal working hours. • Service will have to close to accommodate a software upgrade.

Table 1. Summary of Extended Hours Scenarios

5.2 Service Level and Support

When implementing an extended hours service due consideration to the level of service should be made of the level of service delivered by the radiotherapy centre. A risk assessment should be made regarding the level of support from radiotherapy clinical scientists and technologists based on the complexity of the radiotherapy being delivered. The level of complexity may be summarised by:

1. **Single Point Calculations / Simple Fields:**

   Treatments in which the dose is defined at a single point and the monitor units calculated by tables or a treatment planning system, most commonly used for palliation / emergency treatments. In most cases clinical issues may be postponed until the following working day when clinical scientists and technologists are available**.**

2. **Routine Standard Planned Treatment- Standard Imaging:**

   Treatments which are planned using a forward or inverse planned techniques and delivered using standard conformal therapy, IMRT or VMAT. The patient's position is confirmed using routine imaging techniques such as planar (2D kV/ EPID) or volumetric imaging (CBCT). The planning, imaging and delivery of these treatments is well established within the department. In the majority of these cases, decisions regarding issues that may arise on-set may be postponed until the following day as above.

3. **Complex / Unestablished Planned Treatments:**

   Techniques that have been recently introduced to the department are likely to require input from specialist radiographers, clinical scientists or clinical technologists to answer queries or deal with problems should they arise. As new techniques are introduced and become routine, they may move from this category to the routine category, whereas patient treatments outside of what may be considered as routine, such as rarer cancers with complex immobilisation, anaesthesia etc., may always remain in this category. A risk assessment should be made to determine whether Clinical Scientists or other staff involved in the implementation of a technique are available or if complex treatments that may require an immediate clinical response require the presence of a clinical scientist.

4. **Very complex treatments:**

   These are defined as the most complex of treatments requiring input from a wide range of professionals during the routine delivery of treatment, such as total body irradiation, stereotactic radiosurgery, other stereotactic techniques and online adaptive planning. It is highly likely that a Clinical Scientist with access to an MPE when required should be on site for such treatments.

It may also be appropriate in all cases for linear accelerator engineers to be available on site or on call to deal with faults that may develop, to ensure treatment time for the following working day is maximized.

5.3 MPE Involvement, Staffing and Skill Mix

Before commencing an extended hours service, a risk assessment should be made of the need for radiotherapy physics support during the time out of normal hours that treatments are being offered. This ensures that the correct staff are onsite, or available, to respond to queries or issues as they arise. There is a balance to be found between the resource implications to obtain the benefit of having an immediate response to a query against the significance of delaying the response until the following working day.

IRMER 2017 [31] requires that a Medical Physics Expert (MPE) must "*be closely involved in every radiotherapeutic practice"*. Radiotherapy MPEs have specific responsibilities for the management of the treatment planning, QA and dosimetry processes. This means the main way of being "*closely involved in every radiotherapeutic practice*" is by the MPE setting these up with written processes, procedures and other documentation and monitoring these via a suitable audit process. An alternative, appropriately skilled member of staff with experience in a particular process and equipment/software may also be able to ensure an out-of-hours treatment proceeds as planned.

There is currently no requirement that an MPE be present for every treatment. IPEM staffing level guidance [3] further states that:

> *"This expert must be specifically trained in Radiotherapy Physics and the implication of the requirement is that such a physicist should be available on site for at least part of the day, wherever radiotherapy is carried out"*

It is however likely that some procedures will require an MPE to be present on site such as

- The implementation of a new technique
- The treatment of a patient with difficult set up issues
- Very complex procedures requiring immediate advice such as brachytherapy, Total Body Irradiation (TBI), SRS, SABR etc.
- Returning equipment to clinical use following a period of maintenance and dosimetry.

In considering the degree of MPE involvement required, the staff skill mix available to cover (including MPEs) must be aligned with the planned case and technique mix and clinical service expectations. To that end, it is suggested that local arrangements can be agreed and 'risk assessed' for anything less than a full clinical service.

It should be noted that MPEs are increasingly sub-specialised, and the presence of an MPE does not guarantee that all necessary expertise is available. For example an MPE in brachytherapy may not have the expertise to deal with external beam IGRT issues, or vice versa.

Staff Resource Issues

Experienced and competent staff in radiotherapy have become increasingly difficult to recruit and due regard should be made of this in developing an out of hours service. A failure to recognise the issues in this document may put undue stress on staff, which may impact on patient safety and staff wellbeing, and thus limit the ability of the centre to retain key staff. A desired increase in radiotherapy capacity requires an increase in staffing to perform the required number of tasks for the increased number of patients or complexity. It is vital that the necessary number of staff are in place and receive sufficient training to perform their duties [3].

It may be possible to improve efficiency by adjusting the skill mix of staff by appropriately training staff

and extending their roles. It should be remembered that training requires a considerable amount of time and effort by both the trainers and trainees and time should be made available to staff to complete this, should it be deemed necessary. Similarly, any increase in capacity requires an increase in the overall staff numbers. Since experienced staff are often difficult to recruit a workforce plan may need to be in place involving the commissioning of training places for relevant staff. It is likely that these plans will need to be in place for several years before the necessary experienced registered health professionals are in place.

As well as ensuring staff are employed in sufficient numbers and are adequately trained and supported, it is also vital that the model of working is accounted for in determining the level of support from manufacturers during maintenance contract negotiations and when machines are procured. In the latter case, it should be noted that machines with matching functionality and dosimetric models are available to act as backups when problems arise during the clinical service.

Response Time and Capacity

In assessing which staff are required to be available during treatments, the required response time should be considered. An imaging or positional query for a short fractionation stereotactic patient may require an immediate response requiring suitable staff to be in the building whereas a once-weekly palliative treatment may only require a response within a few days. Traditionally, it has often been acceptable to respond by the following working day if an issue has been encountered with either a patient's treatment or a machine related issue. However, if a problem occurs on a Friday and the patient is scheduled to be treated throughout the weekend, then a response before the following Monday is required. This is similarly the case for on-treatment corrections due to changes in patient anatomy. In larger departments a number of issues may arise at the same time, which should be considered in capacity planning. In order to minimise the number of gaps in treatments the availability of linac engineers to respond to breakdowns rapidly will also be important, especially for smaller departments with few engineers.

Service Level Scenarios

Following appropriate risk assessments an extended working hours service is likely to fit into one of the following categories:

1. **Treatment Delivery Service:**

   This service would be limited to the delivery of radiotherapy fractions only, with imaging if prescribed. It is necessary to ensure that the infrastructure is in place and the patient cohort selected so that no immediate problems are anticipated with any treatment fraction. Should any problem arise it is likely that treatment would be suspended until the following day, when resources would be available to resolve the problem. It may be appropriate, therefore, to exclude patients where a gap in treatment is deemed unacceptable from treatment delivery during the extended hours unless sufficient staff are available to resolve the problem. The most likely cause of this is treatment machine breakdown. It might be possible to mitigate this risk by the use of an alternative machine for use in this eventuality. However, it should be noted that in this case the defective machine may be out of use for some time the following day with implications for capacity. It should be recognised that even palliative and simple conformal treatments are increasingly paired with IGRT techniques requiring expert interventions.

2. Partial Clinical Service:

This is usually a more routine pattern of working, operated for a longer period. Whilst not at the level of a Full Clinical Service, the Partial Service will often have a more extensive case mix and allow for some new courses to start, although some clinical service components may not be provided e.g. Mould Room or Brachytherapy. This level is usually a natural progression from the Treatment Delivery Service and whilst offering efficiencies, the various issues described previously must be considered. As capacity is increased as a result of an extended hours service it may be necessary to extend the working hours of other sections of the radiotherapy service such as planning CT, treatment planning etc. to ensure that the demand is met. In these instances, similar issues surrounding skill mix, machine breakdown and quality assurance exist and must be considered.

3. Full Clinical Service:

The Full Clinical Service requires sufficient staff to be in place from all staff groups involved in the radiotherapy pathway, able to manage all clinical situations to deliver a complete technical and scientific service. To achieve this, all the resources necessary to manage unforeseen situations, unexpected maintenance, or any problems with patient treatment delivery must be available.

Also, if a full treatment service is required, clinical situations may arise where the full range of support services is required e.g. transport, pharmacy, canteen, dietician, skin specialists etc. which will add to the resource requirements at the weekend.

5.4 Equipment Issues

Both the capacity and capability of the radiotherapy treatment equipment will have a bearing on the additional throughput provided by extended hours working. The requirement for Service Resilience Capacity (SRC) in the NRAG report [4] was confirmed by the survey reported in the 2014 guidance [1] and the results from 2019 survey indicate that this is still the case. SRC allows for QA to be carried out during the working day and provides resilience in the service in the event of machine breakdown, enabling the continuation of treatment provided the machines are sufficiently matched or backup plans are available. It also provides capacity for the monthly variation in patient numbers experienced by all departments.

Some machines are capable of faster IMRT treatment delivery using rotational techniques such as VMAT. Additionally, machines with FFF beams can deliver high dose rates and are particularly useful for the large dose per fraction treatments, such as SABR and other hypo-fractionated techniques. However, it is important to note that additional techniques and equipment capabilities require more QA time to ensure patient safety and sufficient time must be allocated to perform these duties. Additionally the more complex plans used in such cases often require more intervention from staff within the physics and radiotherapy teams, away from the treatment machine, requiring access to IT systems used for such tasks. Therefore IT maintenance issues such as upgrades and routine backups must be scheduled outside of the extended hours.

