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Record and Verify Systems for Radiation Treatment of Cancer: Acceptance Testing, Commissioning and Quality Control

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RECORD AND VERIFY SYSTEMS FOR RADIATION TREATMENT OF CANCER: ACCEPTANCE TESTING, COMMISSIONING AND QUALITY CONTROL

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FOREWORD

Quality assurance (QA) in the radiation therapy treatment planning and delivery process is essential to ensure accurate dose delivery to the patient and to minimize the possibility of accidental exposure. To support this, computerized record and verify systems (RVSs) are now widely available in both industrialized and low and middle income countries. Recent publications of errors in radiation therapy have demonstrated that the lack of proper QA procedures for RVSs can result in severe accidents, including death, as a result of accidental exposure. Furthermore, the use of RVSs can have a higher risk of repeated errors due to a false sense of security out of belief that a computerized RVS will generate safer treatment procedures.

It is widely acknowledged that there are very few reports in the peer reviewed literature and no guidance documents available that professionals can follow for a systematic verification of all functionalities of RVSs and their related interfaces with imaging systems, treatment planning computers and treatment delivery systems. The need to develop specific guidelines for acceptance testing, commissioning and quality control of RVSs has been identified through the increased interest of Member States in efficient and safe radiotherapy treatment. To meet this need, the IAEA has convened several consultants meetings to prepare a publication for establishing QA for RVSs. A draft report was generated by the consultants and was submitted for review by manufacturers of RVSs. Furthermore, the draft report was field tested at the General Hospital (Allgemeines Krankenhaus) in Vienna, Austria. The comments of the manufacturers and field testing were incorporated in the revised document where appropriate.

This report is intended mainly for radiotherapy medical physicists, but the information is also useful for radiation oncologists and therapy radiographers working in radiotherapy hospitals. In addition, the guidance given in this report is highly relevant to manufacturers of RVSs. The recommended documentation for type tests and site tests is available on the CD-ROM attached to this report.

The IAEA acknowledges the contributions of J. Van Dyk (Canada), D. Georg (Austria) and J.C. Rosenwald (France) to the present publication. The IAEA officers responsible for this publication were S. Vatnitsky and D. van der Merwe of the Division of Human Health.

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1. INTRODUCTION

1.1. BACKGROUND

Radiation therapy is the medical use of radiation and radioactive materials to treat cancer and a small number of benign diseases. In recent years, rapid development in the technology of radiation oncology has been seen. One of the prime factors contributing to this rapid development has been the evolution of computer technology and its applications in the process of radiation dose delivery. Computer technologies have been applied to cobalt-60 machines, as well as to complex linear accelerators, to control their operation and to manage subsystems such as multileaf collimators (MLCs) for field shaping.

Experience gained over more than 100 years of use has shown that radiation therapy must be delivered accurately; it is believed that an error in dose delivery of as little as 5% can be detected clinically [1]. In addition, delivery of radiation dose to the wrong site can cause significant complications, with resulting morbidity or mortality, particularly if the structures receiving the dose are radiosensitive.

Record and verify systems (RVSs) were initially developed to reduce the risk of treatment errors, where the treatment parameters used for a given fraction were set manually and could differ from the 'prescribed' (or 'intended') parameters [2–6]. These parameters, which were to be applied during the whole treatment course, were obtained as a result of the treatment planning process, either from a real simulation performed with a simulator, including skin marking and image verification, or from a computer based simulation performed on a treatment planning system (TPS), including computation of the provisional dose distribution. Early RVSs were computerized systems attached to individual treatment machines and designed to capture, before each beam delivery, several treatment parameters accessible through encoders (i.e. collimator opening, gantry and collimator angle, and presence of accessories such as wedge filters) and to compare them to the intended parameters, either entered manually or automatically transferred from the simulator or the TPS. In addition, preset treatment time or monitor units (MUs) could be compared with the prescribed values, and the actual time or number of MUs used for treatment could be recorded. In some cases, the parameters used on the first treatment day were captured to serve as a reference for the following fractions. Preset treatment machines deal with many more parameters, all encoded, which must be accurately adjusted (e.g. the position of each leaf of an MLC). For some of these parameters, RVSs are no longer used to check the consistency between prescription and actual set-up, but they are used to effectively control the treatment machine, allowing partial or fully automated set-up and giving access to sophisticated treatment techniques that would not be feasible without such systems [7].

In fact, RVSs are 'medical devices' that are subject to relevant national or regional regulations. They have evolved into complete radiotherapy information management systems that interface with imaging systems, treatment planning computers and treatment delivery systems. Many also provide scheduling capabilities, data analysis, clinical assessment tools, image and photographic storage capabilities, dose alert functionality, intranet messaging services, and gateway and billing capabilities. RVSs no longer simply record and verify the treatment set-up, but function as an integral link in the planning, delivery and record-keeping processes. Figure 1 shows a typical example of the links between an RVS and the other pieces of equipment of a modern radiotherapy department.

Although it is recognized that there are several risks of error related to data exchange between all these components, starting from the difficulty of unambiguously identifying the patients in the various systems, this report will not address these issues.

1.2. SAFETY ISSUES OF RVSs

To function as intended, the RVS must have stored a complete set of information, including the patient's identification, prescription, treatment plan and field parameters, and must allow this information to be entered and called up correctly for each treatment. The RVS must also be provided with details about the treatment equipment, including the coordinate, scale and angle conventions used [8, 9], beam energies, available field sizes and other parameters and limitations. When these parameters are incorrectly entered in the RVS, systematic treatment errors will occur.

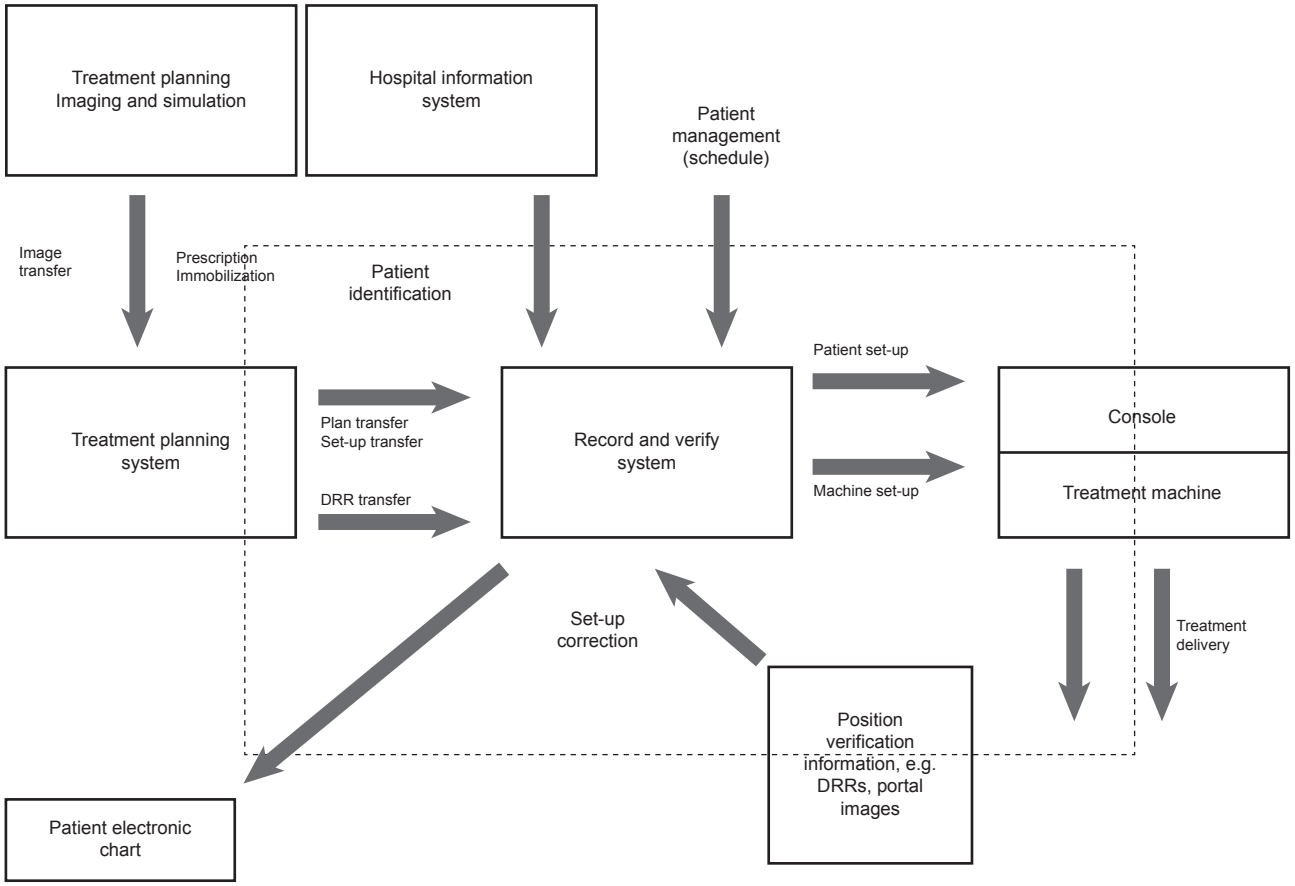

FIG. 1. Illustration of typical data exchanges between the RVS and other pieces of equipment in a modern radiotherapy department. Different vendors may propose different solutions, offering more or less degrees of integration of the various components. The box with the dashed line shows the perimeter intended to be covered by the present report. DRR — digitally reconstructed radiograph.

