

Buyers' guide

Radiotherapy external beam record and verify / oncology management systems

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CEP buyers' guides are intended to provide prospective purchasers of healthcare products on the UK market with general guidance on the technical, operational, and economic considerations to be taken into account in selecting the most appropriate product where a range of similar products exists. They do not include product-specific information, which is published separately via market reviews (which contain product specifications and expert commentary) or evaluation reports (which contain additional technical and / or user evaluation data).

Background

Computers for controlling the treatment machine and systems for checking and recording treatment delivery parameters 'Record and Verify' (R&V) were first developed in the early 1980s (Mohan et al 1984, Podmaniczky et al 1985, Muller-Runkel and Watkins 1991, Greene and Williams 1997). They have been re-developed in more recent times from stand-alone systems, attached to a single linear accelerator (linac), to fully networked systems, often called oncology management (OM) systems. The earliest networked systems shared copies of individual patient data and then evolved into using a common database. The data and the processes used have also evolved from simple storage of the parameters of each treatment field, to comprehensive demographic data, full treatment plan data and elements for booking and scheduling treatments. The latest developments draw together imaging and dosimetric information for each patient (Fontenla et al 1996, Schwarz et al 2001, Eilertsen et al 2004). The advantages here are that all patient data is centralised and use can be made of the crucial verification data (both geometric and dosimetric) for improving the precision of treatment delivery, especially for the highly complex CFRT and IMRT (Fraass et al 1998).

The improvements in precision and the reduction of delivery errors, and their geometric and dosimetric consequences, through the use of quality assurance (QA) programs and R&V systems, have been shown in a number of studies (Podmaniczky et al. 1985, Muller-Runkel and Watkins 1991, Fraass et al. 1998, Klein et al 1998, Klein et al. 2005, Portaluri et al. 2005, Yeung et al. 2005, Erridge et al. 2008). However, whilst this is an obvious benefit of Record and Verify (R&V) systems, it also enhances the chances of errors being introduced by operators pre-treatment, which could then be unnoticed throughout a whole treatment course (Leunens et al. 1992, Barthelemy-Brichant et al. 1999, Patton et al. 2003, Huang et al. 2005). Excessive confidence in the system and automated checking responses may lead to errors in the data input into the R&V system being undetected before exposures are delivered (Macklis et al. 1998, Barthelemy-Brichant et al. 1999, Goldwein et al. 2003, Toft 2005, Toft and Mascie-Taylor 2005, Erridge et al. 2008). Electronic data pathways from the original sources of data, such as the treatment planning computer or simulator, can improve safety and precision still further, for example through the minimisation, of transcription errors (Huang et al. 2005). However, the onus then shifts onto commissioning and testing the RnV/OM system and the electronic data pathways in as detailed and comprehensive a manner as possible, prior to clinical

use (Kirby et al. 2006a). Whilst this makes the data transfer more secure, checking is still required prior to treatment delivery. For example, a plan may have been exported from the treatment planning system (TPS) before the final changes were made in the prescribed dose; this type of error would not be picked up by the R&V system as it can only verify set-up against the data it receives, and cannot authenticate it (Leunens et al. 1992).

The R&V or OM system is now central to a number of key paradigms for ensuring patient safety, and indeed developing a safety conscious culture in radiotherapy, including quality assurance of the whole process. Secure and robust transfer of data between systems used in radiotherapy is vital to the safe delivery of radiation to patients, as well as helping to remove the need for manual data entry and editing of data (Kirby et al. 2006b, Erridge et al. 2008, Amols 2008). Secure and reliable connectivity between systems is vital for this to occur in a safe and predictable manner, hence the requirement for adherence to, clearly defined communication protocols, standards and recommendations for integration, such as DICOM (Kirby et al. 2006a) and IHE-RO (Abdel-Wahab et al. 2010). However, as the systems develop in complexity and functionality their quality assurance, and that of the whole process, particularly in an increasingly paperless environment, becomes more challenging and perhaps in need of different approaches to quality control (QC) and error / failure analysis of both systems and processes (e.g. Toft 2005, Kirby et al. 2006a, Amols 2008, Erridge et al. 2008, Fraass 2008a, 2008b, Rath 2008, Rivera and Karsh 2008, Baiotto et al. 2009, Ford et al. 2009, Furhang et al. 2009, Klein 2009, Siochi et al. 2009).

Scope

Each new treatment machine (linac) is sold with a native R&V system which controls the linac and performs the primary task of verifying the actual machine set-up against the desired treatment set-up prescription, within an acceptable user-defined set of tolerances (Kirby et al. 2006a, 2006b). Although it could operate in a stand-alone manner by interfacing with a TPS or simulator for the transfer of treatment prescriptions, or through manual input of parameters; it is often now a functional part of a wider, full oncology management (OM) system, with centralized database in a fully networked environment including patient scheduling, treatment planning, imaging, statistical analysis, chemotherapy and a host of other functions pertinent to modern radiotherapy (Kirby et al. 2006a). Therefore, interfaces from the OM system are generally to a wide range of other proprietary, and sometimes locally bespoke, systems.

Published guidance on the commissioning and quality assurance of R & V and OM systems exists primarily in the form of UK and US-based reports (e.g. Mayles et al. 1999, Kirby et al. 2006a, Kirby et al. 2006b, Fraass 2008a, Fraass 2008b). There are also a number of studies published that describe user experience of such systems, for example, Podmaniczky et al. 1985, Leunens et al 1992, Fraass et al. 1998, Klein et

al. 1998, Kirby et al. 1999, Erridge et al. 2008, Mandal et al. 2008. The remainder of the literature refers to the need, usefulness and technical capabilities of such systems; however, there is no clear indication from the published literature as to the technical requirements for such external beam radiotherapy systems. In addition this study has found no clear guidance recommendations or legal requirements, documented regarding the minimum, or desired, functionality within an R&V or OM system, or for the communication protocols used between systems.

This guide will look to give recommendations for the technical and operational considerations when choosing an R&V and / or OM system. It is expected, however, that decisions will of course need to consider any local factors such as those listed below prior to any procurement:

- Present radiotherapy equipment
- Present OM or other locally based systems (such as PAS, EMR, RIS, Patient scheduling etc.)
- Radiotherapy equipment (e.g. linacs) being purchased at the time
- Other modalities and systems within the department (e.g. diagnostic imaging modalities, TPS, chemotherapy etc.)

This buyers guide will focus on the functional requirements for modern radiotherapy, including any technical considerations that will need to be made prior to purchase. Due to the rapid pace of change in information technology platforms and infrastructure the latter are described as principles rather than with reference to specific technologies..

Technical specifications

In terms of specification and procurement, the present PASA specification for R&V systems, together with the IPEM report 94 (Kirby et al. 2006b) represent a good starting point for a basic functional specification of the systems attached directly to the linac. As outlined, these systems are generally used for verifying the set-up of the patient on the treatment couch, initiating the radiation exposure(s), and recording the delivered parameters. Some wider functions obtained through the use of an OM system are well covered in the IPEM report 93 (Kirby et al. 2006a).