Making more clinical use of the treatment machines, increases pressure on servicing and QC arrangements, and also creates capacity issues in the event of machine breakdown. This needs careful consideration, particularly in smaller departments where there is less capacity for transferring the additional workload to alternative machines. Contingency arrangements to cover major breakdown involving nearby radiotherapy centres may need to be considered as part of regional radiotherapy network arrangements as discussed in chapter 2.

5.5 Governance Issues

There are a number of options for implementation of extended working hours in radiotherapy, but it is important to consider patient safety, cost and clinical effectiveness. The baseline scientific and technical requirements for a safe radiotherapy service are defined in chapter 3.

It is also essential to identify and minimise the risks. A risk assessment of the planned extended hours service should be made, and repeated whenever there are any major changes. It is possible that risks may be difficult to manage within existing budgets and to that end the requirements of the service may also need to be adjusted, as reflected in the feedback loop in figure 2.

5.6 Implementation

In implementing an extended hours service, it is essential to consider the key issues raised elsewhere in this document, and that all stakeholders are fully involved in discussions. The baseline scientific and technical requirements for a safe radiotherapy service are defined in chapter 3. Whether extending the hours of the service due to the need for additional capacity, or in response to the NHSE Radiotherapy Services specification, there needs to be a robust implementation plan in place. Such a plan will define the clinical service in the extended time period, the additional services provided by radiotherapy physics, the implications of this for staffing and skill mix, including specialist roles such as MPEs, and arrangements for servicing and QA. These considerations are outlined in figure 2.

It is also important to ensure that any use of shift arrangements does not leave core parts of the day understaffed. The IPEM recommendations re staffing in radiotherapy physics [3] state that "*The numbers indicate staffing requirements to allow for provision of a service during a standard 8-hour working day. Additional resources would be required to account for extended working hours and/or weekend working*…". This guidance also highlights the dangers of inadequate staffing levels including underutilisation of equipment and increased likelihood of errors.

The implementation plan will need to be costed and reviewed for effectiveness, and once implemented, will need to be monitored for continued clinical effectiveness and safety.

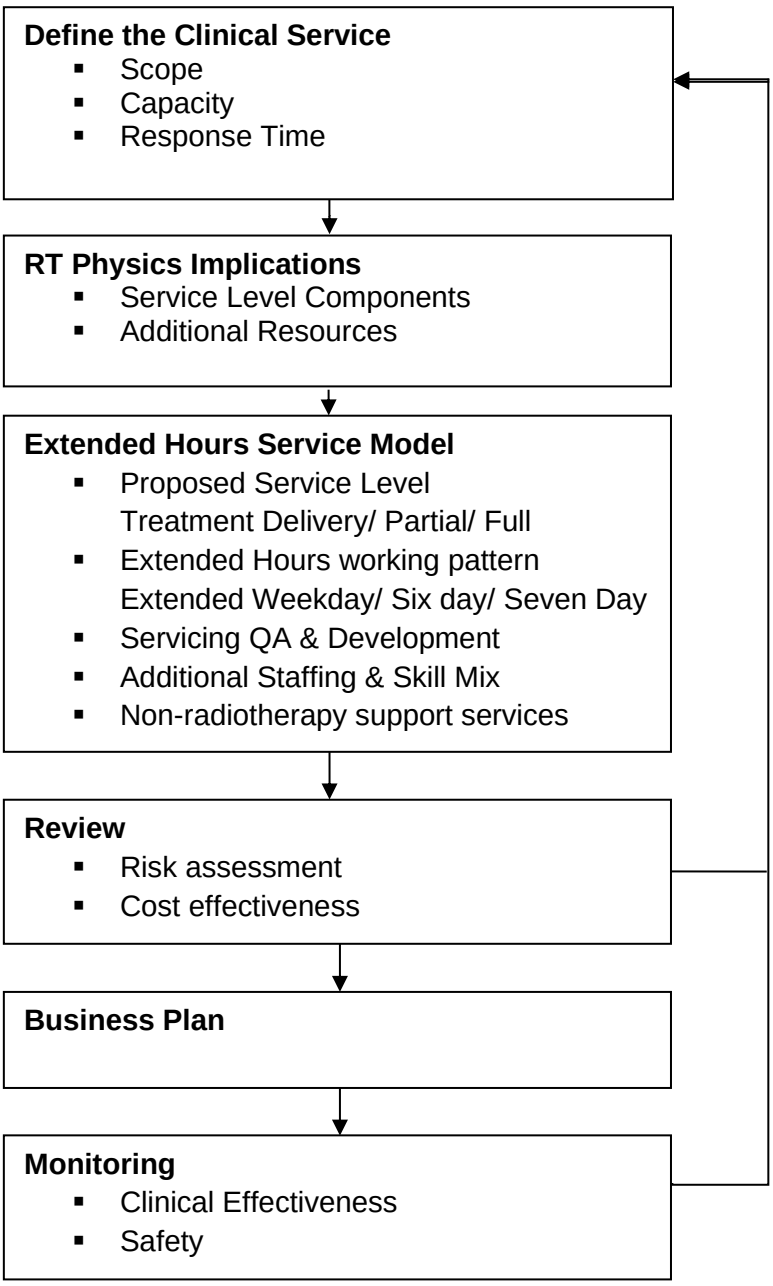

Figure 2 Flow chart for implementation of an extended hours service

Summary of Recommendations & Key Points

- The case mix, capacity and response time should be defined for the clinical service during the proposed extended hours working.
- The service level components required from Radiotherapy physics and technology should be defined based on the planned clinical service.
- A robust plan of the proposed extended hours service should be defined giving details of:
    - The level of working (Treatment delivery / Partial Clinical Service / Full Clinical Service)
    - The period of extended hours working (Extended work day/ Six day working / Seven day working)
    - Additional staffing and skill mix requirements, including MPEs, considering the overall increase in resource requirements not just during the extended working period. It is important that there are sufficient skilled staff both within core hours and over the extended day.
    - Scheduling of QA/Servicing and development work, including IT infrastructure maintenance
    - Non-radiotherapy support service considerations
- A risk assessment including the contingency arrangements should be made for the extended hours work covering:
    - Clinical risks
    - Physics and technical risks
    - Equipment failure
- Models which at first appear cost effective may cease to be so when the costs of mitigating all the risks have been accounted for.
- The workload at which the capacity of the remaining equipment and staffing resources would be exceeded in the case of a major equipment breakdown should be defined.
- Arrangements for the regular review of the clinical effectiveness and safety issues arising from the extended hours working should be made.

6. Manufacturers' Support for Extended Hours Clinical Service

The three major manufacturers supplying megavoltage radiotherapy equipment in the UK were consulted about the implications of providing support services for the three models of extended hours, described in section 5.1. These companies were Accuray, supplier of TomoTherapy and Cyberknife, Elekta, and Varian Medical Systems. Elekta and Varian are both suppliers of traditional linear accelerators. It is likely that any extended hours working will have greater impact on the companies with the lower engineer to machine ratio. Other factors include geography and system density.

The manufacturers outlined the service implications when machines were not replaced within the recommended 10 year life span [2]. These were identified as:

- Issues of increased complexity with newer equipment, training, maintaining engineers' competence over a range of equipment of different ages and thus technology, as well as the technical capability of the equipment.
- Although all the manufacturers endeavour to ensure new developments are 'backwards compatible', it is necessary for machines to be at a certain 'build level' to continue development, and to minimise legacy and compatibility issues.
- Reasonable up time can be maintained for a lifetime of 10-12 years but beyond that more intervention is required from the manufacturer, which is not cost effective.
- Increasing numbers of more complex components failing e.g. with the increase in the number of IMRT treatments and IGRT, mechanical components such as treatment couches, x-ray tubes and imaging panels on IGRT systems, any component that suffers radiation damage. This results in greater down time, and more QA following replacement.
- It is possible that in the future, warranties and reliability of components may need to be based on machine operating hours rather than lifetime, as at present, which could lead to increased costs.
- Obsolescence can occur more often during the lifetime of the equipment so it is quicker to replace whole components rather than repairing them on site, leading to increased shipping and delivery costs.
- It becomes increasingly difficult to get older components repaired, especially where manufacturers employ sub-contractors and the design may have changed. Training of engineers is now to a spare parts level, rather than a component level, to ensure efficiency in returning a machine to clinical use.

Hence, replacement of equipment at 10 years facilitates the provision of radiotherapy in an equipment portfolio suitable for modern radiotherapy techniques, for the benefit of the patient.

6.1 Service Provision by Manufacturers

The level of service provision is dependent on the contract that the individual Trust holds with the manufacturer. Within a service contract, manufacturers provide a number of facilities to ensure satisfactory uptime for equipment and software. Access to each facility is dependent on the service contract agreed with individual Trusts. Some Trusts have a full service contract which covers all breakdowns, servicing and spare parts. Other Trusts do not have any service contract, but have in-house engineers to cover breakdowns and servicing. A number of Trusts have collaborative arrangements where there is some level of service support contract for larger items, together with in-house engineers to respond immediately, thus ensuring greater up-time of the equipment. The advantage of a contract is

that some risks, e.g. loss of machine availability, spare parts procurement, maintenance, can be transferred to the manufacturer.