In fact, although the initial intent of RVSs was to assess and/or reduce the risk of errors, and although RVSs have proven to be effective in reaching this aim [10–13], several accidents, incidents or near misses have been reported that can be attributed, more or less directly, to the use of RVSs [14, 15]. According to the experience at Memorial Sloan-Kettening Cancer Center, there was a 34% decrease in the frequency of treatment delivery errors in the transition period between 2001 and 2004, during which time an RVS was fully implemented, but, in the same time, the errors attributed to the RVS had increased, representing as much as 55% of all encountered errors [16]. Some practical examples of accidents or incidents attributed to RVSs can also be extracted from the Radiation Oncology Safety Information System database (http://www.rosis.info) or found in various reports [17–19].

Some of the most significant types of reported events related to the use of RVSs are summarized in Table 1.

All of these errors might be partially attributed to a lack of appropriate human control, since it is perfectly clear that human and organizational factors are mostly responsible for accidents. In the case of RVSs, it has been further advocated that the radiation therapists, if not properly informed, could be naturally inclined to relax their attention due to an ‘excessive reliance’ on the system, which could contribute to the error rate [15, 19]. Errors are also often due to a lack of well defined workflow and procedures.

Some other errors might be due to problems in the system design or implementation. One particular example is the difficulty of matching regional specifics of language or typography, such as the presence of accentuated characters or interpretation of the decimal point (e.g. comma in France versus period in North America), which could result in erroneous data or results.

One of the areas of significant difficulty in the implementation of a new RVS in a clinical environment is the component that deals with the acceptance testing and commissioning of such a system. Acceptance testing relates to the evaluation by the purchaser of a new RVS to ensure that the system meets the specifications as defined by the

TABLE 1. TYPICAL ERRORS ENCOUNTERED IN DAILY USE OF RVSs

Error description	Possible origin
Incorrect setting of one treatment parameter (could remain undetected during whole treatment course) — critical for treatment time/MUs and for large errors in jaw setting (e.g. inversion of direction for an asymmetric field)	(1) Error in manual input of reference parameters in the RVS (2) Incorrect data transfer (3) Mix-up of automatic transfer and manual correction (doing the same corrections twice)
MUs calculated with wedge but treatment performed without wedge	(1) Erroneous manual input of wedge type identification (2) Automatic data transfer from TPS, but RVS fails to identify the presence of the wedge (e.g. after update of the RVS software)
MUs calculated for dynamic movement of the leaf (intensity modulated radiation therapy), but treatment performed with open static field	RVS software failure for unanticipated sequence of operations (more likely to occur after alteration of the initial plan)
Part of the treatment with incorrect parameters (e.g. MU, field size, MLC setting, gantry or collimator rotation, wedge filter)	(1) Incorrect manual modification of RVS data after treatment modification (2) Proper correction of the plan data after treatment modification but failure to transfer data back to the RVS, or software failure when updating the files (3) Discrepancy found at patient set-up followed by an override with new actual values taken as reference (4) Machine interruption followed by a loss of MUs already given or improper recovery of the data
Treatment of the wrong patient	Wrong patient file selected without verification of the consistency with actual patient (less likely if a photograph is displayed)
Treatment of the wrong site	Fixed patient position with respect to the table not ensured (no indexing) and/or information from table coding not used properly
Wrong number of fractions given	Incomplete or inappropriate field scheduling from the beginning or after treatment schedule alteration (e.g. cancellation of a session)

Note: MLC — multileaf collimator; MU — monitoring unit; RVS — record and verify system; TPS — treatment planning system.

user and/or manufacturer. Commissioning relates to the parameterization and verification that are needed to get the system ready for clinical use. While acceptance testing is a well defined and standardized process for the purchase of other radiation therapy equipment, there currently are no publications that offer guidance on acceptance testing or commissioning of an RVS.

There is, however, an international safety standard that addresses RVSs. In 2005, the International Electrotechnical Commission (IEC) developed IEC 62274 ed.1.0, 'Safety of Radiotherapy Record and Verify Systems' [20]. To quote from the IEC 62274 ed.1.0 standard, an RVS is a:

> "*Programmable Electrical Medical System* or subsystem including its associated peripherals, that is used to compare the set-up of a *Radiotherapy Treatment* machine to predetermined set-up conditions prior to the start of a proposed *Radiotherapy Treatment* and each *Treatment* session, and record actual *Treatment* sessions. It also provides a means of preventing the machine operation if the actual set-up is not the same as the pre-set intended set-up, within *User* defined tolerances."

This standard defines requirements that manufacturers need to implement in the design and construction of an RVS in order to provide protection against the occurrence of hazards associated with incorrect patient treatment. Although this standard has been in print for several years, its existence is not widely recognized. At the present

time, it is infrequent that clear evidence is provided to the purchasers of RVSs that manufacturers have actually complied with this standard or that RVSs actually comply with the specifications set out by the manufacturers. As a result, there is generally no clear evidence for the user that the RVS purchased actually complies with the specifications set out by the manufacturer or that it complies with the requirements defined by IEC 62274 ed.1.0.

The procedure for acceptance testing of RVSs should be similar to that of other equipment used in a radiotherapy department. IEC standard 62274 ed.1.0 requires that: "The *manufacturer* shall provide an installation test document as part of the technical description that includes a demonstration that the RVS performs according to the operational description provided in the *Accompanying documents*".

After installation of an RVS in a hospital, the vendor[1] should perform a series of tests, jointly with the user, to demonstrate that the system performs according to its specifications. Such a procedure implies that the vendor should make available to the customer a document describing the capabilities and correct functioning of the system. The vendor also should include an acceptance test guide that describes the tests to be performed for formal acceptance by the customer.

A thorough commissioning of the RVS should follow the acceptance before it can be used clinically. In addition, an ongoing quality control (QC) programme must be devised to prevent any drift in its performance. Virtually nothing has been published on acceptance, commissioning and QC of RVSs. One report [21] performed an evaluation of the efficiency of a commercial RVS, its integration with the TPS and the impact of manual checking. Although a recommendation was made about performing twice monthly manual checks, this is not always feasible, especially for complex procedures. Moreover, no clear protocol for QC was provided.

1.3. PURPOSE OF THIS REPORT

The main purpose of this report is to describe the acceptance tests and the commissioning process that should be used in conjunction with the installation of a new RVS. Some of the tests performed at installation must be repeated regularly as part of the local ongoing QC programme and on each occasion where there is a possibility that some change has occured in the treatment planning process.

This report will not address the details of the human and organizational aspects, which remain fundamental for the safe use of RVSs (see Ref. [22]). However, some indications will be given about the main issues to be considered when installing a new system.

This report is meant to be prescriptive and to give practical information on how to perform acceptance, commissioning and ongoing QC. However, since there is no existing descriptive document explaining what an RVS really is, this report also contains a short description of the database structure and the main functionalities currently encountered in most existing RVSs. This should help the reader to acquire a better understanding of the whole system. Getting acquainted with the details of his or her own system rather than using it as a 'black box' is fundamental to improving the overall safety.

RVSs are used in clinics with a range of treatment types and planning equipment. It is not possible to anticipate all of the conceivable arrangements of equipment and procedures. Therefore, users should be cautious to ensure that the tests recommended here are appropriate for their specific equipment and procedures.

1.4. TARGET AUDIENCE

This report is aimed at all those individuals who participate in any aspect of RVS installation and quality assurance (QA). In general, such individuals are medical physicists with specialized radiation oncology physics training and practical clinical experience. However, for complex installations, computer specialists are also deeply involved, and they too could benefit from reading this report.

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[1] This publication uses the term 'manufacturer' to identify the organization or individual responsible for the design and construction of the RVS, and the term 'vendor' for the organization or individual responsible for marketing and selling the RVS to the customer (or 'user'). In some cases, the manufacturer and the vendor might be the same organization or individual.

1.5. HOW TO USE THIS REPORT

This report uses the IEC 62274 ed.1.0 standard [20] as its basis for defining the specifications and testing of RVSs. While this report uses this standard as its basis, it is emphasized that what follows in this publication is the result of the IAEA's interpretation of the IEC standard and may not necessarily reflect the true original intent of the IEC standard. However, the IAEA has done its best to adhere as closely as possible to the apparent intent of the IEC 62274 ed.1.0 standard. Where considered appropriate and necessary, this IAEA report goes somewhat beyond the requirements specified by the IEC.

The current publication addresses the procedures for specification and acceptance testing of RVSs to be used by both manufacturers and users at the hospitals. Recommendations are provided for 'type tests' and for 'site tests'. 'Type tests', as defined by the IEC, are specific tests carried out by the manufacturer at the manufacturing facility, on a single piece of equipment that is representative of the model under consideration. The purpose of type testing is to verify that the design of the equipment renders it capable of meeting the requirements of the specifications. 'Site tests' are tests to be performed at the hospital following installation of the customer's system. The purpose of site testing is to demonstrate to the user at the hospital that the RVS meets the specifications as defined by the user and/or the manufacturer, and that the results with the hardware and software as installed at the user's site are consistent with the type tests performed previously by the manufacturer at the factory. A secondary purpose of site testing is to contribute to the training of the user in the safe and correct operation of the RVS. Site tests may comprise the bulk of 'acceptance tests', which are tests performed to ensure that the equipment as delivered and installed meets the requirements of all contractual specifications. Most of the 'site tests' also significantly contribute to the 'commissioning' of the RVS.