Current legislation and guidance for radiotherapy, such as IRR99, IRMER 2000, IPEM 2002 and the Manual of Cancer Services 2004 (DH 2004b), impress the requirement upon radiotherapy departments to operate under clear protocols and within an ISO 9000 accredited quality system. These existing departmental clinical and operational protocols are an ideal starting point for the specification of the OM system, as the system will cover multiple functions across the department . This approach will ensure that the specification is clinically-driven with mechanisms linking the procedures within the electronic (often paperless) OM system, with auditable processes within the quality system including any necessary risk assessments within

the department. This approach should also provide a process-based pathway for change management, which is often necessary when implementing new, or upgraded software, on any system within a radiotherapy department.

In terms of defining and documenting a systems specification, together with initiating a procurement process (see later under purchasing), it is worth emphasizing the importance of creating a multidisciplinary working party. Below are some suggestions for professional inclusion within the working party:

- Project lead and/or manager
- Clinicians (Clinical oncologists, Medical Oncologists)
- Radiotherapy Radiographers
- Radiotherapy Physicists
- Radiotherapy Engineers
- Hospital IT lead
- Nurses
- Administrative staff
- Procurement department lead
- Finance department staff

The principle of a core team within the main working party could be used as the main driving force within the project, bringing in other staff and project team members as required at the various stages within the project lifecycle, such as scoping, specification, tender submission, site visits, tender evaluation and analysis etc.

National guidance

National guidance is provided to manufacturers for the safe and accurate development of linear accelerator systems (BSI 1990), and the R&V systems attached to them (BSI 2005). Some guidance on the relative importance of parameter transfers and their tolerances, particularly between the linac's R&V system and third-party OM systems, are given in the IEC standards (BSI 1990, BSI 2005) and IPEM reports (Mayles et al 1999, Kirby et al. 2006a). Manufacturers of R&V systems must comply with the standards set out in BSI 2005 for the main purpose of providing protection to the patient against the hazards of radiation exposures delivered with set-up parameters which do not match those of the intended prescription, sent to the machine from either the treatment planning system, virtual simulation system or OM system. The systems must also accurately record the treatment delivered (and all associated parameters) for each treatment session. In the case of full OM systems, there is no guidance on what functionality these systems must provide as a minimum. The only guidance currently available to users and manufacturer's is that R&V and OM systems should be used as fully as possible for the electronic transfer of data from one system to another, in order to try and eliminate human errors in different parts of the radiotherapy process, as well as providing functionality to allow for unambiguous patient identification.

The key reports and publications in relation to national guidance on the use of R&V and OM systems in radiotherapy departments are outlined below (in chronological order):

RCR Coin Report 1999 (RCR 1999)

This 1999 RCR report gives specific guidance for the whole of external beam radiotherapy. Within the report it stated that “Radiotherapy machines depend on sophisticated computerised control and information networks and are now essential for optimal use.” The report went on to state that “Machine linked record and verify systems can improve the safety of treatment but can lead to systematic errors if used as a set-up system”. It suggested that “The transfer of treatment data sets should be by local area IT network as far as possible. Manual transfer of data either from [treatment] planning to treatment units [Linac’s] or between treatment units is associated with a high risk of transcription errors”. All these support the need for R&V or OM systems

Toft report 2005 (Toft 2005)

The report published by Toft in 2005 followed a serious, adverse incident for a single patient treated with external beam radiotherapy on a linac. Within its detailed analysis and multiple recommendations it states that departments should possess “A treatment planning system that has the capability to transfer a patient’s complete set of treatment parameters directly to the Linac computer database via an electronic data network.” Here the support is for the network which would contain the R&V or OM system as its backbone (IPEM 93), linking the TPS directly to the linacs for electronic transfer of radiotherapy prescription data.

Additionally, the Toft report also discusses clinical protocols and change management (p22). This is an area often overlooked by radiotherapy professionals and other specialists. As stated in section 1.2 above, the current clinical protocols are an ideal foundation for detailing the specification of the desired OM system. However, a commercial system rarely satisfies all the present needs and workings of a department precisely; therefore changes to existing, and development of new ways of working are often required, which must be tightly bound to the auditable clinical procedures and protocols within the quality system. Multidisciplinary mechanisms must be put in place to ensure that changes necessary in the OM system are mirrored into the QS and vice versa.

Scottish Executive report 2006 (Scottish Executive 2006)

This report, by the Scottish Executive, published in 2006 was in response to another serious adverse incident in radiotherapy. Among its specific guidelines and recommendations around the nature of the incident in question, it highlights:

- Change management: Changes should be managed carefully and precisely, particularly when electronic transfer of data is introduced for clinical techniques. The incident in question was procedural, where data was entered

manually from hand written records and was not related to faults or deficiencies in the OM system. The report highlights that “the needs for changes to working practices and procedures and for additional training to address any potential implications for patient safety of the change in computer systems....were not properly assessed”

- **New technologies:** The report highlights “the potential improvements to patient safety following the introduction of new technologies were not properly assessed or implemented”
- **System changes:** The report highlights that “changes to the treatment planning and delivery systems must be subject to a formal review of possible safety implications by suitably qualified staff”

IPEM reports 93 and 94 (Kirby et al. 2006a, 2006b)

These are national guidance documents for the commissioning and quality assurance of a networked radiotherapy department (2006a) and for the acceptance testing and commissioning of linear accelerators (2006b). The latter includes guidance for testing and commissioning the R&V system. These reports give detailed guidance on the above issues, and summarise many aspects of the networked radiotherapy department, including the multiple electronic connections which are likely in and around the R&V or OM system. They also describe in detail the communication protocols and IT issues within a networked environment and, in particular, the main communication protocol for networked systems; DICOM

RCR Towards Safer Radiotherapy 2008 (Erridge et al 2008)

‘Towards safer radiotherapy’ is the most recent national guidance focussed on improving safety in radiotherapy. Among many of its guidance notes and recommendations are the following:

“**Procurement:** The Procurement of radiotherapy equipment is the opportunity to specify requirements which will enhance overall safety of the service. Major items are usually procured by a tendering process in which the radiotherapy department specifies a series of requirements against which potential suppliers offer their products. **Consideration** with respect to safety should include:

- Compatibility with other equipment to enable easy transfer of patients between machines
 - Ease of connection with existing equipment
 - Training requirements
 - Appropriateness to meet clinical needs.”
- “**Recommendation:** The criteria used in the evaluation of equipment with the procurement process should include a review of both positive and negative implications of performance specifications for patient and staff safety.”

- “Electronic transfer: There is abundant evidence that error rates have been significantly reduced after the implementation of electronic transfer between planning systems and treatment machines”
- “R&V systems: In most cases R&V systems include features which will allow for the automatic loading of machine settings for each patient and for the automatic positioning of the treatment machine. Overall such systems contribute to the avoidance of errors but care has to be taken to avoid the introduction of errors by incorrect loading of verification data”
- “Protocols: clear protocols should exist for the use of R&V systems in assisting treatment set ups”
- Change management: the importance of adopting a full change management approach to implementation.