The manufacturers reported that a number of Trusts only have contracts for spare parts and do not currently include maintenance in their service contracts, which can lead to false assumptions about the true operating costs for radiotherapy equipment. In these Trusts, the costs of in-house maintenance must be included when calculating the overall operating costs. It should also be noted that where a Trust does not have a service contract, access to the help desk and spare parts are still required.

In looking to move to more extended hours working, some Trusts may need to review and increase their level of service contract in order to facilitate the longer up-times required. It is arguable that where a Trust does not have a service contract in place they are likely to be a lower priority. Therefore, in order to maximise uptime an appropriate service contract should be in place.

The monitoring of down time currently depends on individual contracts for some manufacturers. A limited treatment day allows manufacturers to say that after normal clinical hours a machine is no longer 'down' even if it is being worked on. This 'space' will be reduced for any extended hours service and machine downtime calculations will need to be re-visited in considering any extended hours working.

6.1.1 Service Desk Support

In order to obtain maximum benefit from service desk support, it is important to have a trained engineer on the hospital site who can liaise with the manufacturer. This helps reduce clinical down time which becomes more critical within an extended hours service.

Some Trusts with full maintenance contracts often do not employ sufficiently trained radiotherapy engineers. In the event of breakdown, this arrangement can leave Trusts with an idle machine until a Field Service Engineer (FSE) is on site, resulting in greater clinical downtime for an extended hours service.

Two out of three manufacturers currently provide 24/7 helpline support but this would need to be made more robust if extended hours working was introduced more widely, as the volume of calls is likely to increase significantly.

6.1.2 Maintenance or Repair out of Clinical Hours

All manufacturers require the presence of a Trust employee during any maintenance or repair out of clinical hours. This is because of the Health and Safety implications of lone working on high voltage equipment and in some cases is a contractual obligation. Ideally, such a person would need to be a Trust engineer or appropriately trained person, who is able to liaise with the FSE with sufficient knowledge and expertise to enable the FSE to carry out his work within optimum time scales. Currently a number of Trusts with 'out of hours maintenance' contracts supply security staff, but these do not have sufficient engineering expertise for this situation. Trusts will, therefore, need to have a sufficient number of in-house engineers if they wish to carry out any planned or breakdown maintenance out of current clinical hours. The lack of availability of suitable engineering staff and the costs of training such staff are important factors to consider, but where possible having in-house engineering teams enables more efficient use of any extended hours.

Manufacturers and Trusts are bound by working time directives which may lead to the need for more FSEs, as more than one engineer may need to be deployed to any service call or planned maintenance

visit. Figure 3 shows the staff involved from the Trust concerned (blue) and the manufacturer (green) for each part of the breakdown repair escalation process for Trusts with and without contracts in place.

6.1.3 Equipment Repair and Engineer Availability

The main concern from the manufacturers' perspective is the probable need to significantly increase their staffing base, both field service engineers and help desk support, to cover any extended hours working. Whilst this is undoubtedly possible, the manufacturers have stated that there would be a time lag of some 2-3 years to employ and train sufficient staff to be able to support delivery of any form of sustained extended hours working to the UK radiotherapy community. It is more cost effective for the manufacturers to extend the working day over a five day week in the first instance, before extending to routine weekend working, and easier to support planned work at weekends rather than unplanned.

For some machine breakdowns, where the cause is not immediately obvious, the FSE requires backup support from other engineers in the field. This will be more limited with an engineering support base spread over more hours but without an increase in overall engineer numbers, as fewer engineers will be working at the same time. In addition, some engineers are more experienced in particular aspects of machine performance e.g. image guided systems, and delay before they are available, could lead to increased downtime. This is particularly relevant for software support and again supports the need for increased numbers of FSEs.

In general, in order to resolve issues efficiently, timely escalation is critical. In the repair process there are a number of stages irrespective of who is maintaining the equipment.

In a typical collaborative contract arrangement, the in-house team should escalate to the equipment manufacturer's helpdesk typically within 30-45 minutes. If the fault is not isolated after 4 hours then the manufacturer's Technical Helpdesk would escalate to their regional or global support centres. At any time during this process parts could be ordered, or a decision to dispatch the FSE can be made. Trusts without maintenance contracts could be further delayed.

Having an in-house dedicated radiotherapy engineering team will ensure that more work can be carried out during extended hours. Additionally, a quicker response to any breakdown can be made, as well as the provision of some routine maintenance or QA, without the attendance of the manufacturer's FSE.

The most efficient equipment service during extended hours is likely to be maintained where there is a collaborative contract in place involving a combination of service contract and in-house engineers.

Figure 3 Manufacturers' escalation process. Blue = hospital staff. Green = manufacturer.

6.1.4 Availability of Spare Parts

The provision of any extended hours service would require the need for spare parts to be ordered and dispatched at any time upon the FSE's request. Trusts without a service contract will need to ensure sufficient access to senior Trust management who can sign orders for large and/or expensive items at short notice. From the manufacturers' perspective obtaining spare parts from a central warehouse would require it to be staffed during the night and weekends, which will ultimately result in increased costs for the customer. While spare part provision is the manufacturers' responsibility they are all dependant on courier companies for delivery. The UK radiotherapy market is a low-volume customer as far as courier companies are concerned, and the manufacturers therefore have no bargaining power or influence over the service provided by couriers. Therefore, while it may be possible to provide engineering support out of clinical hours, it may not be possible to obtain spare parts in a timely manner, which could lead to delays in the return of equipment to clinical use. These factors contribute to a significant cost increase for next day or overnight delivery, even for small components.

In addition there are sometimes problems regarding receipt of replacement parts at the individual Trust. Trusts would need to ensure that there was an adequate 'round the clock' goods inwards service to facilitate delivery of spare parts. It is currently not always possible to deliver large items on a timed delivery because of the need for two people to lift, and hence the delivery personnel require the assistance of a suitable Trust employee at the point of delivery to the Trust. This can also affect delivery before 9.00am.

Although manufacturers make use of a central spares base it is too costly to hold expensive spare parts and therefore shipping large items at short notice from abroad incurs additional charges. Parts shipped by sea can be subject to delays on account of the weather and capacity on freight aircraft for larger items is also sometimes an issue. Bespoke delivery at weekends would incur significant costs which will inevitably be reflected in increased charges to the customer. In general, the manufacturers feel that they have little control over when parts can be delivered and the more engineers and local departments can diagnose and pre-empt equipment problems in advance, the less the need for next day delivery of spare parts. The availability of spare parts is one of the major limiting factors to introducing full 7 day extended hours working in a small number of centres, but could be resolved if 7-day working were introduced across all departments.

For the UK a central European spares base is currently used for the more expensive spare parts generally enabling next day delivery. It is unknown what effect the planned changes in the trade relationship between the UK and the rest of the EU will have on this and it is hoped that disruption will be minimal.

6.1.5 IT Support

All manufacturers still report difficulties in negotiating the security requirements of Trust IT departments. Trusts will need to commit to better working with radiotherapy manufacturers than is currently the case. For example, internet access is often required by the FSE when they are on site, to enable them to access the manufacturer's engineering information remotely, and access with administrative rights to systems is sometimes an issue for both Trust and non-Trust staff. Similarly manufacturers require the facility to establish 'remote access' into the equipment for remote diagnostics and monitoring of performance. This requirement has increased over the last five years and is likely to increase further as the need for remote diagnosis increases.

In order to comply with patient data regulations, including GDPR [49], there are currently restrictions regarding where patient identifiable data is allowed to be exported outside the EU [50] and as the manufacturers are all global companies there are sometimes issues with their own systems being backed up to systems outside the EU. Trusts need to ensure that their IT departments are fully aware of the RT manufacturers' requirements in order to support an effective RT service, including extended hours. It is again uncertain what effect the changes in the relationship between the UK and the rest of Europe will have on these issues.

Software and hardware upgrades are currently normally carried out at weekends when there is no clinical service. The installation of some new hardware, together with associated QA and clinical testing, does not always require the entire department to cease operation. However, changes to the Oncology Information System (OIS) can only take place when the whole Department is in a 'down' state. There is then a substantial amount of testing that needs to take place before the system can be considered suitable for clinical use. The risks associated with any upgrade will increase for a six/seven day clinical service. It is therefore essential that relevant IT staff are on site for any upgrade, although this is currently not standard practice across the country. Migration of the database is usually the first step in any software upgrade and this can take several hours during which no service access is possible. This is then followed by the upgrade itself and any associated QA post the upgrade. If a department is running a 7 day extended hours service then, when an upgrade is required, there will be times when a 2-3 day break in treatment will need to be scheduled for all patients.

Major software upgrades take place at least every three years with minor upgrades being required at greater frequency. Similarly operating systems can become obsolete very quickly and usually need replacement within 5 years, requiring a similar interruption to service. As the OIS becomes more complex, solutions involving virtualisation become more relevant. These represent a reduction of risk but have a corresponding increase in cost, and there still remains the need for IT hardware upgrades at regular intervals. In addition any virtual system may not be managed by the local Radiotherapy Department but may require the availability of the Trust main IT Department.