A short description of the RVSs and the general process for installation and clinical start of a new RVS are dealt with in Section 2. Section 3 gives some details about their main functionalities. Sections 4 and 5 consist principally of tables adapted from the IEC 62274 ed.1.0 specifications and redesigned to be used for 'type tests' and 'site tests', respectively. Section 6 presents recommendations about the ongoing QC of RVSs. The completion of each of the items described in the tables appearing in Sections 4 and 5 might be confirmed either by inspection of the accompanying documents or by direct testing on the installed RVS. More details on the procedure to be used for direct testing may be found in the Appendix to this report.

2. DESCRIPTION AND INSTALLATION OF RVSs

2.1. DESCRIPTION OF AVAILABLE RVSs

RVSs consist of a set of computers (PCs) and associated software, usually interconnected within a network including a server used to store a database ideally shared between all the treatment equipment. Some of the PCs are generally located close to and directly interfaced with the console of the treatment machines. Others may be distributed throughout the department and are used to input or review treatment parameters. As described in Fig. 1, links should be provided to ensure data exchange with other systems such as a TPS, a hospital information system (HIS) or imaging equipment. Many different solutions could be implemented, depending on the size of the department and the extent to which the RVS is used, not only to 'record' and 'verify' the treatment parameters, but possibly also as a local radiotherapy management system.

The PCs could be supplied by the RVS vendor or by the user. In the latter case, the PCs must strictly meet the requirements given by the vendor. The network integration must also meet the vendor's requirements in terms of the standard being used, the data transfer rate and interconnections with the rest of the hospital network (i.e. the use of 'bridges' to preserve the performance of some critical branches of the network). Special attention must be given to the overall stability and security of the system with proper backup and archiving solutions, since it must be realized that once an RVS is in clinical use, it constitutes the backbone of the treatment process, and any failure of this system is likely to block all the activity of the radiotherapy department. As a consequence, RVSs should be intranet islands; they should be protected from any Internet access or any other external media that may cause virus transfer. Adequate gateways and firewalls should be installed and maintained according to the vendor's specifications. Anti-virus software could be installed, but this has to be approved by the vendor.

Most treatment machine manufacturers provide RVS solutions either developed by them or developed in partnership with other companies. However, it is also common to have machines from different manufacturers in a single department or to decide to purchase an RVS from a manufacturer different from the treatment machine provider. In any case, it is the user's responsibility to obtain, as part of the purchase process, strong written statements from each company representative about the interoperability of the different pieces of equipment and the RVS. If a department is equipped with a large majority of treatment machines from the same manufacturer, it is advisable to choose the RVS from the same manufacturer to simplify maintenance and upgrading.

2.2. INSTALLATION PROCESS

During installation of a new RVS in a radiotherapy department, many different situations might be encountered depending on pre-existing equipment and historical background. Replacing or upgrading an existing system makes things more complex because the patient treatment process should experience minimal interruption while a safe and smooth transition from the old system to the new one is under way. On the other hand, it is useful to have some experience in the use of such systems, since many pitfalls may be discovered when an RVS is put into place and used before all possible consequences of this new approach of managing patient treatments, workflow and the database electronically have been carefully considered.

The installation process must be coordinated between various participants:

- The managers of the radiotherapy department and of the medical physics group must be heavily involved, since the introduction of an RVS will necessitate drastic changes in the overall treatment planning and delivery workflow from prescription to treatment completion.
- A person (in principle, a medical physicist) must be designated as having formal responsibility for the RVS installation, clinical use and follow-up.
- At least one 'backup person' should also be designated, since it is important to always have someone available who is familiar with the details of the system after the RVS is in clinical use.
- The support of local computer/IT specialists is fundamental, with at least one specialist identified to help during preparation, installation, administration and follow-up of the RVS.
- Manufacturer representatives must be identified for (i) helping in the definition of the optimal configuration depending on local needs, (ii) ensuring practical installation of the RVS and interfacing with other equipment, and (iii) training local staff to properly use the system.

This coordination is difficult and time consuming. It requires that the person responsible for the RVS be designated at an early stage of the process. It is recommended that this person be discharged temporarily from other duties.

In spite of manufacturer support, preliminary teaching sessions and visits to other clinical sites, it is often very difficult to have a clear idea of the various functionalities of a new RVS before it is actually installed. Therefore, it is highly recommended to install in advance either a single console or the full system, while keeping the treatment machine working as usual (i.e. either without any RVS or with the old RVS that is to be replaced). The person responsible for the RVS then has the possibility to become acquainted with the details of the system and to prepare the procedures to be followed to match both the specifics of the local treatment planning and delivery workflow and the specifics of the RVS (see also Section 2.4). During this preparatory phase, it is necessary to test the data exchange with the TPS, and it is highly desirable to temporarily have access to the treatment machines in order to achieve and test in advance the hardware and software interfaces. The date of clinical start with the new RVS must be decided after this preparatory phase, taking into consideration the need for formal training of the staff (in particular, physicists, dosimetrists and radiation therapists) a short time beforehand.

Switching from the current system to the new RVS must allow for enough time without patient treatment. This represents typically between 1 and 5 days, with the possibility to reduce the treatment interruption if upgrading is performed partly during a weekend. Part of this time might be necessary for database regeneration if there was already a database that could be reused after proper formatting. The rest of the time is used for practical implementation of the new RVS and final tests. It is conceivable, especially if the new RVS comes with a new machine, to start with a partial connection with one or more of the treatment machine(s) and then to include the

other machines at a later stage, after some experience has been gained. However, this practice is not feasible if it is considered important to maintain a unique consistent database for all treatments.

2.3. PRINCIPLE OF ACCEPTANCE TESTING/COMMISSIONING

Unlike for a TPS, it is difficult for an RVS to clearly differentiate 'acceptance' testing from 'commissioning'. The reason is that an RVS 'sits' between the TPS and the treatment machines and that the main issues are related to safe interoperability between these pieces of equipment. Therefore, the concept of 'generic data', as used for acceptance testing of a TPS (e.g. the IAEA test package supplied in IAEA-TECDOC-1540 [23]), is irrelevant. Instead, at the time of acceptance, the RVS configuration must be consistent with data input from the local TPS and data output to the local treatment machines. In addition, since there could not be a long interruption of treatments, as much as possible should be prepared in advance (described above as the preparatory phase). Then, the 'commissioning' process, which consists of 'all testing, data input and verification checks that are needed to get the system ready for clinical use' [24, 25], must be performed in conjunction with the final installation by the manufacturer and therefore partly merged with the 'acceptance'.

2.4. RVS PARAMETERIZATION

The parameterization (or customization) of a new RVS is an important step of the acceptance/commissioning process. It consists of preparing the RVS taking into consideration:

- The technical data imported from the TPS (and possibly from the simulator);
- The technical data exported to the treatment machines;
- The data imported from or exported to external applications (e.g. input of administrative data, output of medical or administrative data);
- The workflow process, in particular, the definition of staff categories that will use the system and the specific tasks that will be allocated to them.

This parameterization task should be coordinated by the person responsible for the RVS, and could involve a dedicated local computer specialist, but it requires a close cooperation with the manufacturers (the RVS supplier and also the suppliers of the other pieces of equipment or software) and with representatives of all staff categories involved in the future use of the system. It is very useful to obtain support from a colleague from another centre who has significant clinical experience in the daily use of the same system.

For image exchange and radiotherapy technical data exchange, the Digital Imaging and Communications in Medicine (DICOM) standard (http://dicom.nema.org) makes the task much simpler. However, some data matching is generally still required to link the terms and scales used by the TPS to those used by the treatment machine through the 'bridge' of the RVS. The acceptable range must be set for each of the machine parameters according to the local practice. Parameters include, for instance, the choice of energies, dose rates, accessories (including their codes, orientations and maximal allowed field sizes) and limiting angles.

Another aspect of the RVS parameterization is the need to define users' groups with proper rights (e.g. allowance or not to change the machine parameters), and to assign to all potential users usernames and passwords, together with the definition of the group to which they belong. This is difficult because a balance should be found between flexibility and safety: if many rights are given to too many users, there is a risk that a person not being properly trained or not having the adequate level of responsibility makes a severe error; on the other hand, if the rights are given to too few people, there is a risk of being 'stuck' when responsible people are not available to perform tasks that are frequently required.

Table 2 summarizes the main items that should be considered in the parameterization process of a newly installed RVS.

TABLE 2. TYPICAL STEPS RELATED TO THE PARAMETERIZATION OF A NEWLY INSTALLED RVS

1	Definition of the names of the machines, and for each of them, the attached modalities, energies and dose rates (MUs/min)
2	For each machine (and modality), identification of the internal variables used to describe all the mechanical parameters that will be verified or controlled, including a list of possible accessories (trays, MLCs, wedge filters, etc.)
3	For each parameter, definition of the allowed direction, range (minimum–maximum values) or related specificities (e.g. wedge position and orientation, allowance or not for remote automated set-up)
4	Preparation or verification of mapping tables ensuring a one-to-one match for each parameter between names, scales and orientations used by: (i) the TPS and RVS and (ii) the RVS and each treatment machine (including simulator)
5	Customization of data exchanges: definition of IP addresses of external devices, preparation of import/export filters according to the type of data to be exchanged (i.e. RTP Connect, DICOM and DICOM RT objects, patient identification, medical records); definition of the paths for data archiving and retrieving
6	Definition of users' rights according to professional categories and departmental policy
7	Definition of tolerance tables according to the degree of accuracy expected for each different type of treatment (see Section 3.3.3)
8	Definition of various 'preferences' specific to each RVS and pertaining, for instance, to options for screen display, for printing, for management of patient schedules, etc.

Note: IP — input; MLC — multileaf collimator; MU — monitor unit; RVS — record and verify system; TPS — treatment planning system.