WHO Radiotherapy Risk Profile (WHO 2008)

This world health organisation report discusses a number of the risk areas within radiotherapy. It emphasizes that:

- “The highest number of injurious incidents (N=1702, 22% of all incidents) were reported in the ‘planning’ stage, and the highest number of near misses were related to the ‘information transfer’ stage (N=1732, 22% of all incidents).”
- “The transfer of information from the plan to the treatment machine is a critical step. It may require software from different vendors to interface correctly, or require correct manual data entry.
- Random and systematic errors may occur.
- Protocol checklists will prevent the implementation of unauthorized plans, and clear documentation standards will reduce errors from poor record keeping and handwriting.
- Signature policies should be in place and audited.
- Independent checking is a mainstay of error reduction from transcription and communication errors, but is subject to automaticity errors.
- Modern “record and verify” systems reduce random transcription errors, but require quality assurance regimens to prevent systematic errors.”

IAEA report: Setting up a Radiotherapy Programme (IAEA 2008)

Within this international report, it discusses R&V systems in section VI.8.4. Within it, it states that:

- “An R&V system (see also Section XIII.9) may be a useful addition to the safety of radiotherapy treatment, although it is not a substitute for careful checking of the treatments, especially before the first fraction. The supplier

should be asked to demonstrate that data transfer between the particular TPS, the verification system and the linac is possible. Errors in such transfers are not uncommon and are likely to occur in a systematic way. If careful systematic checking is not carried out, more errors may occur than would have occurred without the electronic system. For simple treatments it is possible to work without an R&V system.”

Although it states that it is possible to work without an R&V system, this is not strictly true for modern treatment machines (linacs), since the drive mechanism for initiating radiation in a clinical mode is the linacs raw R&V system. Radiation exposures could be delivered in a service mode for a clinical situation, but this is not recommended in any circumstance.

RCR report: On Target - Geometric Verification in RT (Hoskin et al 2008)

This report is principally about geometric verification of treatment accuracy during delivery, but also describes how OM systems are expanding rapidly to encompass these non-traditional aspects of R&V, by stating “Ideally there should be a link to the imaging system for automatic recording of set up errors and to the record and verify system to use the patient database”.

General considerations and specifications

The first key consideration is that of the main infrastructural and configuration requirements for the R&V or OM system. Since even the simplest R&V must be networked to at least one other device (the TPS) for the delivery of modern radiotherapy, consideration must be given to the network infrastructure; the existing infrastructure, new software installed alongside the system, network management and key process diagrams etc. Chapter 1 of Kirby et al. 2006a gives some of the key issues associated with the network. The buyer should look to consider:

- The present or required network infrastructure within the hospital or department, and be aware of the possible need to change it or enhance it depending upon the technical demands of the R&V/OM and other necessary, associated systems
- The development of the core team (see section 1.2 above) at a very early stage, crucially involving IT management at this stage
- Developing an understanding of the requirements of the system developed from the clinical protocols and processes necessary. Even at this early stage, initiate the actions necessary for likely process change and its management within the quality system for clinical techniques and protocols
 - The system might be a single, stand-alone R&V attached to the linac, simulator or other treatment machine. All linacs come with their own R&V interface for driving and initiating radiation exposures, and purchase of the treatment machine may also be part of the procurement process.
 - The system might be a single, stand-alone R&V attached to a single treatment machine but be required to interface to other, incumbent systems (e.g. TPS, scheduling system, PAS, EPR system, EMR system, other present OM system etc.). Developing an anticipated process diagram (chapter 1, Kirby et al. 2006a) based on the clinical protocols is to be recommended. Additionally, understanding the needs of a stand-alone system and its functions as a pure R&V unit is key, and the user may find it useful to examine this from a technical, commissioning perspective, as given in chapter 11 of Kirby et al. 2006b or Fraass 2008a
 - Full OM system, with a need to connect with multiple systems both within and out with the radiotherapy department (e.g. chemotherapy). Issues of data security and resilience (for maximum efficiency and uptime/availability) are to be considered (see section 3.5). The topics within chapters 1-3 of Kirby et al. 2006a will be useful.
 - Full OM system working across multiple geographic sites (e.g. with satellite departments). Considerations must be given to performance of the associated network infrastructure, resilience,

master copies of data within the database, indeed single or multiple databases etc.

- The present, incumbent systems (e.g. PAS, third-party patient scheduling etc.) which may be desired to work operationally with the new system(s), or indeed integrate with them

Patient management and scheduling

This is perhaps one of the most important functions of the R&V or OM system and should provide:

- Robust and secure access to electronic patient data:
 - Access should be security controlled using passwords and other standard IT access controls, and utilize a number of unique patient identifiers, such as the NHS number
 - Buyers should enquire about locking functionality, which helps to ensure that there is single access control (i.e. one edit or use at a time) to prevent multiple copy and issue problems
 - Patient identifiers must be unique. Indeed, this is a key recommendation from reports such as Toft 2005 and Erridge et al 2008, and enquiries should be made of the range of identifiers available; e.g. unique ID number, bar-coding, biometric data, use of photo ID procedures and abilities etc.
 - The use of signatures and counter-signatures (see also section 2.8) and their configurability for editing and saving patient and treatment delivery data
 - The system should be capable of setting access controls and levels for different staff members for editing/saving patient prescription and other data. For example some staff members require access to only certain areas of the patient record and should only be able to edit/save data in certain areas; other users will require full, administrator access rights
 - Integration or connectivity with other clinical patient databases (e.g. PAS, EPR) should be investigated, together with its nature (i.e. how automatic or manual a process it is) and whether there are examples of it working at user sites
- Scheduling should be robust and flexible:
 - Scheduling should be possible according to patient, location and staff members, and there should be a system for checking/alerting for conflicts in these
 - Scheduling should be possible both with and without the patient present. E.g. volume definition for a clinician could be scheduled for a patient, but the patient need not see this action on their list of appointments etc. The ability of the systems to do this without burdening the patient with extraneous, unnecessary details, is highly desirable

- It should be possible to schedule non-patient related activities such as machine QA and IMRT plan verification
- Appointment slots should be flexible and it should be possible to schedule different time slots for different activities. E.g., 5 or 10 minute slots for treatment delivery, 15 or 30 min slots for pre-treatment simulation or mould-room activities
- It should be possible to download the schedule on a treatment unit in real-time on a daily basis
- The integration of patient scheduling with other clinical systems, such as PAS, EPR, third-party scheduling, should be investigated
- Abilities to customize scheduling according to local protocols and to clearly identify procedures / processes 'off-protocol', including any necessary authorisation requirements, particularly for the latter
- Other key patient related activities:
 - Patient log-in mechanisms (e.g. self log-in, barcode scanning)
 - Notification of patient arrival and waiting (including times for audit purposes)
 - Patient location and status within the department; notification mechanisms to patients (patient call) for attending procedures when on site
 - Ability to utilize unique patient IDs within various parts of the radiotherapy process; For example ID within patient review and simulation, individual patient ID codes on patient immobilization devices and their links to treatment set-up and delivery, class identifiers for immobilization equipment for treatment set-up etc.