In the future there is likely to be a move to storing information in the 'cloud' and moving to a cloud based software rental system may change the manufacturers' models of support to one that is more revenue based. However, there is currently a reticence in the market to move in this direction due to the risks regarding service resilience, particularly in regard to managing the threat of malware or virus attack and GDPR regarding the hosting of patient data by a 3rd party. When the 'WannaCry' Virus struck in 2017 [51] a number of UK Trusts dealt with the situation by isolating their systems from the external network. With cloud based systems there is a strong reliance on an external network connection and any disruption, such as that affecting the volume of data traffic, bandwidth or termination of network connection (as a response to a virus) will affect the delivery of services.

6.2 Factors affecting Manufacturers' ability to Deliver Extended Hours Service

6.2.1 Training

It takes approximately 18 months to train an individual engineer who is recruited with relevant transferrable skills and experience and often takes longer due to lack of experience. This is also applicable for Trust employed engineers.

6.2.2 Further National Agreement

From the manufacturer's perspective, there would need to be a national agreement for weekend working across the country with a long term commitment, without which the manufacturers are unable to fully support the Radiotherapy Services Specification [2] proposal. All the manufacturers indicated that they currently have no capacity to support weekend PMIs, although software support is currently available over extended hours and at weekends. Elekta reported that it resolved 30% of issues remotely, however the logistics are such that if a spare part is required, a person is required to be available to order it and this is currently not the case. It is not economically viable for manufacturers, who are currently tasked with reducing overtime and other overheads within their own companies, to train a large cohort of engineers with the long lead-in time required, without some commitment from the Radiotherapy community as to how extended hours are likely to be introduced on a national basis.

6.2.3 Timeframe for Implementation

The manufacturers indicated that it would take 2-3 years to be able to fully support any extended hours service on a national basis. Some aspects could be implemented more readily and careful consideration needs to be undertaken as to which tasks could be implemented at weekends, depending on the risk to the clinical service. It is recognised that the 2019 Radiotherapy services specification [2] supports a pattern of machines being available for clinical treatment 5 days out of 7. However, no qualification of this statement has been given concerning departments who extend their working days in order to increase capacity as the first step. It is likely to be more cost effective for Trusts and more achievable for the manufacturers to comply with the services specification by increasing the length of the working day in the first instance, although this will need to be assessed at a local level.

Whilst none of the above factors are insurmountable, it is clear that the manufacturers do not currently have the infrastructure to support extended hours. It is important that the Radiotherapy community continues to engage with them, if possible, with a national perspective, to ensure development of extended hours services in a safe and efficient manner.

6.3 Cost Indicators for Provision of Extended Hours

The major cost to manufacturers will be in the employment and training of more field engineers with some parts of the country requiring more than others. The three manufacturers have estimated that there will be an uplift of up to 70% to current service and maintenance contract costs, to enable them to provide help desk and FSE provision 7 days a week. There was a range of cost estimates for both extended hours, Monday to Friday, and Saturday working. Accuray engineers already work into the evenings during the week, and this is included in their current service contracts. Both Elekta and Varian indicated that working until 9pm Monday to Friday with full manufacturer support, and/or carrying out planned maintenance on Saturdays would result in a similar, and significant, cost increase.

Summary of Recommendations & Key Points

- Engagement with the manufacturers is essential for the implementation of extended hours to 6 or 7 day working, in an efficient manner.
- At present the manufacturers are not able to fully support the RT services specification without a national service agreement for a countrywide extended hours service. Implementation time following agreement is likely to be 2-3years.
- Trusts must employ a sufficient number of trained engineers dedicated to radiotherapy, to liaise with FSEs, for the safe introduction of any extended working hours.
- Trusts will need to ensure due consideration is given to logistical issues for extended working hours manufacturer support such as arrangements for order and delivery of spare parts.
- Trusts must ensure that their IT departments fully engage with manufacturers in order to facilitate efficient working practice.
- For Oncology Information System upgrades a 7 day service must plan for 2-3 day breaks in treatment service approximately every two to three years. A 6-day service will require 1-2 days breaks in treatment service.
- Up-time guarantees would need to be revised by manufacturers.
- An uplift of up to 70% on current manufactures' maintenance contracts is anticipated for 7-day extended hours working.
- The cost of weekend working may outweigh the cost of increasing the number of linacs and a detailed study of the financial implications would need to be undertaken.
- Extension of the working day Monday to Friday is the preferred approach from the manufacturers as this will have least impact on existing working arrangements and is likely to be the most achievable and cost effective method of increasing treatment capacity from their perspective.

7 Current Situation in UK

A survey was produced and distributed via e-mail to the UK Heads of Radiotherapy Physics in February 2019 with the aim of collating objective information concerning times for equipment QA, patient-specific QA with the large increase in IMRT since 2014, contingency treatment capacity and bank holiday working. The survey sought information on changes to QA models which might liberate or reorganise clinical time to minimise patient disruption. Corrective maintenance hours which were not covered in the previous survey were requested. Information was requested on the availability of decant bunkers, MPE support, as well as funding for extended day working

In addition, comments were welcomed on implications for the Physics workforce resulting from the revised RT service specification and evolving cancer networks in England.

The survey was requested to be completed with information as of 1st January 2019. Replies were received from 35 of the 62 centres polled in the UK with results detailed below.

The responding centres reported a total of 194 (vs 164.5 in 2014) clinical linacs with the number of linacs varying from a maximum of 13 linacs, minimum of 2 and mean/centre of 5.5. This may be taken as a reasonably representative sample of small, medium and large departments.

7.1. Operational Hours

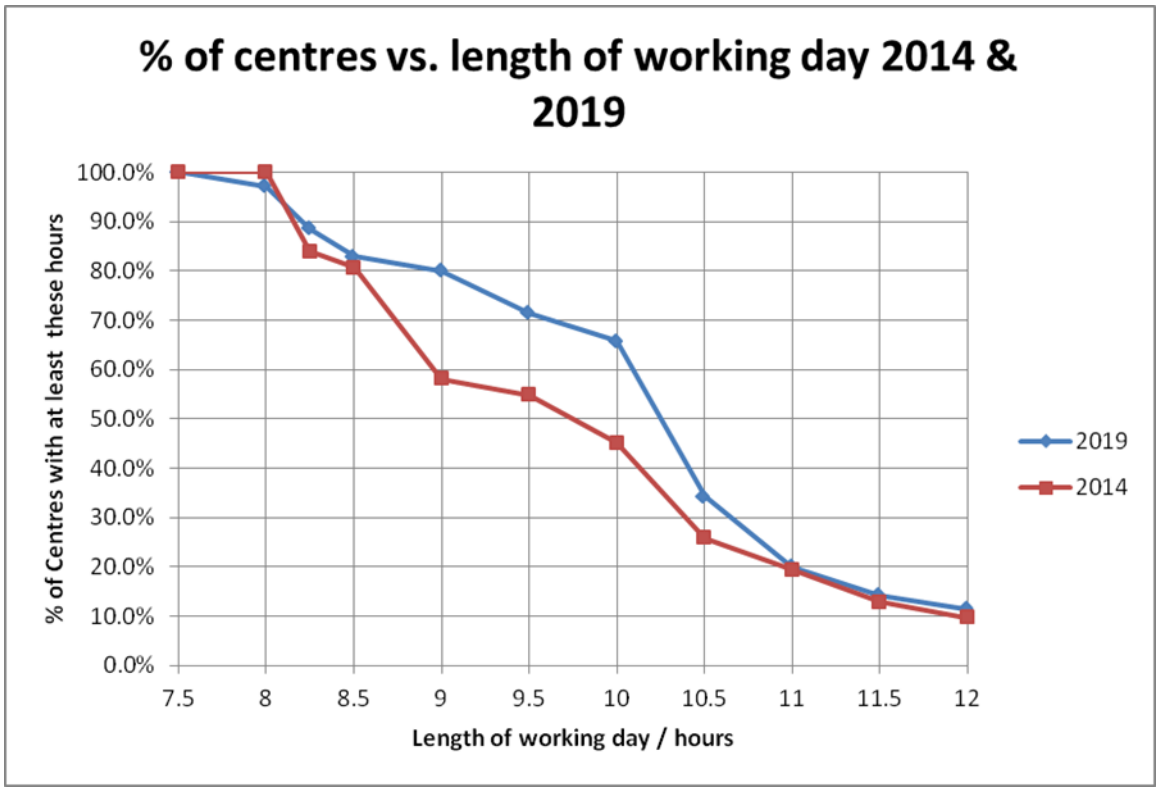

Figure 4 The length of working day in centres around the country.

Approximately 80% (vs 60% in 2014) of departments are running at least a 9 hour day with over 60% running at least a 10 hour day.

Many centres are already operating on an extended day basis, with over 60% of centres opening between 08:00hrs and 08:30hrs (vs 50% in 2014) and over 65% still operating at 18:00hrs, 20% at 19:00hrs, and 11% operating till 20:00hrs.

Five departments routinely treat patients on a Saturday.

7.2 Bank Holiday Treatment

It has become common practice since 2014 to treat patients on a number of Bank holidays throughout the year, generally excluding Christmas and New Year Bank holidays.