This parameterization must be reviewed and/or revised each time a software or hardware change occurs in one piece of equipment interconnected with the RVS (see Section 6).

2.5. RVS TESTING

It is difficult to describe the tests that are needed to guarantee the quality of the installation and use of an RVS. In this report, the focus is on a minimum list recommended to serve as a basis for the 'acceptance' of the system. It is split into 'type tests' and 'site tests', as described in Sections 4 and 5, respectively. In the Appendix to this publication, some specific tests are described, which can be considered as contributing to the 'commissioning' process. However, these lists are not exhaustive, and each department must develop its own QA procedures that must include 'periodic checks' of the entire system, following the general principles given in Section 6.

Most practical tests require a 'dummy patient' to be defined. This dummy patient should not interfere with the actual patients in the RVS database, so it is important to define from the very beginning a standard naming convention (e.g. starting the patient identification number with 'test', using the date of the test as part of the identification number, referring to the type of test in the patient name, etc.). In practice, several 'dummy patients' will be necessary to cover the whole range of possibilities of a given RVS. Some 'generic dummy patients' might be provided by the manufacturer as part of the system or defined by the manufacturer representative during installation. Once a 'dummy patient' has been 'treated', it must be realized that the record is updated and, therefore, there should be provision for repeating the 'treatment' as often as required.

The QA procedures should be based on the errors that have been recognized as more likely to happen (see Table 1) and the description of the functionalities of RVSs given in the following section.

3. THE RVS DATABASE: TYPES OF DATA AND MAIN FUNCTIONALITIES

3.1. INTRODUCTION

Since the basis of standard radiotherapy treatments is the delivery of multiple 'fractions' (or 'sessions') over a given period of time, the major function of an RVS is to ensure the consistent and reproducible delivery of these fractions according to the prescribed 'treatment plan', considering both the dose and the geometrical points of view.

3.2. DATABASE STRUCTURE — HIERARCHY OF THE OBJECTS

3.2.1. General

All RVSs are built around a database that contains different types of data, which can be either imported from another system (e.g. oncology information system, TPS; see Fig. 1) or entered manually. Sometimes, they also offer the possibility of capturing some parameters at the treatment console after the treatment unit has been set manually. It is essential to have a clear understanding of the processed data and their internal relationships. The 'objects' related to the treatment plan are generally organized in a hierarchical structure, where the patient is at the top and the beam data at the lower level (Table 3). Depending on the RVS manufacturer, the name given to the various objects may be different, but the general organization is relatively standard. This organization is described in the following sections, but it should be stressed that the names given and the overall layout may differ significantly among systems and departments. In all cases, it is important that the naming conventions adopted by the user to designate the instances of the different objects, such as treatment phases, beams, etc., be carefully thought about and kept consistent within each patient record and among all patients recorded in the database. Since the user generally does not have much control of the names chosen by the manufacturer, a special effort should be made by the staff in charge of user training to carefully explain the meaning or the names given to the various objects and processes.

3.2.2. Patient

Patient identification can be entered manually, but it should preferably come from the HIS, where proper checks should be performed to ensure that the spelling is correct and each patient is recorded only once in the system, so that it can be retrieved unambiguously. For verification purposes, it is preferred to have a photograph and/or a bar code attached. To ensure unique identification of each patient, a unique identification number (ID) is usually attributed to each patient. This number could be a national ID, or a hospital or radiotherapy department ID. The RVS should accept any ID format to cope with local habits. This ID must be complemented by a mandatory core of data entry fields, entered manually or imported from the HIS, in order to allow verification of the identification of each patient. Complementary information, such as administrative data or medical status of the patient, might be recorded in the RVS. However, duplication of such data should be avoided as much as possible, or a mechanism should be provided to prevent a lack of consistency following data updates in separate databases.

3.2.3. Treatment phase 'course'

For a given patient, the overall long term treatment may consist of several phases separated by a significant amount of time (typically more than 1 month), either as part of the initial treatment strategy, or in case of clinical need for complementary treatment (long term interruption, recurrence, secondary cancer, etc.). All data related to the same phase of treatment may then be grouped into one object called the 'treatment phase', 'treatment course' or simply the 'course' or 'treatment' related to a specific anatomical site. Some RVSs allow the definition of an additional intermediate level, describing the several 'phases' belonging to one 'course'.

TABLE 3. HIERARCHICAL ORGANIZATION OF TYPICAL RVS DATABASE

Patient (unique ID) — administrative data and identification photograph

Treatment phase (course) — diagnostic and anatomical site

Treatment plan (group of beams)

Prescription[a]
- dose point(s)/volumes
- total dose, dose/fraction, breakpoints[b]

Beam (field) (used either for set-up or treatment)
- machine, modality, energy
- MUs, time, MU rate (except for set-up)
- mechanical set-up (collimator, gantry, table, etc.)
- accessories (wedge, block, MLC, etc.)
- tolerance table
- reference image
- field or set-up photographs
- free comments
- dose per field[b]

Treatment schedule

Note: ID — identification number; MLC — multileaf collimator; MU — monitor unit.

[a] The prescription could also be defined at a higher level, i.e. one prescription for several 'treatment plans'.

[b] Depending on the RVS, the dose related data could be completely defined within the prescription where the dose contribution from each beam would then be given; alternatively, the dose contribution may be attached to the beam description.

3.2.4. Treatment 'plan'

During a given treatment phase, several target volumes may be treated with different beam arrangements and different schedules. It is practical to group all beams contributing to the dose delivered to the same volume as belonging to one 'plan'. Additional restrictions might be required for some RVSs, e.g. all beams belonging to the same plan should be treated within the same fraction. Then, it is easier to assign a dose at a reference point as coming from a specific 'plan' (see Section 3.3.1.1). It must be possible to arrange the plans in a sequence clearly defined to avoid concurrent delivery of several plans that should be treated sequentially and vice versa. This could be achieved by 'hiding' and 'unhiding' the plans according to the progression of the treatment course. The description of the plan sequence may be carried out using specific 'scheduling data' (see Section 3.3.5).

3.2.5. Beams (or fields)

A 'plan' may contain one or multiple 'beam objects', or simply 'beams' that contain all data necessary to set up the treatment machine with respect to the patient (see details in Section 3.3). These beams are generally 'treatment beams' that are actually designed to deliver a contribution of the total dose at the target volume.

The treatment beams might be used to generate single or double exposure portal images, but another possibility for checking the patient position with respect to the machine consists of designing specific beam arrangements for this purpose (typically, an orthogonal pair with one beam at anteroposterior and one at lateral incidence, or a cone beam computed tomography (CT) reconstruction). Such beams may be called 'set-up beams' or 'verification beams'. They differ from treatment beams, especially as far as the dose contribution is concerned. They may or may not have a specific number of MUs attached to them (see Section 3.3.4). Such verification beams may be allocated to a plan, or to a course separated from the treatment beams.

3.3. TYPES OF DATA

3.3.1. Prescription data

3.3.1.1. Volumes — Points

It is usual that after each fraction, the RVS accumulates the dose at some specific prescription point, usually coinciding with the point used for dose reporting as defined in the International Commission on Radiation Units and Measurements (ICRU) recommendations [26–29]. Before each treatment session, the dose planned for the current fraction is added to the dose cumulated from the previous fractions, and the sum is compared with the prescribed dose. If this sum will exceed the prescribed dose, a warning is displayed and an interlock is triggered. Additional points may be provided to monitor the dose in other parts of the target volume, or in organs at risk. The identification of such points, their relationship with anatomical structures and the contribution of each beam (or plan) to the dose at each point for the prescribed number of MUs are part of the data stored in the database (see Section 3.3.2.5). Ideally, they are exported from the TPS, but they can also be entered manually, e.g. from TPS paper output.

3.3.1.2. Dose per fraction

The dose delivered at each fraction in a given volume or at a given representative reference point (see Section 3.3.1.1) is part of the medical prescription. Usually, only those beams are considered that belong to one ‘plan’, contributing directly to the volume, but it should be recognized that other beams (e.g. treating adjacent lymph nodes in the case of a breast treatment) might contribute a small proportion to the daily dose. To take this small percentage into account, it must be previously calculated in the TPS. Moreover, it could be necessary to export all beams that contribute directly and indirectly to the dose at the reference point as a single ‘plan’. This dose could then no longer be a simple integer (e.g. prescribing a 2 Gy/fraction while calculating 2.015 Gy). Each institution should make a clear decision on how these small dose contributions in the RVS will be managed.

3.3.1.3. Number of fractions and total dose

For each ‘plan’, the number of fractions has to be defined. It is used to calculate the total dose from the dose per fraction. Alternatively, the total prescribed dose may be given as input, and the number of fractions calculated by the RVS from the ratio between the total dose and the dose per fraction.

It is quite common that the total dose in a target volume may be delivered by several ‘plans’ treated either simultaneously (e.g. one plan with photon beams and one with electron beams at different treatment machines) or sequentially (e.g. a boost dose to a smaller volume). The total dose (and number of fractions) must then be for the different plans being used to treat this target volume.

Like the dose per fraction, for each plan, the total dose and/or number of fractions could be imported automatically into the RVS from an external system or be entered manually. These numbers are used to monitor the treatment progress and verify if the total dose or the total number of fractions does not exceed the prescribed one (see Section 3.4.1.1).

3.3.2. Beam data used either for set-up or treatment

3.3.2.1. General

Once a treatment plan, prepared at a TPS or determined from simulation, has been selected and formally approved, the corresponding beam data must be transferred to the RVS. These data consist of identification photographs and geometrical, mechanical, imaging and dosimetric parameters that are attached to each beam; they should be identical in the TPS (or at the simulator) and in the RVS. Therefore, automatic transfer of as many parameters as possible is desirable. However, it is quite common that some data are not available or not compatible on both sides, requiring complementary manual data input in the RVS.