Reporting and statistics

Patient statistics in terms of patient numbers, coding and types of treatment, radiotherapy activities and requirements, numbers of exposures, use of complex procedures such as IMRT and IGRT, payment-by-results, are now a key requirement of radiotherapy departments. The OM system, together other hospital systems such as the EMR / EPR, are the main systems which can produce this data in a timely and efficient way, through the effective use of database reports and data mining Key points for the buyer to consider and investigate with the supplier are:

- The nature and flexibility of reporting and letter generation from the main database:
 - Whether there are a number of existing, supplied reports which would satisfy the data and statistical acquisition requirements within a department (both local and national)
 - The availability and flexibility of tools for writing departmental reports and generating data

- The availability of reporting tools for both automatic, routine and scheduled report generation, including immediate data access
- Coding and national requirements
 - Adequate fields and flexibility within the database to assign to HRG and other codes
 - Sufficient customizability within fields in the database to record all necessary data for NATCANSAT etc. as well as local requirements
 - Flexibility and customizability to locally name data fields and designate them as mandatory for data input
- Other functionality
 - Ability to track notes and results for patients and groups of patients
 - Customizability of drop-down menus for ensuring mandatory and consistency of data entry
 - Ability to customize appearance of menus and reports to local and national requirements
 - Ability to analyse data in multiple, locally defined ways and review data rapidly and routinely

Treatment verification (non-image based)

This is often regarded as the most critical aspect of R&V or OM systems as it is responsible for ensuring that the delivered treatment matches (in terms of both dosimetric and geometric parameters) that which is planned and authorized by the prescribing clinician, maintaining an accurate and secure record. Obviously the systems can only verify against data given to them; 'garbage-in, garbage-out, however vernacular, is still true in this critical environment (Leunens et al. 1992). Hence the connectivity between systems, the integrity of the data transfer, in terms of maintaining the correctness of what was planned, and the quality assurance of that process is vital (Kirby et al. 2006a).

Many of the key considerations for the user in the technical aspects of treatment verification, data importance and the robustness of the interfaces which the user should consider and ask of the supplier, are mentioned technically in section 3.3 and also published in chapter 11 of Kirby et al. 2006b and throughout Kirby et al. 2006a. Some key operational considerations are:

- Which treatment units can be connected to the R&V or OM systems and what parameters can be verified, what MLC configurations can be modelled etc.
- What tolerances can be set on which parameters, and the flexibility of verifying/not verifying specific parameters (e.g. couch parameters)
- Ability to verify absolute and relative couch movements

- User defined tolerances and machine defined tolerances during both set-up and exposure
- Data recording and integrity during normal operation and also during machine faults, interruptions, terminations and faults / breaks in the network communication.
- Nature of data recording, real-time, DICOM prescription download and retrieval to native treatment machine verification system etc.
- Recording, download and subsequent (fractional) implementation of couch parameters and gantry / collimator parameters / deviations in set-up for electron and other bespoke patient set-ups (palliative setting)
- Unambiguous display of treatment parameters at the control console and within the treatment room
- Customisability of the displays and menus for treatment parameters
- Good graphical interface to the linac, and ability to configure displays and readouts to different conventions (to ensure parity between treatment machines displays and the R&V / OM system)
- Access to treatment recording logs and authorisation (signature) trails for investigating treatment machine faults and incidents
- Efficient handling of data for routine, complex delivery procedures such as IMRT (static and dynamic), IGRT and rotational IMRT
- Facilities to run clinical prescriptions in a service / QA mode for the purposes of patient specific treatment QA / verification (e.g. IMRT verification). Data is not recorded as part of the patient's treatment record
- Ability to quickly and easily identify and interrogate the patients treatment history, in terms of geometric and dosimetric treatment parameters, for each and all fractions
- Abilities to integrate dosimetric treatment verification methods and protocols, such as in-vivo dosimetry (Essers et al. 1999, Huyskens et al. 2001), into the patients record and treatment history

Pre-treatment simulation

The number of treatment simulators within radiotherapy departments is decreasing with time as they are slowly being replaced by CT simulators which are generally wide-bore CT scanners with virtual simulation software, there are still a number of departments that will continue to use these systems for a number of years to come. Many of the points mentioned in section 2.5 (regarding geometric parameter recording) apply equally well to the pre-treatment simulator.

- Displays must be clear and unambiguous, both at the control desk and within the examination room

- The R&V / OM system should be configurable for the settings and range of parameters of the simulator; as too for its naming/numbering conventions for gantry sign, collimators sign etc.
- The same must also apply for virtual simulation and treatment planning software in terms of connectivity and conventions
- The users should critically enquire of suppliers (of both OM system software and the simulator itself) about longevity of support for the interface, considering that treatment simulators are a decreasing market

Treatment verification (image-based)

The advent of improved portal imaging technology and cone beam based IGRT makes image based treatment verification one of the cutting edge innovations within radiotherapy at the moment (Herman et al. 2001, Henry and Sykes 2005, Kirby and Glendinning 2006, Hoskin et al. 2008). Most R&V or OM systems are now fully expanded into integrating image based verification data and treatment planning information, because of the recursiveness of IGRT and dose guided RT. The abilities of the OM system in the realm of image registration, analysis, evaluation of systematic and random geometric placement errors and trending and technique analysis, are all key components which should be discussed in depth with the supplier (Kirby et al. 2001, Hoskin et al. 2008). Some key operational considerations are:

- Connectivity and import of image (planar) and cone-beam (volume) data into the OM system, and the tools for analyzing and implementing on-line / off-line / systematic geometric corrections to patient set-up
- Methods and algorithms for image registration and matching, and their ease of use
- Methods of review, approval, scheduling of imaging needs, authorisation (and interlock of prescription) before further treatments following image analysis and approval
- Links to patient set-up data (couch set-up) following image analysis and correction
- Ability to analyse and trend geometric verification data for groups of patients, clinical techniques, immobilization devices etc.

Audit trail and configurability

It is highly likely that a commercial system will match the clinical practice and workflow of a department precisely. Changes are often required on the part of the department to accommodate the workings of the software, and sometimes to accommodate its faults and bugs – change management and links to auditable mechanisms within the QS is the key to minimising the risks involved with this.