- 30/35 (86%) routinely treat on the Bank holidays.
- 5/35 (14%) have alternative arrangements in place; including hyper fractionating patients, or treating on Saturdays as a cheaper option to ensure all category 1 patients are treated.
- 10/35 (29%) treat only Category 1 patients on Bank holidays with 18/35 (52%) treating other category patients in addition, as far as capacity allows.
- 2/35 (6%) treat only emergency patients.
- 3/35 (9%) offer a full service however not necessarily all Bank holidays.
- 12/35 (34%) run a restricted number of linacs.
- Most centres deliver treatment on the Bank holidays with minimal levels of clinical or Physics support.

In summary, the survey shows that Bank holiday treatments are being delivered in a safe and risk aware manner i.e.

- Run a restricted number of machines to ensure backup.
- Treatment only with no mould room or CT scanning taking place.
- Some centres do not start new patients on the Bank holidays.

7.3 Daily Treatment

Historically, under a monthly QA schedule, some patients have been scheduled to miss a treatment. The survey requested information as to whether all patients were treated every day, to gauge the impact on patient scheduling of the QC session and on alternative models of QA scheduling in place to minimise gaps in treatment.

- All Category 1 patients are treated daily.
- 24/34 (71%) of centres treat all patients every day.

This is achieved by

- Ensuring sufficient linac capacity and the ability to transfer patients to matched machines running extended days.

- 4/34 (12%) using a service contingency or resilience linac where either an additional linac is available for QA or treatment, or where models of service are in place to plan QC time in shorter sessions during the working day balancing capacity across a number of shared linacs so all patients are treated without gaps.
- 6/34 (18%) performing QA outside of clinical hours.
- Minimising the impact of prolonged maintenance by sub-dividing, where possible, day to half days tasks.

Where centres are unable to treat all patients daily, Category 2 and other patients may be rested. Some centres plan to revise QA schedules as above to minimise impact on gaps, or anticipate having capacity to minimise gaps routinely once linac replacements were completed and a selection of matched machines becomes available.

7.4 Planned resilience capacity

- 20/35 (57%) have planned resilience capacity.

A mixed picture has emerged where some centres are running at 80% capacity so have treatment capacity contingency whereas others are booked >100% capacity. Some centres have service efficiency machines or spare capacity on private linacs. A few centres are running models of QA divided into smaller components performed across the working day which yields resilience capacity as QA may be moved to accommodate downtime where possible. Traditional models, where machines are taken out of service for 1 - 1.5 days per month also deliver some resilience in case of serious breakdown on parallel machines where the machine may be handed back to clinical use and QA moved to an alternative time which may be out of hours. Otherwise centres tend to approach the need for capacity in an ad hoc way by extending the working day or treating at weekends to catch up for maintenance, QA and breakdowns.

7.5 Unplanned breakdowns

In the event of breakdowns, plans to ensure treatment continuity include:

- Prioritising patients in RCR Category order to determine treatment priority.
- Transfer of patients to matched machines.
- Extending the treatment day on parallel machines in an ad hoc way.
- Moving planned PSQA, QA sessions to free up clinical capacity.
- Postponing patient fractions.
- Using the weekends to catch up.

7.6 Maintenance and QA models

- 24/33 (73%) of centres have not changed their method of QA scheduling since 2014.

However, 9/33 (27%) have revised their model and have sought to maximise clinical time by a number of models which include:

- Moving QA out of clinical hours or to later in the day.
- Breaking the QA into smaller slots moving away from full day QA sessions with variations on QA models including fortnightly slots to modular QA using a few hours per day on a linac every day of the week.
- Moving the QA from 4 to 6 weekly rota along with a reduction in QA time.
- Incorporating some QA into daily run up time

The impact on clinical availability of the revised models is difficult to quantify except where QA time is removed from the clinical day and the gain in clinical time, if usable by the radiographers, is explicit.

- 4/9 (44%) of those who have changed their model have seen an increase in clinical time.

One site has moved to fortnightly half days from monthly sessions. The impact on clinical availability has not been quantified, but qualitatively leads to fewer patients being 'rested', and has the benefit that this model provides more timely opportunities to address emerging faults, and enables a QA backlog to be quickly recovered if a service is cancelled due to breakdown of another machine.
This has resulted in some gain in clinical hours when moving QA outside of working hours.

- 5/33 (15%) are planning to review their maintenance and QA model.

Of these, 3 are planning to review in light of the service specification, with the other 2 seeking to introduce more modular QA as mentioned above. This leads to improved service contingency while achieving the aim of minimal disruption to patient treatment despite some QA on clinical days.

Centres mention purchasing of QA tracking software, and daily check arrays to make the QA process more efficient.

No significant changes to overall maintenance and QA times were apparent in the 2019 survey so times may be taken to be consistent with the figure of approximately 250 hours/linac in the 2014 report [1].

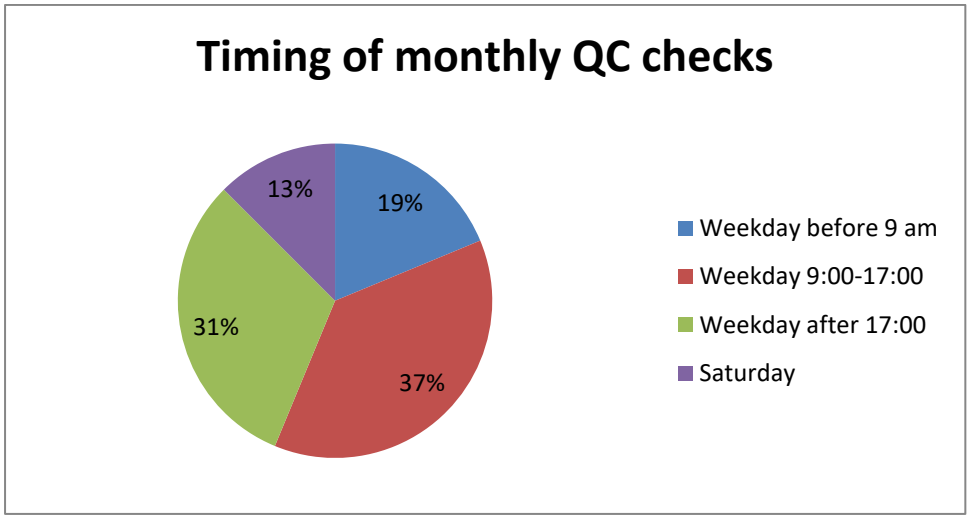

Figure 5. Timing of QA vs time of day

A summary of the limited responses (16) from centres who reported QA times suggests 78% of QC is carried out out-of-hours including daily QA.

7.7 Maintenance and QA outside of the normal clinical day

A number of centres routinely perform some maintenance and QA outside the normal working day (though it was difficult to quantify exactly how many hours from the survey)**;**

- 15/35 (43%) perform some maintenance outside of clinical hours (Mon-Fri).
- 12/35 (34%) perform some maintenance and QA at weekends (Sat-Sun).
- 23/35 (66%) perform some QA outside of clinical hours (Mon-Fri).

Weekends are not routinely used for maintenance though one centre reportedly plans for all maintenance to be performed at a weekend. Some centres use the weekends as a contingency for maintenance and QA including annual QA.

With the lengthening of operating hours as shown in Section 7.1, it is likely that maintenance and QA is being pushed further outside of the normal clinical day.

7.8 Corrective maintenance and breakdowns

- Average time for corrective maintenance and breakdowns 67.5 hours/linac (± 44.2 1SD).

The data contained in this section is very variable as some responses have only included planned corrective maintenance, others complete downtime including spare parts delivery. Others have taken an indicative figure of 3% assuming 97% uptime.

An estimate of the corrective (and in particular unplanned) downtime should be taken into account when capacity requirements are being specified with an estimate of the magnitude and impact taken into consideration.

7.9 Patient-Specific Quality Assurance and Treatment Plan Validation

Patient-specific QA measurements for IMRT, VMAT and stereotactic patients are commonly required prior to treatment to verify individual patient's treatment plans. These require linac and Physics staff time to perform and then analyse. The proportion of plans verified varies between departments, with some measuring all plans, while others QA a limited number for a new treatment site, then use a combination of sampling and software based methods for verification. Future software products may well reduce the proportion of actual plans required to be measured. However introduction and development of innovative techniques will continue to require validation by patient-specific QA measurement. Extending the day for clinical treatments has a double impact; both reducing linac availability during normal working hours for plan validation due to increased patient workload, as well as increasing the number of plans required to be validated, given the national drive for increasing amounts of advanced radiotherapy.

- 22/35 (63%) of centres report a reduction in numbers of physical PSQA measurements since 2014

Reductions in PSQA have been made through increased use of independent MU calculators e.g. Radcalc, Mobius, Diamond, the use of portal dosimetry products, and methods of sampling 1st x patients before dropping PSQA measurements, introduction of standard plans, and increased linac QA.

There appears to be considerable disparity in both the time centres reportedly spend on each PSQA, as well as in the percentage of patients who require PSQA. This may well relate to the type of delivery equipment, QA equipment available, and maturity of large volume clinical sites receiving IMRT treatments per centre.