In addition to the geometrical beam parameters, information on the set-up of the patient relative to the treatment couch is required. Moreover, it should be possible to indicate any devices used for patient set-up. If there is no explicit database field designed to store this information in the RVS, it could generally be added as a 'free comment' attached as a note to a prescription, course, plan or beam.

Instructions, reminders or alerts can be added as free comments (see Section 3.3.2.4). They are often associated with dose (e.g. addition of shielding after a certain dose level), and there should be a possibility to acknowledge them electronically as having been read.

3.3.2.2. Machine, modality and energy

For each beam, the database must contain information about the machine, the modality (photons, electrons, etc.) and the energy that will be used for treatment. Sometimes, the dose rate (e.g. in MUs/min) is also required. This information is used to block the possibility to activate this beam on another machine and/or with a different modality and/or energy. The data should be unambiguous, and the machine and modality identification should be consistent with the RVS parameterization (or database set-up) (see Section 2.4). If different machines or modalities are being used for a patient during one treatment course, specific grouping of beams into the various 'plans' or 'sessions' may be required.

For a given machine, there might be coordinate and scaling conventions that do not meet the IEC standards [8] or match the conventions used in the TPS or at the simulator. This is normally taken into account by the introduction of conversion tables ('mapping'), defined during the RVS parameterization (see Section 2.4). In most systems, the prescribed treatment parameters and the actual values set up at the treatment unit are displayed on the screen. In some systems, the order of display is changed according to the selected piece of equipment, requiring the user to become familiar with the screen appearance for each different type of machine. This could be confusing and should therefore be avoided if possible.

For each machine, modality and energy, some restrictions can normally be configured during the RVS parameterization, limiting the range of each parameter and the accessories that are allowed. It is also possible to select which parameters are to be verified, e.g. a centre may choose to not verify couch longitudinal position.

3.3.2.3. Geometrical parameters and accessories

(a) Gantry and collimator rotation

Whatever convention is being used at the planning stage, the RVS data must reflect the machine conventions for orientation and scale. Since it is sometimes possible to reach one position from two different directions (i.e. 180° IEC gantry angle from clockwise or counter-clockwise), it is sometimes possible to add an indicator about the choice that should be made for automatic set-up.

The risk of using another unit than degrees (°) is limited, but the unit must be clearly displayed and the use of fractional degrees should be allowed.

(b) Field size/leaf setting

The X and Y directions of the main jaw movements, as well as the X1, X2, Y1 and Y2 values for the individual jaws or the corresponding values for individual leaves of an MLC, are defined by the IEC [8]. However, it is important to note that manufacturers do not always follow these conventions consistently. The RVS data must be consistent with the internal machine conventions. As recommended by the IEC, the unit (cm or mm) should always be displayed. In addition, it should be possible to use fractional values.

It is quite common to indicate explicitly if asymmetric jaw settings are being used in either of the two directions (e.g. using a checkbox), and if an MLC is present (in addition to, or as a replacement for, one of the jaw pairs).

Although the main jaw position may be entered or edited manually, this is impractical for MLC settings, so this information generally comes from the TPS. Except when very simple editing of leaf positions is required, the MLC shape is generally modified at the TPS, after which the modified data are imported into the RVS.

(c) Beam modifiers

Beam modifiers such as blocks (usually fixed on a Perspex tray), wedges or compensators might be attached to the collimator. Since they can drastically change the dose to MU relationship, it is essential that the RVS properly checks their presence and orientation.

On modern treatment machines, 'hard wedges' (i.e. mechanical wedges that are inserted manually) are equipped with a socket that connects to the treatment head, providing the treatment console with a unique identification code. When there are several possibilities for wedge orientation with respect to the collimator (e.g. thin edge towards either Y1 or Y2), the orientation information is also part of the identification code. In such cases, the RVS must allow for comparison of this code with the value expected from the approved treatment plan. A software interlock must prevent the treatment of the patient if there is a discrepancy.

When integrated motorized mechanical wedges are being used, intermediate wedge angles might be obtained by combining fractions of MUs with and without the wedge. Then, this information comes from the TPS through the RVS and, since there is no manual insertion of a mechanical device, the treatment is normally given according to the prescription. The same applies to dynamic wedges (also called 'virtual' or 'soft' wedges) where a wedged fluence is obtained by continuously moving one jaw during irradiation. In both situations, if a machine breakdown occurs while the beam is on, there must be a process in place to ensure that the proper information is recorded and that it is possible to restart the treatment where it stopped. The simulation of such incidents must be part of the RVS acceptance.

On some older machines, it is possible that no interlock exists for the presence of wedge filters. In that case, special precaution from the staff is required, especially on systems where an RVS is used, since the radiation therapists tend to relax their attention when they know that an RVS is normally checking the consistency between prescription and execution. Another major risk of error that has led to severe accidents is related to the confusion between 'hard' and 'soft' wedges if both types might be used, and the possibility of computing the MUs for one type of wedge and using a different one for treatment exists [19] (e.g. when data transfer from the TPS is not fully automated or is not working properly).

Similar risks exist when the presence of a shielding tray is not automatically detected. If the tray is missing although accounted for in the MU calculation, the patient could be overdosed by several per cent. In addition, there is a risk of exchanging shielding blocks or other accessories designed for different fields or different patients. This could be avoided for customized blocks and accessories, if they are equipped with a coding system that is detected by the machine and checked by the RVS.

(d) Table position and angles

Most treatment tables are equipped with encoders allowing the display of the three coordinates (vertical, lateral and longitudinal) and the rotation(s) (couch isocentric and/or table top), as defined in the IEC standard [8]. However, this information is often not available in the TPS since the beam position with respect to the patient is generally defined with respect to an anatomical coordinate system. One reason is that the patient is generally not reproducibly positioned on the table top, resulting in variations in the lateral and longitudinal position of the table at daily patient set-up. This is not quite true for the table rotation(s) and for the vertical coordinate, which should remain constant throughout the treatment course, provided that the patient is carefully aligned using the laser system and that the table top surface provides a good rigid reference. For non-coplanar treatments, the couch isocentric rotation is clearly a fundamental parameter that must be part of the treatment plan prepared at the TPS.

Depending on the treatment machine and RVS, the table coordinates may or may not be included in the database. Being able to use these coordinates in the RVS increases the safety since it could prevent an error in source–surface distance (SSD) (i.e. mixing up between an SSD and an isocentric technique) or treating the wrong anatomical site or side. The possibility to use 'indexing' systems where patients are positioned in 'casts' always fixed at the same position on the table top gives more confidence in the use of lateral and longitudinal coordinates (see Section 3.4.1.3). One cannot associate different verification parameters to different patients. If indexed immobilization and positioning systems are introduced, they have to be used for all patients treated on the unit.

(e) Graphical representations

Graphical displays at the treatment console, based on the actual beam settings at the linac, are frequently provided as help to easily understand the main geometrical characteristics of the beams that are to be treated. A 'beam's eye view' showing the jaws and MLC settings, possibly also including the collimator rotation and/or wedge, superimposed on a reference image (see Section 3.3.4) is frequently available. Colour codes and additional warnings are often available to enlighten any inconsistency with the prescription. A 'room's eye view' of the collimator assembly, gantry and table might be of additional value.

3.3.2.4. Free comments

Since RVSs tend to be used as a replacement or duplication of the paper treatment chart (see Section 3.4.3), they generally offer the possibility to display all information useful for machine and patient set-up on a monitor located in the treatment room. Therefore, it is very useful to include in the database free text, attached to a prescription, to a beam, to a 'plan' or to a 'course', allowing the physicist or radiation therapist to mention helpful information to correctly deliver the treatment. Some examples are alerts, indications of the presence of bolus or the use of immobilization devices and accessories that are not automatically detected by the system (see Section 3.3.2.3).

3.3.2.5. Monitor units

RVSs are designed to monitor and record the prescribed dose, the dose per beam (see Section 3.3.1) and the number of MUs (per beam). It is clearly essential that the number of MUs is the same as planned for the prescribed dose and that an interlock prevents setting a different MU value. However, all these parameters are closely correlated. In some systems, they could be processed as independent parameters but, ideally, the dose per MU should be used internally in the RVS to update the cumulative dose to prescription points or organs at risk. In addition, if beam delivery is interrupted due to a technical problem, or if the prescribed dose is modified during the course of the treatment, this quantity is an essential parameter allowing the resumption of a treatment with the right number of MUs until the (updated) prescribed dose is reached. In some systems, TPS and RVS functionalities are partly merged into a single system. Then, the MU data are considered so critical that they are locked as soon as the treatment is started, making it quite difficult to make any subsequent modification of the prescription or schedule. It is the responsibility of the users to understand in detail how MUs, prescribed dose and beam weight/dose per beam are handled and interrelated in the RVS and TPS, respectively.

3.3.2.6. Control points concept — Intensity modulation

Most modern treatment machines offer the possibility to deliver the dose from multiple 'segments', each of them contributing a fraction of the dose per beam and per session. This allows the delivery of beam modulation (intensity modulated radiation therapy, IMRT), aiming at a more conformal dose distribution. Each segment consists of a specific field shape defined by the MLC. More recently, the possibility to deliver these segments while simultaneously rotating the gantry has been provided (intensity modulated arc therapy). The radiation might be stopped between consecutive segments ('step and shoot' mode), or the beam could be kept on while the leaves and/or the gantry move (dynamic mode).