However, the software within any R&V or OM system should have some capability for configuration towards local needs and the display of menus / items / drop-down selection boxes etc.; these should be thoroughly explored with the supplier. Some points to consider are:

- Ability to customize appearance and to generate lists of mandatory and non-mandatory items for progressing the radiotherapy process (matching clinical protocols and legal requirements)
- Ability to use protocols and checklists within the software to guide and make consistent radiotherapy processes
- Ability to assign / configure access codes and passwords for staff, levels of password protection, levels of access to patient database and other key system areas within the software
- Ability to require multiple signatures and authorizations for specific procedures, and to possibly initiate interlocks to prevent treatment until specific authorizations have been given
- Access to extensive audit logs and trails for incident investigation and auditing responsibilities for processes (Toft 2005)
- Well thought-out and flexible staff security levels (e.g. trainee, radiographer, physicist, registrar, clinical consultant, engineer, administrator, superintendent etc.)
- Import/export of data from the database of the OM system and from other historical databases from other systems for maintaining continuity of clinical care and records

Future innovation

Radiotherapy is a continually expanding discipline and the OM system should be developing in the same, or similar, ways to cope with increasingly complex clinical demands. Users should ascertain the future for the OM system from suppliers or manufacturers, which could include a view of:

- How software development and upgrade is handled (see sections 2.10 and 3.7) and how training is developed for the user
- How the systems are developing for paperless working (throughout the process, not just at the treatment delivery stage), patient ID and log-in, wireless working, remote access (e.g. for clinical review), web based initiatives, integration into modern communication devices (such as PDAs, tablets and phones)
- Abilities to import, display, approve other information such as treatment plans, consent forms, booking sheets, set-up sheets, dose calculation and other forms (in Word, Excel, VBasic, HTML, PDF and other formats) and other pertinent clinical information

- Abilities to export treatment prescription data back to other systems, such as TPS, VSim software, MU Calculation software
- Future proofing through database development and clinical continuity of records particularly for archived data
- Integration of new and developing imaging and treatment modalities
- Integration into the expanding national IT structure through PACS and EPR/EMR (DH 2002, DH 2003, DH 2004a)
- Expandability in terms of licenses (floating/fixed/functionality etc.) and software functionality The cost of software developments, options and upgrades
- Expandability in terms of links to commercial software such as MS Office, Acrobat software, MS Outlook and other e-mail software

Infrastructure and hardware

The hardware required for the native R&V which comes with a treatment machine (linac) is always supplied as part of the purchase of the linac itself as its clinical use is not possible without it. It is becoming increasingly common for suppliers not to supply IT hardware, such as workstations and servers, but to give details of specifications requirements instead. This is because it is now more cost effective, in most cases, to procure IT hardware through the national frameworks which are now in place within the NHS.

The case is the same for the network infrastructure which will connect the workstations and servers of the OM system, thereby forming the physical connectivity to other devices within the radiotherapy department and beyond. It may only be for new, full turnkey projects that a supplier will provide installation of associated network infrastructures, however, this will often be subcontracted. Clear guidance is given in Kirby et al. 2006a regarding hospital networks and IT infrastructure. Although the principles contained therein will still apply, the specifications often go rapidly out of date within the IT industry.

Careful attention must be paid to the specifications provided by the supplier, and indeed to their recommendations regarding the technology platforms (e.g. SANs, virtualization, CITRIX, thin/thick client etc.). Although software and processes will generally run on a minimum specification, the performance is often sub-optimal for practical, clinical use, allowing no room for development or expansion; it may also be rapidly superseded following software development and upgrades by the supplier.

Key points for consideration are:

- The IT network must be robust, resilient with adequate capacity for the network traffic likely to be encountered (which can be very large now with the advent of volume image data packets for image registration and 4D imaging/treatment). Support processes and devices for ensuring continuity of service and data traffic for critical systems should be future proofed. The IT department's, backup, archive and disaster/recovery procedures should be examined and discussed at a very early stage, particularly with regard to the high availability (> 99%) required for radiotherapy applications and the need to maintain service for fractionated treatments
- It must be capable of existing and operating across a large network, and possibly over large geographic distances for satellite radiotherapy departments
- The radiotherapy service delivered must not be affected significantly by other peaks in hospital traffic
- The architecture and platforms for servers must be carefully formulated with the IT department to utilize modern, cutting edge IT technology (e.g. SANs with clustering and virtualization, thin / thick client technology, high capacity,

fast access storage, backup and archive media). The architecture should be thoroughly discussed with the suppliers, so that the software is supported to run in such an environment

- Where possible, test environments (servers, databases etc.) should be available and built into the structure to aid software testing, fault finding and upgrades
- Where possible, the network infrastructure and hardware should be in line with local and national guidance for IT (DH 2002, DH 2003, DH 2004a)

Connectivity

Getting the technical specification right for the OM system and its connectivity to other devices and services is key to efficient and effective networking within radiotherapy; and hence the global operation of the OM system. Developing process diagrams, as mentioned above, is vital to this understanding, as is the anticipated data streams. The importance of such data, what parameters are expected / desirable / essential in the connectivity, what is the desired means of connectivity and whether any manual processes are involved etc. (Kirby et al. 2006a) should be considered. Key points are:

- Links to incumbent, hospital systems (such as EPR, EMR, PACS, PAS, billing and scheduling systems)
- Interoperability with different makes, models and software versions of
 - Treatment delivery machines
 - TPS systems,
 - Vsim systems
 - Imaging modalities
 - Imaging systems (MV and kV)
 - Simulators
 - Dosimetry equipment and devices
 - Other image guidance systems
- An understanding of the standards used for communication and connectivity (e.g. DICOM) and their development in the national and international arena (e.g. IHE-RO)
- An understanding of the nature of connectability; when the processes are fully electronic, intervention-free and seamless, and when some form of user intervention is still required. Access to users of current systems and the software versions/builds involved
- A clear understanding and interpretation of the conformance statements offered by suppliers and to which hardware/software they apply
- Preparing detailed, site specific information of present user's systems and configurations to which suppliers are asked to connect their proposed equipment
- Ease of migration from incumbent and historical systems for maintaining continuity of clinical care and records

Treatment verification (image and non-image based)

The intricacies, technicalities, tolerances and the necessities of parameter verification on radiotherapy machines are well covered elsewhere in the literature (Mayles et al. 1999, Kirby et al. 2006a, Kirby et al. 2006b). Understanding the nature of the verification and the nature of tolerance tables for different treatment techniques and protocols is of high importance. Other points which need technical consideration are:

- The interface to new and existing equipment must be robust and well proven. Evidence for this should be gleaned from other clinical sites and users with the same equipment, software versions and also some understanding of the similarities (or not) of the network infrastructure between the sites
- Good, clear access to user and other machine logs for fault finding and audit purposes
- Parameter display and recording
 - Clear, unambiguous display of parameters
 - Clear understanding of units, their precision and accuracy
 - The nature of rounding and rounding errors in display and internally within the system
 - The relationships with treatment machine displays in both clinical and service modes
 - The accuracy and precision of recording treatment and set-up parameters
 - Understanding displays of recorded data internally within the system and within the database
- Ability to run service and clinical prescriptions in a multiple use / QA mode whereby data is not recorded within the patient database as fractional exposures (e.g. for IMRT verification and QA)
- Clear understanding of the handling of static and dynamic treatments, particularly under normal and fault conditions (including the loss of network connections)
- Disaster recovery procedures within the servers and the network, and their effect on verified and recorded treatment data

Installation, testing and acceptance

In the earliest versions of computer system for R&V and networking, often the systems were tested in isolation; this often caused discrepancies and problems when many, multi-vendor radiotherapy systems were connected within the clinical setting within the department (Kirby et al. 2001). The nature of installation, testing and acceptance should always be queried with the supplier; although one must never expect the supplier to be able to test and evaluate all possible expected connections to their OM systems, particularly when they are third-party. Some elements to consider are:

- An understanding of the testing environment used by the supplier in developing their software and systems – lab environment, use of reference sites, recursive and soak testing
- An understanding of the nature of version and build control; and in particular comparison with other clinical sites and equipment
- The nature of the installation process, particularly with regard to database development and upgrade, the import of other, historical data
- The nature of testing, and understanding of the lines of accountability and responsibility for connecting to existing systems
- Clear, audited QS procedures for installation and customer acceptance testing
- The availability of clinical and technical support staff through first clinical use

Training, support and maintenance

Training, support and maintenance are the key issues for the revenue costs of the R&V/OM system. Users should become familiar with:

- The licensing and software structure of the system, how it operates (floating/fixed/functionality etc.); the effect of system development, expansion, software functionality expansion, upgrades etc.
- System maintenance costs and how they are implemented. Annual maintenance costs for both hardware and software, and where the two are not mutually exclusive
- Levels of support expected from the supplier (helpdesk hours, response times, system downtime and resilience, remote access and support etc.)
- The training expectations; following first purchase and throughout the life of the software/hardware. The types of training in terms of applications and system administration (hardware and software), and the resources used (classroom based, on-hand training, web based and remote, on-line and off-line documentation (and the update cycle)
- Ability of the supplier to respond to new national initiatives, and to meet present and future local, national and international requirements
- The development cycle for software development and upgrades, and the incorporation of user needs and comments into that development cycle
- Backup, archive and other system maintenance measures. Are they in line with national guidance (RCR 1996, RCR 2002)?

Failure, disaster recovery and resilience

As the OM system becomes larger and more multi-functional, more reliance is put upon the resilience of the data within a single database. Whilst making procedures considerably easier and more efficient, centralizing all patient data puts greater onus on technology for maintaining availability, security and integrity of the data.

- Disaster and recovery procedures should be drawn-up jointly with the IT department following their standard practices, but with particular emphasis on the critical, clinical nature of fractionated radiotherapy
- These should be examined and matched with recommendations from the potential supplier. Examples of clinical availability and instances of disaster / recovery with the OM system should be sought from the manufacturer and verified with other users
- Availability of helpdesk and other technical staff should be ascertained for fault and disaster conditions, particularly the availability of remote access, configuration and other remote procedures which may be possible by the supplier and permitted by the local IT department
- Any guarantees for availability should be sought from the supplier, together with information on technician availability, call out response etc.
- Advice should be sought on matching IT departments regular, routine running and testing of disaster / recovery procedures with advice from the manufacturer
- The nature of backup and restoration procedures and recommendations should be well understood, as well as the nature of the timing of data storage and any potential loss of patient data following restoration of backups
- The use of mirroring software and resilient servers (including its speed of implementation) should be carefully discussed with the supplier to ensure that practices are in line with suppliers recommendations and the clinical operation of the software

Security

Security of patient data and the security of the system as a whole in order to prevent malicious intent and denial of service, are standard practice within IT departments (Kirby et al. 2006a). Again, the issues of security must be carefully questioned with the manufacturer, since there will be policies and procedures whereby only certain software and platform versions (e.g. of the operating system) have been validated successfully with the clinical software, and anti-virus / firewall / other security measures are recommended on only certain medical systems and on specific areas of the software structure during live, clinical use (e.g. real-time antivirus scanning of the live clinical database is often not recommended). Users should consider:

- The agreed, permitted operating system versions and patches which have been tested and validated for the OM system software, and the methods the suppliers use for disseminating this information
- The suppliers should be questioned on how procedures should be implemented for system administration which carefully follows the guidance of the manufacturer, rather than automatic OS and patch upgrades which are common amongst MS operating systems

- The suppliers should be questioned on how rapid, vital software patches can be implemented following known national / international security threats in operating system and other commercial (non-supplier based) software
- Assurances should be sought on how suppliers and users can together conform to best practices within IT systems, subject to issues with medical devices
- The nature of user IDs and password should be discussed with suppliers, including how these are implemented, any automatic procedures for renewal and refresh of passwords, other methods of user log-in (for example biometrics), overrides for workstations log-ons, setting and assigning multiple signatures and counter signatures for specific procedures
- The nature of administrator level access and control within the software and within the IT platform itself

Administration, maintenance and upgrades

How the OM system is administered, the methods by which it can be upgraded (both in hardware and software terms), the support obtained from the manufacturer and the costs involved in the regular ongoing support and maintenance, are all key areas to discuss with potential suppliers at an early stage of the procurement process. For example:

- The nature of any system administration, and the training given by the supplier
- The recommended methods for administration in terms of backup, archive and recovery; the possible use of virtualization and data mirroring
- The possibility of separator system and application administrator roles
- Administration procedures for single and multiple databases (only where the latter is necessary)
- The levels of support provided by the supplier, and their costs; particularly helpdesk availability, on-site response (both from the supplier and from companies supporting the hardware, where this is not supplied by the OM system supplier), weekend response
- Potential for remote access support and the types of procedures / faults / configuration issues which can normally be solved remotely
- Security policies for anti-virus and firewall software on servers, workstations etc. running the OM system software
- Policies for other software (third-party) running on servers, workstations etc. running the OM system software
- The nature and frequency of upgrades, such as quarterly, annually, at least three yearly (NRAG recommendation), and the normal downtime expected during upgrades. Timing of upgrade procedures (e.g. over weekends) and

- cost implications for the user for (a) the upgrade software itself and (b) personnel costs for performing the upgrade
- Ability to implement upgrades in a small, local test environment before going live on the full clinical system
- Capacity recommendations, particularly for image based verifications, with appropriate archive facilities in line with national standards
- The dissemination of information from the supplier on the changes expected from upgrades, functional changes, database structure changes, interface changes (particularly with treatment machines), known bug fixes, new bug introductions for the specific version and build for the upgrade
- The routine dissemination of information on software problems to all users of OM system software when found at other sites. Mechanisms for dissemination (software alerts, mail-bases, website pages etc.)
- The regularity of user meetings and the structure for involving user instigated changes to software functionality

An understanding how the suppliers respond, in their software design, administration and maintenance, to outside standards (such as Connecting for Health) is particularly important. The hospital IT department will be driven towards adherence to these standards by the DH and NHS for other medical services, and the radiotherapy world (particularly where global brands are concerned) are often slow to respond, if indeed there is a response at all. For example, integration with the hospital's active directory structure and still complying with the ISO27000 suite of standards covering information security. Other points to gather information on are:

- The suppliers policies and views on
 - Allowing antivirus and authentication under active directory
 - Allowing computers to be in the AD structure
 - Validating OS updates in reasonable timescales (not six months or even not at all)
 - Avoiding group logins
 - Allowing local changes in administrator username and passwords in line with local policies

Although one may immediately think about capital costs as being the major contributor to a cost analysis during purchasing and procurement of this type of equipment, whole life-time costs need to be considered prior to purchasing to ensure that the ongoing commitment is clearly understood and approved. Cost items such as power consumption, maintenance, upgrade costs and training should also be considered. A linacs lifecycle is approx ten years, however the user may want to consider the lifecycle of computer hardware as the main timescale for the OM system. IT departments will have rolling programmes for other medical and non-medical servers and IT equipment, and it would be advantageous to use these in any lifetime cost analysis.