- The majority of PSQA measurements take place prior to 9:00 or post 17:00.

IMRT

- Over 16,000 PSQA measurements were reported taking 6,750 linac hours. No differentiation was requested between IMRT (Step and shoot) and VMAT techniques.
- 51% of IMRT plans have PSQA measurements performed.
- Meantime per PSQA of 24 mins and median time 30 mins.
- A few departments presented as outliers with times in excess of 1 hour per PSQA however it is unclear from the data whether the data is linac time only or the whole PSQA process.
- It is estimated that the average department still spends around 211 hours per annum on patient-specific QA measurements (200 hours in the 2014 report [1].
- Some centres report that their number of PSQA measurements has not reduced overall as the % of IMRT treatments has increased significantly.
- 5 centres continue to perform PSQA for all patients.

SRS

- 10 centres responded under SRS.
- 77% of SRS plans have PSQA measurements performed.
- Average time per PSQA of 1 hour 25 mins.
- (9/10) 90% of centres delivering SRS measure all plans. The remaining centre uses software to perform the independent check and reports very few PSQAs for SRS.
- It is estimated that departments delivering low numbers (<10) spend around 10 hours per annum on SRS patient-specific QA measurements, those delivering >50 ~134 hours per annum. Times are dependent on equipment and technique being used.

SABR

- 21 centres responded under SABR.
- 68% of SABR plans have PSQA measurements performed.
- Average time per PSQA of 42 mins.
- 67% of centres delivering SABR measure all plans.
- Half the departments take <1 hour and the other half between 1-2 hours for a PSQA. This may reflect whether linac only or total time is included in the survey return or the type of equipment being used in the department for SABR.

- It is estimated that the average department spends around 46 hours per annum on SABR related patient-specific QA measurements.

Breast /Other PSQA

- 11 centres reported PSQA measurements for breast patients, cranio-spinal patients or TBI patients.
- PQSA numbers per year range from 2-390.
- Average time per patient of 43 min.

It appears that the anticipated reduction in time related to PSQA measurements has not decreased significantly and this is likely to be related to the increased number of patients being treated using IMRT as IMRT is rolled out more widely to treat other clinical sites.

7.10 Availability of Service Efficiency Machines and/or Decant Bunkers

The survey indicates that there is under-provision of both resources.

- 4/35 (12%) of centres have a service efficiency or resilience machine
- 24/35 (69%) have a decant bunker.

However it was noted that of those having a spare decant bunker, a couple were filled with very old machines or CT scanners, or required major refurbishment work so the space was not readily available for machine replacement. Some centres reported spare bunkers to be at an alternative e.g. satellite site.

7.11 Availability of Medical Physics Expert Advice

There remains significant variation in response to how formalised the role of the Medical Physics Expert (MPE) is in respect of extended day working. No doubt this is dependent upon what cover is being provided, the number of linacs being run, what category and complexity of patients are being treated and whether advice for treatment from an MPE is routinely required.

- 11/35 (32%) centres indicated they had access to an MPE during extended operational hours, of which 7/35 (20%) provide MPE cover on site and 4/35 (11%) provide formal telephone cover.
- 24/35 (68%) centres provide no guaranteed access to MPE advice outside of core clinical hours, of which 11/35 (31%) provide no cover, and with 13/35 (37%) providing informal telephone contact only.

Given the above information it remains important to determine safe staffing levels and availability of appropriate levels of experience of staff supporting extended day working using risk assessment.

7.12 Consultation on network impact on extended day working

The responses to the question reflect the uncertainty as to how and what impact regional networks as defined in the 2019 service specification [2] will have. Of those that responded;

- 3/34 (9%) were not centres in England.
- 11/34 (32%) indicated that it was too early to predict the likely impact.
- 13/34 (38%) anticipated no impact.
- 7/34 (21%) anticipated a negative impact.

Negatives include the possibility of demand from radiographers for more weekend working; difficulties of governance and IT links within networks; possible changes in referral pathways having a negative impact on capacity and demand; and resource implications for Physics in terms of extended hours working.

7.13 Impact of revised Service specification

The survey revealed that 75% of centres consider the 9,000 attendances/linac/year figure in the service specification [2] as very challenging particularly to departments delivering well below this number, as well as to those providing high percentages of IGRT and/or delivering specialised techniques such as SRS, TSE, TBI where treatment timeslots are longer. Concerns are raised about a fraction target figure in relation to the anticipated moves towards hypo-fractionation. Additional staff would be required to cover the increase in hours across all staff groups. If an increase in in-house maintenance was not available then more manufacturer contracts would be needed (subject to the manufacturer being able to provide engineering support – see chapter 6).

Moving QA to other days is perceived as achievable only with increased staffing however challenges remain around manufacturer support at weekends, the costs involved, and the ability to provide adequate servicing and QA time.

Weekend working is seen as unpopular across all staff groups and might potentially have an impact on recruitment and retention within professions that are already 'shortage' professions.

Contingency treatment across the network in the event of significant breakdowns is perceived as difficult to achieve especially in short timescales and where departments have different equipment. Support is usually offered only for low numbers of emergency patients only.

Summary of Recommendations & Key Points

- Over 80% of Radiotherapy Centres are already providing a clinical service outside the hours of 09.00hrs – 17.00hrs Monday to Friday, a significant increase when compared to 50% in 2014.
- Over 65% of departments are now running at least 10 hour clinical days.
- All Category 1 patients are treated daily in all centres.
- 71% of departments treat all patients every weekday.
- A few radiotherapy centres currently work routinely at weekends outside of on call arrangements.
- QA arrangements are under review by a number of centres, however most are continuing with QA schedules as in 2014. The few that have changed have recorded some small benefit in increased clinical hours, largely through moving QA out of clinical hours.
- Modular models, dividing QA into smaller sections scheduled daily, may aid in patient scheduling, minimise disruption to patient treatments and provide service contingency.
- An estimate of the corrective (and in particular unplanned) time should be taken into account when capacity requirements are being specified.
- The response for MPE cover in extended hours working indicates that 32% of departments provide MPE cover either on site or by formal phone cover. 68% provide no guaranteed cover.
- The average time per patient for PSQA for IMRT has decreased since 2014, but the total time has not changed largely due to the increase in IMRT numbers. Validation of complex plans by measurement on a linac continues to be required during the introduction of new treatment techniques and for IMRT treatments. Extending the clinical hours of work impacts significantly on the access arrangements for these measurements.
- There appears to be considerable disparity between centres in the amount of time they reportedly spend on each PSQA, as well as between the percentage of patients who require PSQA measurements.
- The 9,000 attendances per linac per year target is seen as very challenging to meet for departments delivering well below that figure now and for those delivering high percentages of IGRT and specialist techniques, and in addition, against the increasing trend for hypofractionation.
- Access to linacs is still required for a range of activities essential to maintain the radiotherapy service, such as commissioning of new dosimetric equipment, system upgrades and testing, service developmental work, clinical trials work, R&D, training, dosimetric inter-comparisons and computer system backups. The 2019 survey did not request updated information about times for these activities. However, anticipating times are similar to those given in the 2014 survey, and including maintenance, QA, and PSQA times from 2019, the overall time required remains consistent with the figure of approximately 3000 hours per annum [18% of linac activity] for an average department, from 2014.

8 The Impact of Extended Hours on Different Size Radiotherapy Centres

The size and configuration of a department is most likely to influence the decisions made regarding the model of QA used and issues affecting extended hours working. For this reason, based on the responses to the survey carried out in February 2019 (and reported on in chapter 7), several different sized radiotherapy departments were contacted to further discuss their experiences with regards to extending the clinical day. A summary of the points raised is provided in this chapter.

Additionally, a high percentage of centres (70% of respondents to the survey – see section 7.12) indicated that they anticipated no impact or that it was too early to understand the impact of the revised service specification [2] on extended day working. However 75% of respondents (section 7.13) foresee challenges around the 9000 attendances/linac/year figure in the revised service specification [2]. We have identified and presented the experience of one centre that currently meets the required national benchmark of 9,000 attendances per year expected by the revised service specification.

8.1 Centre meeting 9000 attendances per year

A seven linac radiotherapy department within the NHS which is currently achieving the national benchmark of 9,000 attendances per year has shared their experience for this report. The centre currently utilises four of the linacs over an extended day for clinical treatments (10.5 hours) with the other linacs working a normal day. The department carries out a lot of servicing/PPM work at weekends. Patient-specific QC and some linac QA activities routinely take place outside clinical hours.

In making increasing use of VMAT and optimising the use of on-treatment imaging the centre employs a 10 minute minimum appointment time and will use longer slots for first appointments and complex sites which take longer to treat. The centre's experience in trying to treat patients at such a high throughput rate without significantly increasing the clinical day further is that the patient experience suffers. Additionally the centre finds it challenging to introduce some developments in patient treatment techniques, for example, deep inspiration breath hold (DIBH) for all left-sided breast patients which would significantly increase treatment time for a large number of patients and therefore impact on treatment throughput and capacity. This centre's experience suggests that meeting the national benchmark of 9,000 attendances per year to improve equipment utilisation rates can be unrealistic when aiming to deliver advanced radiotherapy using the latest evidence based protocols.