Whatever mode is being used, the leaf positions and (for rotational therapy) gantry angles of the different segments are stored in the database as 'control points' belonging to one 'beam'. Each 'control point' is associated with a cumulative number of MUs (or a fraction of the total number of MUs per beam).

3.3.3. Tolerance tables

For most of the machine parameters listed in Section 3.3.2, a small deviation may exist between the prescribed and the actual values used during treatment. The magnitude of the deviations that are considered clinically acceptable depends on the type of treatment (from highly conformal curative treatments to low dose palliative treatments for patients with pain) and on the parameter under consideration. Some parameters (e.g. table coordinates) might also

be kept uncontrolled. As an example, for an uncooperative patient where the patient position on the table might vary considerably between fractions, deviations of several centimetres on the lateral and longitudinal coordinates of the couch and 1° for the gantry might be acceptable. In contrast, for a highly conformal curative IMRT treatment, the tolerated deviations could be as small as a few millimetres and 0.2°.

To deal with these different situations, the concept of 'tolerance tables' has been developed: it is the medical physicist's responsibility to define, as part of the RVS parameterization, a series of tables, each of them having a specific name and containing, for each machine parameter, the acceptable range beyond which a software interlock would be triggered (see Section 3.4.1.1).

3.3.4. Verification images — Verification beams

The verification of the patient position with the help of portal images may be considered as a complement to the verification of the machine parameters with the RVS. Therefore, several manufacturers have included the possibility of storing and manipulating images in the RVS. These might be both reference images (from the simulator or from digitally reconstructed radiographs generated by the TPS) and portal images directly obtained during treatment delivery at the accelerator.

The beams used for imaging could be either the actual treatment beams (single or double exposure) or additional 'set-up beams' or 'verification beams' (e.g. anterior–posterior and lateral) used exclusively to check the patient position (see Section 3.2.5). The dose contribution from these beams often used to be neglected. However, with the increased use of these images and functionalities like the megavoltage cone beam CT, for instance, the imaging dose cannot be ignored any longer, and it should be evaluated for each treatment protocol. Most RVSs include the possibility to record the MUs used for taking the images. Sometimes they offer options either to convert this MU into dose and account for it in the cumulative dose to the target or to subtract the corresponding number of MUs from the treatment MU setting. However, it should be recognized that there is no simple solution since the verification beams or the open field portion of double exposure images contribute to volumes that are different from the fields used to treat the target volume. Another approach would be to include these 'verification beams' in the TPS plan.

3.3.5. Scheduling data

The beams or plans must be organized in such a way that they can be sequenced according to a given schedule consisting of the repetition of fractions throughout the treatment duration. Basically, this is performed by filling in a table giving the list of all the 'plans' that are to be treated sequentially. This table typically contains as many lines as the number of planned fractions, sessions or appointments. The verification images that are planned could also be included in the table.

The table could explicitly assign a specific day to each fraction, or this could be left open, provided that an external application is used to schedule the patient treatments and that a link is provided between the treatment schedule provided by this system and the RVS database. In all cases, it is necessary that the RVS automatically records and makes inaccessible the fractions that have already be given in order to ensure a correct follow-up of the treatment sequence.

The RVS should be designed to prevent the delivery of multiple treatment fractions to the same patient on the same day, except for some special protocols where multiple fraction delivery is allowed within a specific time frame (e.g. 6 h). An indication about the number of fractions treated per day and the minimum time frame between two fractions should be part of the database information associated with each 'plan'.

3.4. RVS FUNCTIONALITIES

From its name, 'record and verify system', the main tasks of an RVS are self-evident. However, as indicated in the Introduction, these systems are increasingly being used as a fundamental component of a complete 'radiotherapy information system', which itself is part of a full HIS (see Fig. 1). Therefore, an RVS might also be used as a computer solution for the replacement of the paper patient chart and as a platform for data exchange of administrative, clinical, billing or statistical information.

3.4.1. Treatment verification

3.4.1.1. Machine set-up (including table)

The main task of an RVS is to verify that the actual machine set-up is consistent with the treatment parameters specified during treatment planning or simulation and subsequently stored in the RVS. Therefore, a communication link is required between the treatment delivery unit and the RVS. If the machine set-up corresponds to the intended settings, the delivery of a beam can be executed. Machine set-up parameters that are usually verified include beam quality, beam energy, field size and leaf settings, collimator and gantry angles, presence of beam modifiers, table position and table angle (see Section 3.3.2). If any of these treatment parameters does not match its intended value within the limits prescribed in the tolerance table, treatment delivery is prohibited, and a warning is given to the user.

In the case that the RVS is not connected to the treatment unit, treatment delivery cannot be verified. In such a case, it is still possible to store the prescription in the database and to manually record that a session has been completed. However, recording will then be based on prescription data rather than on actual beam delivery.

The treatment geometry related parameters are usually influenced by the mechanical performance of the treatment machine. Therefore, most RVSs allow the user to select a tolerance table for a specific beam or plan (see Section 3.3.3). Usually, machine set-up parameters are verified continuously, both before the start button is pushed and during treatment delivery, via a dedicated interface between the treatment console and the RVS. During patient set-ups, a monitor located in the treatment room displays, side by side, a list of the prescribed and the actual parameter set-up at the treatment machine. If one of these parameters falls out of its tolerance, this is indicated visually (generally using a different colour). A warning is also displayed at the treatment console and the beam-on function is disabled until the parameter is set within tolerance.

Alternatively, it is usually possible to 'override' some of the individual parameters and proceed with treatment outside the normal tolerances. However, only those who have been authorized in the RVS parameterization of users' rights (see Section 2.4) should be capable of giving an override by providing their electronic signature and corresponding password. Override rights should be given to persons who did not carry out the set-up so an additional check is carried out prior to overriding.

Another functionality that is common to state of the art RVSs and accelerators is that machine set-up parameters can be retrieved from the database and sent to the delivery unit, so the machine set-up can be performed automatically, either from inside the treatment room or from behind the treatment console. This applies to static treatments, where for critical parameter set-up (i.e. collimator or gantry rotation), it is necessary to confirm the action by keeping pressed a 'dead man' switch or having to press two keys simultaneously using both hands on the treatment console. It also applies to dynamic or rotational treatments with the difference that the parameter, which changes continuously while the beam is on, is monitored by the treatment console rather than directly by the RVS. This automated process includes the automatic sequencing of the various beams, segments for each beam and verification images within each individual fraction.

In some cases, automated couch movements are allowed. One should be very careful when using such automated sequences since the anti-collision features, if they exist, are very often inefficient. It is therefore necessary for the radiographers to make a systematic pretreatment check of the full sequence, after the patient is installed and while still present in the room. This is mandatory at least for the first fraction of each new set-up, but it must also be repeated at each fraction if the clearance is too tight.

3.4.1.2. Monitor units and dose

In general, RVSs do not perform dose per MU calculations, neither as a primary calculation as part of the treatment planning process, nor as an independent dose calculation as part of a QA procedure. It is common practice to either transfer MUs from the TPS to the RVS through the network using standard export functionalities of the TPS or to manually input MUs into the RVS. An automated data transfer should be in place for advanced treatments based on three dimensional treatment planning, such as MLC based conformal radiotherapy or IMRT, while a manual procedure can be used for treatments that are based on a more simple treatment planning process, e.g. simulator based planning with hand calculation. Within the scope of this publication, MU checks refer to 'consistency checks' in terms of data transfer from the source of primary dose calculation to the RVS. MUs are part of the treatment specific beam data that are directly linked to the prescribed dose and the beam weight (see Section 3.3.2.5).

MUs represent a special case of machine set-up parameters because they are permanently increasing during beam delivery. From the treatment unit, the number of delivered MUs is fed back to the RVS, and if the prescribed number of MUs has been delivered, the beam is terminated. In case the beam is terminated prior to delivery of the requested number of MUs, the actually delivered number of MUs is recorded. Depending on the RVS and its configuration, the missing number of MUs might be automatically displayed and delivered subsequently, after the problem causing the treatment interruption has been solved. In many cases, this does not happen with a termination or emergency stop or power outage, for instance, including when it is necessary to remove the patient from the room in order to resolve the problem. Then, the RVS expects a whole new treatment session, and an override is needed if one wants to complete a partial treatment instead. Manual correction of delivered doses and rescheduling of the subsequent fractions could then be required.

For each fraction, the actual delivery of the prescribed dose is ensured by comparison of the prescribed number of MUs stored in the database and the number of MUs actually delivered. Therefore, it is fundamental that the relationship between dose and MUs (see Section 3.3.2.5) is well understood and updated if the prescription or the treatment technique is changed. In practice, a session should not start if the preset number of MUs at the treatment console is different from the prescribed number of MUs in the RVS, and the treatment should not be interrupted until the prescribed number of MUs has been reached. An underdosage could occur as a consequence of a premature beam interruption (although a warning message is normally displayed when the user proceeds with the next beam, the next fraction or with a new patient), or if a fraction is missing. Forgetting to treat the last fraction(s) is more likely to occur if the patient schedule is not regularly updated for breaks or non-arrival, for instance, and if current practice does not include a systematic 'closing' of the treatment (i.e. changing the status of the treatment from 'active' to 'completed') immediately after the last fraction has been delivered.

3.4.1.3. Patient position and imaging (image comparison)

Verification of the patient's position is partly achieved via table coordinates including the table angles. Table angle and vertical position can be verified for all patients, but accurate verification of longitudinal and lateral table positions requires the application of indexed immobilization systems. If a patient is positioned on the treatment couch without immobilization aids, it does not make much sense to verify longitudinal and lateral table positions because overrides should be given in most treatment fractions to allow treatment unless large tolerance values (see Section 3.3.3) are given for these parameters.