Primary costs

The main costs to consider when purchasing this equipment have been separated into project-related, capital and revenue expenditure. These will need to be estimated based on experience or provided by the supplier where appropriate:

- Project costs
 - These should be estimated over the lifetime of the procurement process, which could be up to 12 months
 - Estimates of staff time and resources
 - Any outside agencies used (e.g. architectural for building works associated with server rooms or infrastructure costs)
 - Site visits and equipment evaluation for members of the project team. Suppliers will often wish to take buyers to their headquarters to show equipment and software, in addition to clinical site visits to see the product working. If the user wishes to see connectivity with different types of equipment, the supplier may not have a single site which will accomplish this and may have to recommend more than one site visit
 - Time and resources for tendering and procurement
 - Time and resources for tender evaluation, follow-up, clarifications

- Capital costs
 - Those associated with all computer hardware (servers, mirrored servers for resilience, software, costed options, workstations and monitors, bar-code readers and scanners, webcams, separate network wiring and switched for resilience, mirroring software, backup and archive hardware, software and media)
 - Installation costs – supplier personnel and resource, own staff and resource, staff overtime / cover for any interruptions to service
 - Depreciation following capital purchase
 - Loss of interest (when least expensive option is not chosen)
 - Removal / disposal of previous equipment / rooms etc.
 - Commissioning and testing

- Staff and resource for commissioning new software, hardware and processes
- Electrical testing requirements
- Training – applications, administration, support, maintenance
- Revenue costs
 - Maintenance contract (post warranty period) – supplier
 - Maintenance and administration (if applicable) – local
 - Costs for software upgrades
 - Software (if not covered by maintenance contract)
 - Hardware (if required because of changes in recommended specifications for running the software)
 - Suppliers upgrade fees (for on-site and remote work)
 - Local resource and staff costs for testing following upgrades
 - Costs of helpdesk (standard, out of hours, enhanced) and remote assistance
 - Power usage
 - Reduced Paper costs
 - Improved efficiency costs (wastage – see below)
 - Staffing costs for extended services
 - Possible efficiency savings (staff, media etc.)
 - Archive and Backup Media

Hidden costs

- Power supplies for servers and server room, if not supported by present systems
- Cabling associated with the above
- Preparatory works – in advance of building works (e.g. for moving services, cables etc.)
- Building works for server rooms and cooling requirements
- System integration and connectivity with other systems (TPS, PACS, PAS, EPR, EMR etc.); these may have one off costs involved in the simple act of integration for the new OM system
- Full cost of network infrastructure – network cabling, switches, routers, firewalls and other security measures
- Data storage for archive and backup – the storage of large image data sets may make this a considerable amount
- Bespoke interface software costs – where connectivity is possible and technically feasible between systems, but no supplier will supply it
- Items associated with paperless working – whilst the functionality of the OM system aids paperless working, often there are extra costs associated with making the clinical processes work. E.g. bar-code readers, scanners, fax scanners, web cams, PDF and other software, requisite numbers of

licenses for full efficiency, multiple monitors per workstation, upgrades to standard PCs to look at data remotely, PDAs, tablet PCs etc.

- Items associated with the end-of-life of the equipment, such as appropriate and legal, removal and disposal. These should be in-line with the regular routes and costs used by the IT department. Similarly data migration (from the old system to the new) may be of issue, particularly for archived data from previous versions of software

Economic considerations

There is very little information available on the cost-effectiveness of OM system software, and therefore costs associated with the gained clinical efficiencies and reduction of both physical and staff-related (time) waste. Some key areas for consideration are:

- Time for patients waiting for procedures and information
- Time and resource for staff handling, storing and retrieving paper records
- Time and resource for staff to input data into systems or transfer data from one system to the next (where an electronic connection could be possible)
- Actual paper costs for standard printouts of set-up sheets, consent forms, booking forms, prescription sheets, treatment plans, image printouts (DRRs), MLC templates, calculation sheets, review sheets etc.
- Inefficient or non-scheduling of patients and processes
- Non-scheduling of patient related processes (e.g. IMRT verification)
- Data input and transcription where no electronic data tracks exist

Lean methodologies (NHS 2006) offer methods for assessing the radiotherapy processes and workflow, in order to identify and address potential areas of waste, in the hope of implementing rapid improvement cycles, regularly auditing and reviewing the results of implementation and continually refining pathways. Additionally, process engineering services are offered by a number of manufacturers to analyse the use of software (such as OM system software) within a department and compare the use and functions of the software with departmental clinical protocols and procedures. The results may suggest ways in which functions within the software could be used to better effect (or even used at all), or changes within processes and procedures could be simply and easily made to use the software to better effect. These changes could include recommendations for becoming paperless or paper-light in terms of the clinical processes currently in use.

No rule-of-thumb exists for what these cost efficiencies might be, since every radiotherapy department has a unique mixture of equipment and staff make-up. But the use of such methodologies within a department is to be highly recommended.

Purchasing procedures

There is nothing specific or remarkable about the purchasing of the R&V/OM system for a radiotherapy department. It will follow a fairly standard, recommended method of purchasing and procurement through NHS routes (e.g. through the hospitals own procurement department, or through NHS Supply chain or indeed a combination of approaches). Alternative methods of purchasing (compared with straight capital outlay) could be considered – e.g.

- Finance loans for capital expenditure
 - Helps with smoothing cash flow, but more expensive long-term
- Leasing of equipment
 - Unlikely to be of interest since no particular resale value of the equipment
- Purchase as part of a treatment machine(s)
 - Has benefits in possible reductions in costs as incentive by the manufacturer, and often a relatively small fraction of the machine cost
- Purchase through a managed equipment service
 - Possible benefit, but only if part of a larger equipment portfolio
- Purchase through locally or nationally organized frameworks
 - Possible benefit, but depends on size of framework which could be negotiated and IT costs are often volatile and heavily market driven

The standard procurement process, usually found within the Trust Operational Purchasing Procedures Manual, provides details of the procurement process which will satisfy the procurement of an OM system. An outline of the high-level process is provided below:

- Project set-up, scope, timescale and initiation
- Establishment of project and evaluation teams
- Establishment of business case (including estimates of all envisage costs and contingencies) if not already done
- Evaluation of purchase methods, procurement options (e.g. turnkey, framework, OJEU competition)
- Development of specification and scope (including, in the case of OM systems, specification of current incumbent systems requiring connectivity)
- Preparation of tender documents, including specifications, costing requirements, scoring criteria etc.
- OJEU advert and preparation of site visits (following close of tender)
- Tender responses; analysis (by project subgroup) and conducting site visits
- Clarifications, where necessary, and final scoring; includes cost and non-cost scoring and evaluations
- Final evaluations and decisions; preparation of board papers
- Award of business , standstill period and appropriate feedback to all suppliers
- Project evaluation and self-assessment; closedown

European Union procurement rules apply to public bodies, including the NHS, for all contracts worth more than £90,319 (from January 1st 2008) [B] (appendix 2). The purpose of these rules is to open up the public procurement market and ensure the free movement of goods and services within the EU. In the majority of cases, a competition is required and decisions should be based on best value.