8.2 Small Radiotherapy Centre (3 or fewer linacs)

The radiotherapy departments of the Royal United Hospital (Bath) and Peterborough City Hospital are both currently independent two or three linac centres. With a small department the provision of service resilience capacity is challenging.

If a large proportion of non-clinical activities required to deliver a safe clinical service are moved outside clinical hours then this has a considerable impact as they are left with only skeleton physics, and in particular engineering, staffing during core clinical hours. However, both departments have limited the impact of this when necessary by running one linac for extended hours compared to the other, allowing QA and PM activities to take place during clinical hours. This is less of an issue for small satellite centres, for example, the Christie satellite departments, as there is a larger pool of staff at the main site which can be called upon to provide cover if required. Additionally, if centres start working as networks as proposed in the 2019 service specification [2] then this may become an option for all MPEs (and other

staff groups) within the network to work as a single pooled staff resource providing cross cover. This will require:
(1) staff trained in operational procedures across the multiple sites and are able to maintain competency,
(2) that centres are within commutable distance,
(3) resilience of staffing at all centres is maintained, and
(4) governance issues including cross site contracts being resolved.

In order for this model to work efficiently in a small department it is necessary to have matched machines to give some flexibility in scheduling patients. For smaller centres there could potentially be difficulties in providing a safe service when the linacs are due for replacement as one may require back-up planning for patient treatments. Additionally, running one linac for extended hours with full ancillary services for patients could prove to be very expensive.

Any kind of major upgrade to the linac or associated imaging equipment which cannot be scheduled over the weekend can be a major problem due to having only one/two linacs to treat two/three linacs' workload. For example, Peterborough had an upgrade to a linac that was scheduled over four working days which meant the second linac was required to treat clinically from 07:30hrs to 22:00hrs over this time. Any kind of downtime on the clinical linac or extended hours working during this upgrade period would have made the clinical day unfeasibly long and required the cancellation of some treatments or transfer to contingency weekend days.

Peterborough currently carries out large amounts of PM and more extended QA on linacs during the weekends. If any kind of six or seven day working is implemented then this may impact on such a model of working depending on how extensive a clinical service is offered.

8.3 Medium Radiotherapy Centre (4 – 6 linacs)

Oxford University Hospital radiotherapy department currently has six linacs, which enables service resilience capacity to be provided when required for servicing, QA and breakdown. The department has a long history of some form of extended hours working on an intermittent basis. Over the years several specific agreements have been negotiated between the department and the Trust in terms of the amount of extended hours working required, including staffing level needed (numbers and experience) and payment provisions.

The department's normal treating hours are 08:00hrs to 18:30hrs on weekdays. Recently, the department has found it difficult to maintain service resilience due to capacity issues and having major upgrades on linacs which require extensive periods of commissioning. This has meant that QA and PM activities have had to take place in the evenings. For these reasons, since June 2013 the department has implemented weekend working with two linacs treating for four hours on both Saturday and Sundays (staff preference was to have two linacs treating over a shorter day instead of one linac treating a full day) rather than further extending the weekday treating hours. In the department's experience further extending the weekday clinical hours would require a shift based working pattern as worked at Norwich (see below) which is more difficult to staff at Oxford.

The department only treats reasonably fit patients during the weekend and does not start any new patients, therefore reducing the number of ancillary support staff required. Physics and engineering

cover during the weekends is provided by one MPE, one engineer and one-three physicists/technologists, who are able to carry out QA, PM and development work on the non-clinical linacs.

Norwich Radiotherapy department is slightly smaller than Oxford and currently has five linacs, which jointly include provision of service resilience capacity equivalent to one linac. This machine is commonly used for breakdowns, service days and to cover peaks in demand. It is in routine use over 95% of time across the year. The remaining 4.7% of time is used for project work or other testing, such that the machine is never left idle. The department has been working extended hours routinely since 2010, treating up until 20:00hrs in the evenings. One engineer and one Clinical Scientist (any grade) participate on a late shift rota with staff given clear work procedures in the event of a problem scenario. Although initially the department insisted no new patients were planned to start treatments in the evening, they have had to relax this requirement as it has become increasingly difficult to maintain due to capacity pressures.

At the centre radiographers work a four extended-day week with a number of Clinical Scientists also working a four extended-day week. For clinical scientists working four days a week one of the days is incorporated as a 'late shift' day, ie a 12hr working day. The department's experience with such a system of working has been positive as the rota has been able to accommodate flexibility for staff in a number of ways, for example, those who want a fixed day working late or a fixed day off. The radiographer's four day week working pattern consists of working either an early or a late shift with a rolling day off. Sometimes more staff are present in the middle of the day, which is arguably less efficient, although with some staff working less than fulltime and others covering areas such as CT, brachytherapy and superficial units this inefficiency is minimised. When there are further capacity pressures at the centre, the radiographers work overtime on a Saturday by voluntary agreement, with an engineer usually present for support. This is clearly unsustainable as a long term option.

Due to the availability of service resilience capacity most PM and QA is carried out during the core clinical hours, with some work carried out during the late shift, however, the department's experience of this is that the amount of work carried out in the evenings is very dependent on the knowledge and experience of the staff covering the shift and is not guaranteed. The routine QA schedule has been revised so that all annual and three monthly checks are spread over the monthly QA slots thus making scheduling more efficient on an on-going basis.

There have been some occasions at the department, when one machine has been on service and another has broken down at the same time, however, it is very rare at the centre for a patient's treatment to be cancelled completely on any particular day even in such a scenario.

8.4 Large Radiotherapy Centre (7 or more linacs)

Mount Vernon Cancer Centre is a seven linac cancer centre which currently works extended hours from 08:00hrs to 20:00hrs during the weekdays (CHART patients treated until 21:00hrs). The centre has a rota for the presence of an MPE or Band 8 training as an MPE on site, having previously relied on MPE phone cover. The centre utilises one of the linacs as service resilience capacity. When the extended day was introduced, the physics team negotiated with the radiographers to pair linacs such that one worked an extended clinical day whereas the other finished sufficiently early, nominally 17:00hrs, to allow for patient-specific QA to take place for complex treatments. Unfortunately this has not proved to be sustainable due to radiographer staffing and the tendency is for all machines which are not working the

extended day to finish at 18:30. On occasions this has meant the physics staff working past 20:00 to finish urgent QA.

Due to the availability of service resilience capacity (equivalent to 1 linac) the majority of the PM and QA work takes place during the clinical day at this centre, with cross calibrations and most development work also carried out during the clinical day.

The experience of this centre is that corrective maintenance suffers due to extended hours working as most work needs to be carried out late in the evenings when engineering staff is limited and not all engineers can carry out all maintenance tasks. The centre limits specific treatment techniques to certain linacs; this reduces the overall amount of QA required within the department, for example electron beams are only used clinically on three of the seven linacs and as a result electron QA is only carried out on those three linacs. This results in a reduction in physics QA time of around 1-2 hours per month per linac.

The Christie radiotherapy department has nine linacs at the main Withington site. Additionally it has two satellite centres with two linacs each. Each site currently works from 08:00hrs through to a nominal 20:00hrs finish and their experience of extended hours working at the main Withington site is similar to that of Mount Vernon Cancer Centre. This is mainly due to having service resilience capacity at the main site. From a staffing perspective the department operates a late MPE rota in the same way as Mount Vernon; however, only one MPE is required to cover all three of the Christie sites as all the patient related information is available on any of the sites.

The service resilience capacity (equivalent to 1 linac when no other linac is being commissioned) is regularly (approx. 70% over the year) used to allow servicing/PPM and QA to be carried out during clinical hours. The remaining 30% is utilised during breakdowns and to cover peaks in demand. A small proportion of the service resilience capacity is used for additional project work or investigations such that the service resilience capacity is fully exploited. Run-up time for linear accelerators have been driven down to approximately 30 minutes which allows smaller items of routine monthly QA to be carried out during run-up. Other larger QA items are completed either during the clinical day when service resilience capacity allows or in the evenings and weekends. Any service development work and cross calibrations are routinely done outside clinical hours. In such a large department with numerous dose-meters, the annual cross calibration round can be an onerous task that can take 4 weeks or more to complete.

The Christie carries out a large number of complex treatments which presents a significant challenge in terms of patient-specific QA. Given the volume of plans requiring QA even with service resilience capacity this is primarily carried out in the evenings after clinical treatments have finished. Well matched machine plans are batched so that plan verification does not need to occur on the patient's treatment machine, thus allowing more efficient plan verification. However, on occasions, staff have carried out plan verifications very late into the evenings, i.e., beyond 21:00. More recently the Christie has been transferring linac based patient-specific QA to a software based system so the number of physical verifications can be reduced which decreases the hours of work required by physics outside of the extended clinical day.

The Christie physics and engineering department has a minimum staffing level policy in place which ensures that staffing levels are not reduced to a level which may impact on the clinical service during normal treating hours due to the amount of evening/weekend work carried out. If staffing levels fall below the minimum required, staff are only allowed to take lieu time in exceptional circumstances.