As it is difficult to specify the table position (height, longitudinal and lateral position) during treatment planning, it is common practice to define the exact table position during the first treatment session. Table coordinates of the first session serve as the standard for all subsequent sessions. As for other parameters, warnings are given if there is a deviation larger than the tolerance between actual position and the intended one.

In the light of advanced radiotherapy techniques, accurate verification of the patient's position is essential. This requires that images (e.g. portal images, volumetric image information) are frequently acquired throughout the treatment to verify and correct patient set-up. It is common practice to compare or register 'images of the day' with reference images and to calculate translation and rotation displacements to be applied to the table parameters to correct the patient set-up. With modern radiotherapy equipment, set-up corrections might be performed automatically from the treatment console. As there are time dependent effects during the course of radiotherapy (e.g. weight loss), which might require systematic patient set-up corrections, it may be practical to define as a reference a new table position instead of performing the same corrections on a daily basis. For such applications, it is important that any modification of the table position data is correctly traced and referenced. One possibility to record the information that relates the new table coordinates with the original coordinates is to add it in the 'comment window' of the treatment related file of the RVS (see Section 3.3.2.4).

3.4.2. Treatment data recording

3.4.2.1. Systematic record of machine parameters

The recording functionalities of the RVS might be more or less extensive. The minimal information to be recorded is the number of MUs actually delivered from each beam at each fraction, with proper indication of the machine, course, plan and fraction identification (i.e. fraction number in the sequence) and exact time at which

the fraction has been given. The geometrical parameters of the treatment machines are supposed to be kept within the tolerances. However, it is very useful to systematically record each of them in order to assess a posteriori their variation or to investigate further if an incident occurs. With the increasing number of parameters and development of dynamic techniques, it could become impractical and not very useful to record and keep the details of all parameters (e.g. individual leaf position) in the long term, unless specific software is developed to automatically analyse these data.

Any abnormal behaviour should be automatically and systematically recorded, e.g. when a beam is interrupted before the prescribed number of MUs has been given and when the treatment is resumed at a later instant. It is also advantageous to record the number of MUs given for MV imaging purposes or other parameters related to kV imaging. In some instances (i.e. in case of network breakdown), it could happen that the RVS is no longer able to perform data recording. This should be recognized, and specific procedures should be developed to deal with such situations (generally by recording all treatments that were delivered in the meantime manually in the RVS after the problem was solved). The risk of being faced with RVS failure is very high; therefore, it should be made clear at the local (or national) level if treatment without an RVS is allowed, for how long, who should be informed about it and what reinforced safety measures should be implemented.

To identify an operator and to trigger the adequate level of user's rights, it is common to ask the user to log in to the system with his or her own username and password that will be attached to any action performed manually by him or her. As an example, if a parameter is overridden for any reason, this should appear in the session record. It is useful to have the possibility to incorporate free comments in such records to explain the reason for the override.

The recorded information is usually accessible by consulting the chronological list of delivered treatment fractions with the possibility of investigating various levels of detail. It should not be possible to change any information automatically recorded by the treatment machine, but there should be some provision to manually correct any abnormality (e.g. the manual recording of a fraction that was performed without RVS connection, or the correction of an error in the accumulated dose resulting from a wrong dose per MU input).

3.4.2.2. Additional information

Since the RVS is used to store information related to the treatment process, it might be useful to record other information in the database. An example is the possibility to use the RVS to store treatment verification images, which requires a storage capacity that is large enough to deal with the high demand of such functionality. Another example is the recording of in vivo dose measurements, which could be attached to the record of a specific treatment fraction.

There is no limit to the type of data that can be stored in the RVS database, but it should be recognized that, generally, specific tools are required to extract and analyse these data. Therefore, the question arises of how to decide what should be handled as part of the RVS and what should be handled by an external system. Depending on the actual solution, the requirements for QC of RVSs will be site dependent to some extent.

3.4.3. Electronic chart and supplementary functions

In most radiotherapy departments, current practice is to prepare a paper document for each patient, usually called a treatment chart, containing minimal administrative data, a summary of the radiation oncologist's prescription for the current treatment course, and for each beam, the technical parameters to be set, including number of MUs and related dose. At each fraction, the MUs actually given are transcribed on this document and the dose is accumulated. This allows continuous information on the dose actually given and for it to be related to the clinical consequences of the treatment progress.

The same functionalities are provided by modern RVSs and, in principle, it will not be necessary to use physical (i.e. on paper) treatment charts. However, before deciding to completely suppress manual recording, a careful analysis of the situation has to be carried out. This analysis should consider safety and liability issues, the handling of electronic signatures, medical data security, the development of robust backup solutions in the case of computer or network failure, and assurance that electronic data will always be available in a reasonable period of time. The need to maintain easy access to information (e.g. when the patient is seen for weekly checks during treatment) must also be considered. An intermediate solution is to keep a paper document and to redesign the patient chart in order to include a large proportion of data printed directly from the RVS. If manual and electronic

records are used simultaneously (as a temporary or definitive solution), it should be clear to all staff what the reference data set is, since there is a high risk of forgetting to copy some information from one system to the other. If the RVS is used as a reference, the initial and ongoing QA procedures must include a verification that the system is permanently updated with consistent and complete data during patient treatment and follow-up (see Section 6).

As soon as many patient and treatment related data are stored within the system, it makes sense to try to use them in conjunction with external applications (see Fig. 1 and Section 2.1). The main applications that could benefit from exchanges with the RVS are:

- Patient identity server;
- Administrative management (e.g. activity analysis, billing);
- Medical record information system (restricted to radiotherapy or more general).

Depending on the architecture of the local solution, some of these functions could also be included in the RVS (e.g. statistical tools). Testing these functionalities is outside the scope of the current report.

4. RVS TYPE TESTS

Type tests refer to those tests that are to be carried out by the manufacturer to establish compliance with specified criteria. These tests are normally carried out at the factory. In some of the type tests, the vendor needs to provide the documentation as indicated in Table 4 by 'accompanying documents'. Usually, these documents will be provided as part of the user's manual; however, if they are not provided in the user's manual, the installer should provide these documents at the time of 'acceptance'.

As indicated in Section 1.5, this report uses the IEC 62274 ed.1.0 standard as its basis for defining the 'specifications' and 'acceptance tests' of RVSs. Note that the presentation has been converted into a tabular form (Table 4) and that the IEC 62274 ed.1.0 clause numbering has been retained.

Note on type tests

Note that IEC 62274 ed.1.0 clause 4.1 requires the manufacturer to retain the compliance statement at the factory as a permanent record; however, this IAEA protocol requires that the results of tests performed in IEC 62274 ed.1.0 clauses 6–9 be provided also to the user at the time of installation. In addition, within clause 7, which refers to the actual verification of the RVS communication with the treatment machine, the IAEA provides details on specific tests to be performed during installation (see the Appendix to this publication). To perform these tests, it will be necessary to define at least one 'dummy patient' (see Section 2.5).

A description of type tests is given below where the manufacturer needs to state compliance or the lack thereof by the 'yes' or 'no' answers.

A copy of Section 4 with the list of 'type tests' is attached to this report on a CD-ROM, and should be used for documenting the test results and signing by the manufacturer and the user at the hospital.

TABLE 4. TYPE TESTS PER IEC 62274 ED.1.0 [20]

Clause	Requirement	Compliance?	
4.1	**Testing during development** Compliance with IEC 60601-1-4 requires identification of HAZARDS, assessment of their RISKS, and appropriate verification and validation of RISK controls. Demonstration of compliance with the requirements of this standard shall be included as part of the above processes, with explicit reference to each requirement. The MANUFACTURER shall retain compliance data as a permanent record. Each test shall include a protocol containing all the necessary input data, sufficient detail to provide for exact reproducibility, and the expected result. *Compliance is checked by inspection of the ACCOMPANYING DOCUMENTS.* ***IAEA Note:** The requested ACCOMPANYING DOCUMENTS will be referred to in the following clauses.*	Yes ☐	No ☐
6.1	**RADIATION quantities** All values of RADIATION quantities requested, displayed or printed shall include their units. Units of RADIATION should conform to the SI convention. Units (e.g., "monitor units" (MU)) describing dose delivery shall be consistent with those used by the TREATMENT machine. *Compliance is checked by inspection of the DISPLAY and output information.*	Yes ☐	No ☐
6.2	**Date and time** When the date is displayed or printed, correct interpretation shall not depend upon the OPERATOR's interpretation of format, and a DISPLAY of the year shall be in four digits. *Compliance is checked by testing and by inspection of the DISPLAY and output information.*	Yes ☐	No ☐
	When the time is requested, displayed or printed, it shall be represented on a 24-hour clock basis, or if a 12-hour clock is used it shall be unambiguously indicated whether it is a.m. or p.m. Measurements of time shall include units (hr, min, s). *Compliance is checked by testing and by inspection of the DISPLAY and output information.*	Yes ☐	No ☐
	When time is entered, displayed or printed, each denomination of time shall be labelled. To prevent confusion with numbers, single-letter abbreviations of time denomination shall not be used (e.g., h, m, s). *Compliance is checked by testing and by inspection of the DISPLAY and output information.*	Yes ☐	No ☐
	Time-sensitive functions shall be performed correctly at transitions such as year boundaries, leap years, etc. *Compliance is checked by testing and by inspection of the DISPLAY and output information.*	Yes ☐	No ☐
6.3	**Coordinate systems and scales** It shall be possible for the OPERATOR to perform all RVS functions with the scales and coordinates of RADIOTHERAPY TREATMENT EQUIPMENT displayed according to the IEC 61217 convention. If, in addition, any convention other than IEC 61217 is employed for scales and coordinates, the conventions shall be identified. The units shall be the same as are used in the RADIOTHERAPY TREATMENT EQUIPMENT. *Compliance is checked by testing and by inspection of the DISPLAY, output information and ACCOMPANYING DOCUMENTS.*	Yes ☐	No ☐
	The method and format of DISPLAY of scales shall be explained in the INSTRUCTIONS FOR USE. *Compliance is checked by inspection of the ACCOMPANYING DOCUMENTS.*	Yes ☐	No ☐
6.4	**Protection against unauthorized use** Means shall be provided to prevent unauthorised changes. Where changes to the data are permitted by authorised persons means shall be provided to prevent a person making changes he/she is not authorised to make. *Compliance is checked by testing and by inspection of the ACCOMPANYING DOCUMENTS and INSTRUCTIONS FOR USE.*	Yes ☐	No ☐

TABLE 4. TYPE TESTS PER IEC 62274 ED.1.0 [20] (cont.)