NHS Supply Chain (www.supplychain.nhs.uk), a ten year contract operated by DHL on behalf of the NHS Business Services Authority, offers OJEU compliant national contracts or framework agreements for a range of products, goods and services. Use of these agreements is not compulsory and NHS organisations may opt to follow local procedures.

Sustainable procurement

In terms of sustainability these are more specifically related to standard IT equipment compliments and renewal cycles since it is primarily only the OM system software which is sourced from the supplier and hardware is more often purchased through standard hospital routes and frameworks. Issues relating to energy efficiency, energy consumption, renewability, reusability and recycling of hardware should consider those relating to standard hospital IT equipment, including the standard disposal procedures which must be followed within the NHS.

The UK Government launched its current strategy for sustainable development, *Securing the Future* [C] in March 2005. The strategy describes four priorities in progressing sustainable development:

- sustainable production and consumption – working towards achieving more with less
- natural resource protection and environmental enhancement – protecting the natural resources and habitats upon which we depend
- sustainable communities – creating places where people want to live and work, now and in the future
- climate change and energy – confronting a significant global threat.

The strategy highlights the key role of public procurement in delivering sustainability.

End-of-life disposal

Consideration should be given to the likely financial and environmental costs of disposal at the end of the product's life. Where appropriate, suppliers of equipment placed on the market after the 13th August 2005 should be able to demonstrate compliance with the UK Waste Electrical and Electronic Equipment (WEEE) regulations (2006) [D]. The WEEE regulations place responsibility for financing the

cost of collection and disposal on the producer. Electrical and electronic equipment is exempt from the WEEE regulations where it is deemed to be contaminated at the point at which the equipment is scheduled for disposal by the final user. However, if it is subsequently decontaminated such that it no longer poses an infection risk, it is again covered by the WEEE regulations, and there may be potential to dispose of the unit through the normal WEEE recovery channels.

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BSI	British Standards Institution
CFRT	Conformal Radiotherapy
CT	Computed Tomography
DH	Department of Health
DICOM	Digital Imaging and Communication in Medicine
DRR	Digitally Reconstructed Radiograph
EMR	Electronic Medical Record
EPR	Electronic Patient Record
HTML	Hypertext Markup Language
IAEA	International Atomic Energy
IGRT	Image Guided Radiation Therapy
IHE-RO	Integrating the Healthcare enterprise in Radiation Oncology
IMRT	Intensity Modulated Radiation Therapy
IPEM	Institute of Physics and Engineering in Medicine
IR(ME)R	Ionising Radiation (Medical Exposure) Regulations 2000
IRR	Ionising Radiation Regulations 1999
kV	Kilovoltage
MLC	Multileaf Collimator
MU	Monitor Unit
MV	Megavoltage
NATCANSAT	The National Cancer Services Analysis Team
NHS	National Health Service

OM System	Oncology Management System
OS	Operating System
PACS	Picture Archiving and Communications System
PAS	Patient Administration System
PASA	Purchasing and Supply Agency (NHS)
PDA	Personal Digital Assistant
PDF	Portable Document Format
QA	Quality Assurance
QC	Quality Control
QS	Quality System
RCR	Royal College of Radiologists
R&V System	Record and Verify System
RIS	Radiology Information System
RT	Radiotherapy
SAN	Storage Area Network
TPS	Treatment Planning System
VSIm	Virtual Simulation
WHO	World Health Organisation

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Lease options

National frameworks are in place for operating leases to help the NHS procure leases more cost efficiently and effectively. Further details are available from the PASA website [E].

EU procedures

The Public Sector Directive (2004/18/EC) has been transposed into UK law via the following statutory instruments:

- the Public Contracts Regulations SI 2006 No.5 (the regulations)
- the Utilities Contracts Regulations SI 2006 No. 6 (not relevant to this guide).

The regulations apply to contracts worth more than £90,319 (from January 1st 2008) [B] over their whole life, and specify the procedures to be followed for public sector contracting, including adherence to strict timetables, requirements for advertising, invitation to tender and the award of contract. Organisations undertaking a procurement exercise covered by the regulations must give all suppliers an equal opportunity to express an interest in tendering for the contract by placing a contract notice in the Official Journal of the European Union (OJEU).

At all stages of the procurement process, the purchaser must be demonstrably fair, as any decision made can be challenged by the unsuccessful suppliers.

Establishing a procurement strategy

To achieve a successful outcome, decisions need to be made on:

- whether an existing contract/agreement can be used
- the need to consider sustainable development issues
- whether EU directives apply
- the type and form of contract
- sourcing potential suppliers
- duration of contract and opportunity to review/extend
- payment schedules
- how to minimise any risks with the chosen strategy, including supplier appraisal and evaluation/clarification of suppliers' bids.

Preparing a business case

A business case should be drafted and approved before conducting any procurement exercise. Further guidance on preparing business cases is available from the Office of Government Commerce [F] and an illustrative example is provided in the *NHS PASA Operational Purchasing Procedures Manual*, Procedure 1-01 [G].

The EU tendering exercise

EU procurements usually take between 4 and 6 months to complete. This needs to be taken into account in the planning stages. The length of the exercise depends on the chosen procedure (open or restricted). Further information is available from the Department of Health [H].

The procurement panel

A multidisciplinary team should be selected to guide the purchase. Representatives from clinical, user, technical, estates and financial areas should be considered.

Identifying potential suppliers

Criteria for supplier selection must be established. A pre-qualification questionnaire, seeking background information (eg on the skills and experience of the service engineers) may be employed as an initial screen to exclude unsuitable suppliers.

Evaluation criteria

Performance specifications should be derived from local operational requirements, and agreed by the procurement panel. They will form the basis for assessing the adequacy of suppliers' technical specifications, provided in response to the technical specification questionnaire.

It is important to have agreed on the performance specifications of the product as they will be used in the adjudication against company specifications.

Requests for features which are supplier-specific are not permitted under the regulations. Very specific features which are not supported by operational requirements are also not allowed.

Award of contract

Following award of the contract to the successful supplier; unsuccessful suppliers may need to be debriefed. This is at the supplier's request.

Buyers must be aware of the 'Alcatel' procedure (see the *Trust Operational Purchasing Procedures Manual [A]*, Procedure No.T-08, section 6 - *Mandatory Standstill Period*).

For more information on procurement please refer to the Department of Health Website [1]

**Buyers' guide:
Radiotherapy external beam
record and verify / oncology
management systems**

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About CEP

The Centre for Evidence-based Purchasing (CEP) is part of the Policy and Innovation Directorate of the NHS Purchasing and Supply Agency. We underpin purchasing decisions by providing objective evidence to support the uptake of useful, safe and innovative products and related procedures in health and social care.

CEP publications since 2002 are available from our website.

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