Additionally, overtime is available for staff below Agenda for Change (AfC) band 8. With the current staffing levels not fully accounting for extended day working, the Christie model is extremely challenging to maintain due to the now regular nature of extended hours working which leads to the physics and engineering staff being pushed to regularly work very late in the evenings and weekends. This also attracts unsocial hour's payment under NHS Agenda for Change which needs to be accounted for. This approach requires careful consideration of additional staffing resources to maintain the regular nature of extended hours working. Additionally, here the Norwich model of staff working extended day shift patterns may be helpful.

The experience of both the radiotherapy department at St James's Institute of Oncology (Leeds) and the Christie is that having a mixture of linac types within the department can make it very challenging to manage service resilience capacity and deal with any major unplanned breakdowns. Patients may not be able to be transferred efficiently across the department without dual planning, due to differences in linac manufacturer/treatment head characteristics. In these cases servicing, PPM and QA activities present similar challenges to that in a small department operating at near or full capacity.

One of the other points raised by Leeds, which is a ten linac radiotherapy centre, is Private Finance Initiative (PFI) contractual hours. The department is a PFI build and currently has a good agreement allowing some extended hours working over six days a week if necessary. However, flexibility for extended hours working for some PFI build departments (of any size) can be very limiting. For example, although Norwich radiotherapy department is not restricted in terms of linac use, any use outside core hours (07.00-20.00) is at the NHS Trust's risk. If any radiotherapy equipment (e.g., Linac, record and verify system, CT scanner) were to breakdown outside core hours then the PFI Company is not liable for any penalties that would normally be imposed for such a breakdown during core hours and which would result in percentage uptime below contractual requirements. Another example is the radiotherapy department at the Beacon Centre (Taunton), where any use of the linacs outside core hours of 09.00-17.00 attracts an additional cost to the NHS trust. Additionally, engineering support for breakdowns on the linacs cannot be provided outside core hours by the PFI Company, so any linac breakdown is dealt with the following day. Any extended hours working cannot therefore make use of all of the linacs at the department as a breakdown would affect the next day. Changes required to PFI contracts can prove to be very costly and time consuming to make.

Summary of Recommendations & Key Points:

- A robust implementation plan must be developed taking into account additional staffing levels required when introducing any form of extended hours working in a department.
- Extending clinical hours in smaller departments can significantly impact staffing during core hours, especially if all servicing and QA is carried out outside clinical hours.
- The provision of service resilience capacity, which can be challenging in a small department, can help limit the amount of physics and engineering work that is required to be carried out outside clinical hours.
- Pairing of linacs such that one works an extended clinical day whereas the other finishes sufficiently early can also aid with the reduction of physics and engineering work that is required to be carried out outside clinical hours and also shares the burden of extended hours working between different staff groups.
- Limiting specific treatment techniques to a small number of linacs in the department reduces the overall amount of QA required within the department.
- PFI contracts vary considerably and can limit the flexibility of a department to operate an extended hours clinical service but if considered beforehand can result in increased use of equipment.
- Changes required to PFI contracts can prove to be very costly and time consuming to make so it is important to bear in mind extended hours working in advance of any contract being drawn up.

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Appendices

A Copy of Maintenance and QA Survey Proforma

IPEM WORKING PARTY - Impact of extended hours working on Radiotherapy Physics **20 19** **VERSION 1.5 FINAL**

CENTRE

RT Service specification and revised network arrangements

What impact will revised network arrangements have on extended day working arrangements? (If any) **England only**	Comments:
What impact will the published RT Service specification have on extended day working arrangements? (If any) **England only**	Comments in particular responding to : i) plans for / feasibility of Utilisation rates of 9,000 #/yr, ii) machine treating at least 5 days/week iii)servicing & QA on other days of the week not to disrupt treatments, iv) contingency plans for treatments during staff shortage or breakdown across the network

Centre Data

Number of Clinical Linacs						
	Monday-Friday		Sat		Sun	
Usual Clinical Working Day (hh:min-hh:min)						e.g. 8:00-17:30 format hh:mm-hh:mm
Total hours worked per day (summed over all clinical linacs)		Hours		Hours		Hours e.g. total planned clinical hours/day
Are all patients treated every day (i.e. without gaps due to QA time)?		y or n?	Comments e.g. Running paired machine longer to cover QA time, alternative service and QA models, moving all QA out of clinical hours			
If yes, how is this achieved? If no, explain measures adopted to minimise loss of capacity						
Do you have planned service resilience capacity?		y or n?	Comments: e.g. service efficiency machine, planned extension of			

If yes, how is this achieved?		the working day, booking at 87% capacity, booking 4.5 of 5 linacs routinely etc
How do you deal with unplanned breakdowns?		Comments: e.g. move patients to service resilience or alternative machine, extend the working day, use Saturdays /weekends to catch up
Do you have a spare bunker available for linac replacement?	y or n?	

Bank Holidays

Do treatments take place on bank holidays? What category of patients do you treat on bank holidays?	y or n?	Comments e.g. Cat 1s, cat 2s , all, emergency only,
Is a full service offered as per a weekday? If No, add comments to explain the differences	y or n?	Comments e.g. restricted number of machines, no new starts, no mould room or CT and/or related to wider service, restricted clinical, nursing cover

MPE Support

Do you provide MPE support 'out of hours'? How is this provided, e.g. on site/off site, telephone ?	y or n?	Comments: e.g. formal on-call / informal via telephone / MPE on site at all operational times/ad hoc arrangements

Servicing/QA

QA and maintenance figures were obtained in 2014.
Rather than reproducing the survey from 2014, we seek to understand changes in the way QA is being scheduled and the impact on clinical hours, and QA time taken

Are Maintenance and QA performed using an alternative model to the 2014 survey or are you planning to revise the model you use?	y or n?	Models other than taking a fixed 'service day' per month are sought here to inform the community
Has this change increased clinical linac availability?	y or n?	
What gain in clinical hours has been achieved?	**Linac Hrs/day**	

How has this been achieved? Please outline the model in use	Comments:- e.g. model used, when is QA done or what changes are planned etc. Complete the table below if this aids in explaining the model-otherwise leave blank

Please complete the table below if this aids in explaining the model described -otherwise please leave blank

Machine Type 1. No. of machines following this pattern. [ ]

Performed by (Tick all that apply)

All values in hours/machine	Monday-Friday before 9am	Monday-Friday **Hours/linac** 9am-5pm	Monday-Friday after 5pm	Sat any time	Sun any time	Rads	CS	Tech/ Dosimetrist	Eng	FSE
Daily checks (per day)										
Weekly checks (per week)										
Monthly QC checks (per calendar month)										
Monthly Servicing(in-house) (per calendar month)										
Monthly Servicing(company)(per calendar month)										
Annual Servicing (in-house) - per annum										
Annual Servicing/PMI (company) - per annum										
Annual QA - per annum										
Other intervals (Note task and interval as required)										

If more than two patterns of servicing/QA are in use, please copy the above cells as necessary

What equipment (if any) has been purchased to enable the change?	Comments:- e.g. additional dosimetry equipment
What changes(if any) have been made in staffing levels, or rotas, to achieve the change?	Comments:-
Has the overall time taken for QA/maintenance changed? [ ] y or n?	Comments:-

If so, please summarise the impact in time and on staff of the new model	

If Maintenance and QA are routinely performed outside of the normal clinical day, please estimate the times/linac if possible

Mean annual hours /linac for Maintenance Mon-Fri		**Hours/linac**
Mean annual hours /linac for QA Mon-Fri		**Hours/linac**
Mean annual hours /linac Maintenance Sat-Sun		**Hours/linac**
Mean annual hours /linac QA Sat-Sun		**Hours/linac**

Corrective maintenance and breakdowns

In 2014 we did not explicitly ask for the time recorded for corrective maintenance

Mean annual hours /linac recorded for corrective maintenance		**Annual Hours/linac**	*(Separate from planned maintenance and QA)*

Patient Specific QA Measurements

Have the no of Patient specific QA measurements reduced since the 2014 survey		y or n?

How has this been achieved?	Comments:- e.g. increased use of software solutions e.g. Mobius, etc, measuring 1st 10/20 patients of a new treatment site only
What equipment (if any) has been purchased to enable the reduction in PSQA?	Comments:- e.g. Mobius, plan comparators, hardware for in-house solutions

Times for PSQA

Number of IMRT PSQA measurements/year		
Total time taken (Hours)/year		**Annual Hours**

Monday-Friday	Sat	Sun	**Performed by**	(Tick all that apply)

Average Time(mins) / patient for:-	before 9am	9am-5pm	after 5pm	any time	any time			Rads	CS	Tech/ Dosimetrist		
IMRT Patient specific QA measurements												
% of IMRT patients having patient specific QA measurements												
Number of SRS PSQA measurements/year												
Total time taken (Hours)/year		**Annual Hours**										
Average Time(mins) / patient for:-												
SRS patient specific QA measurements												
% of SRS patients having patient specific QA measurements												
Number of SABR patient PSQA measurements/year												
Total time taken (Hours)/year		**Annual Hours**										
Average Time(mins) / patient for:-												
SBRT/SABR patient specific QA measurements												
% of SBRT/SABR patients having patient specific QA measurements												
Miscellaneous												
Number of breast/Other patient PSQA measurements/year												
Total time taken (Hours)/year		**Annual Hours**										
Average Time(mins) / patient for:-												
Breast / Other patient specific QA measurements												
% of Breast /Other patients having patient specific QA measurements												