Clause	Requirement	Compliance?	
	Where network connection is permitted by the design, the following requirements apply. (a) Access to the RVS shall be provided only to EQUIPMENT or individuals who are authorized (for example, by a password under the control of the USER). *Compliance is checked by testing and by inspection of the ACCOMPANYING DOCUMENTS.*	Yes ☐	No ☐
	(b) Access to TREATMENT prescriptions and other data containing the PATIENT identification information through the network shall be restricted to prevent unauthorized access. *Compliance is checked by testing and by inspection of the ACCOMPANYING DOCUMENTS.*	Yes ☐	No ☐
	(c) The MANUFACTURER shall recommend some means of virus protection in the INSTRUCTIONS FOR USE. *Compliance is checked by inspection of the ACCOMPANYING DOCUMENTS.*	Yes ☐	No ☐
6.5	**Correctness of data transfer** The MANUFACTURER shall identify RVS data transfer protocols in the technical description. Data transferred from and to the TREATMENT machines or other devices, "excluding hardcopy devices" shall include a protection against data transmission errors. Means shall be provided to warn the OPERATOR that expected data have not been transferred. Examples: DICOM 3 or FTP, each of which includes error detection, or a proprietary format that includes a checksum of each input or output data set. *Compliance is checked by inspection of the protocol specifications and by inspection of the ACCOMPANYING DOCUMENTS.*	Yes ☐	No ☐
6.6	**Data acceptance** Means shall be provided such that the TREATMENT machine set-up data and other patient TREATMENT data shall be available for TREATMENT use only after the OPERATOR has acknowledged that they have been reviewed for correctness and completeness. *Compliance is checked by testing and by inspection of ACCOMPANYING DOCUMENTS.*	Yes ☐	No ☐
	Where design allows, machine set-up data and other patient TREATMENT data shall be reviewed or approved by entry of an authorised identification: (a) any modification to the data shall result in invalidation of the authorised identification; (b) after modification of the approved data a new authorised identification shall be required; (c) the RVS shall provide a means for preserving the history and the record of the authorised identification; and (d) the INSTRUCTIONS FOR USE shall describe how these features are to be properly and safely used. *Compliance is checked by testing and by inspection of ACCOMPANYING DOCUMENTS.*	Yes ☐	No ☐
6.7	**Deleting and editing data** Means shall be provided to restrict the ability to edit TREATMENT history data to persons who are authorised to carry out this function. A record of the change details shall be retained. The fact that the TREATMENT history has been modified shall be apparent to a person using it e.g., by a visual indicator. *Compliance is checked by testing.*	Yes ☐	No ☐
6.8	**Backing up data** Means shall be provided for backing-up data onto a separate medium from the primary storage, such that it can be restored in the case of a failure of the primary data storage device. NOTE Usually a backup provides a means to restore data in the case of system failure. *Compliance is checked by testing and by inspection of ACCOMPANYING DOCUMENTS.*	Yes ☐	No ☐

TABLE 4. TYPE TESTS PER IEC 62274 ED.1.0 [20] (cont.)

Clause	Requirement	Compliance?	
6.9	**Archiving data** Means shall be provided for archiving sets of data for long term storage, such that the data can be accessed at a later date. NOTE Archiving is the process of moving or copying sets of data from the primary storage to a separate storage media. Standardizing the archiving process is highly desirable. By using established standards such as DICOM or HL7, archiving would be vendor and media independent. *Compliance is checked by testing and by inspection of ACCOMPANYING DOCUMENTS.*	Yes ☐	No ☐
7	**TREATMENT machine set-up verification**		
7.1	**Prevention of TREATMENT** The RVS shall provide a means by which the operation of the TREATMENT machine shall be prevented in the event that the machine set-up does not correspond to the prescribed data within prescribed tolerances. *Compliance is checked by testing.*	Yes ☐	No ☐
7.2	**Override** If an override capability is provided, the USER shall: — acknowledge the override parameters; — provide authorised identification. The fact that an override has been made shall be recorded. *Compliance is checked by testing.*	Yes ☐	No ☐
7.3	**Transfer of prescribed TREATMENT data** If the design of the RVS allows transfer of the prescribed TREATMENT parameters to the TREATMENT machine, the RVS shall prompt the OPERATOR to confirm that the transferred data are correct prior to the first use, and after any modification. NOTE This confirmation may be through not performing the download for the first TREATMENT session after entry or modification, so that the OPERATOR is required to set up the machine from a separate source of information. For TREATMENT session where this is not possible, confirmation may be implemented by requiring that the OPERATOR confirm, prior to the RVS allowing the TREATMENT to proceed, that a new or modified set-up has been verified by other means. *Compliance is checked by inspection of the protocol specifications, and by inspection of the ACCOMPANYING DOCUMENTS.* ***IAEA Note:** This clause may be irrelevant if the communication between the RVS and TREATMENT machine is bidirectional with a feedback mechanism that checks consistency.*	Yes ☐	No ☐
7.4	**Accompanying information** The ACCOMPANYING DOCUMENTS shall include a caution to the OPERATOR that the correct operation of the RVS depends on the connection of the RVS to the radiotherapy system, which may include the RADIOTHERAPY TREATMENT PLANNING SYSTEM (RTPS) and the RADIOTHERAPY SIMULATOR, as well as the TREATMENT machine. Any change to the radiotherapy system to which the RVS is connected shall require testing to confirm correct operation. *Compliance is checked by inspection of the ACCOMPANYING DOCUMENTS.*	Yes ☐	No ☐
8	**TREATMENT recording and reporting** For each patient the RVS shall provide a means by which the OPERATOR can retrieve and report all recorded TREATMENT machine parameters used in the previous TREATMENT sessions. NOTE The guides and contents of the record and report may be found in ICRU publications 50 and 62 for photon beam therapy and 58 for BRACHYTHERAPY. *Compliance is checked by testing.*	Yes ☐	No ☐

TABLE 4. TYPE TESTS PER IEC 62274 ED.1.0 [20] (cont.)

Clause	Requirement	Compliance?	
9	**Accuracy** The MANUFACTURER shall state the accuracy of the RVS for all of the TREATMENT parameters recorded. *Compliance is checked by testing as described in the ACCOMPANYING DOCUMENTS.*	Yes ☐	No ☐
10	**Abnormal operation and fault conditions**		
10.1	**General hardware diagnostics** Facilities shall be provided so that the correct function of the means referred to in 7.1 and the communication between RVS and TREATMENT machine can be checked. The ACCOMPANYING DOCUMENTS shall contain an explanation of the function of these facilities. If these facilities require actions of the OPERATOR, such actions shall be described in the ACCOMPANYING DOCUMENTS together with a recommendation of the frequencies with which such checks should be made. *Compliance is checked by inspection of the ACCOMPANYING DOCUMENTS.*	Yes ☐	No ☐
10.2	**Data and code** Executable program code, TREATMENT machine set-up data and other patient TREATMENT data shall have a checksum or other equivalent protection that ensures that they will not be used if modified through a hardware fault, through a virus, accidentally during servicing, or by any other unauthorized manner. In the event that an error is detected the MANUFACTURER shall provide instructions to the OPERATOR for restoring correct operation, either on the DISPLAY or in the INSTRUCTIONS FOR USE. *Compliance is checked by inspection of the DISPLAY of the ACCOMPANYING DOCUMENTS.*	Yes ☐	No ☐
11	**Human errors in software design** The requirements for software development process and RISK management that are defined in IEC 60601-1-4 shall apply. In applying the requirements of IEC 60601-1-4, the term PEMS shall include an RVS. *Compliance is checked by testing and by examining system documentation to the requirements of IEC 60601-1-4.* ***IAEA Note:*** *PEMS = Programmable Electrical Medical System.*	Yes ☐	No ☐
	The MANUFACTURER shall describe, in the INSTRUCTIONS FOR USE, a means by which the USER can report errors in the operation that are observed during use or testing. *Compliance is checked by inspection of the ACCOMPANYING DOCUMENTS.*	Yes ☐	No ☐
12	**Change in software versions** The following requirements apply when a new version of the software is provided to the USER by the MANUFACTURER. (a) If the installation is not performed by the MANUFACTURER, the INSTRUCTIONS FOR USE shall provide clear instructions for the installation of a new version, and for any tests that are required to determine that the installation was successful. The INSTRUCTIONS FOR USE shall advise the USER to maintain appropriate records of software updates. The MANUFACTURER shall keep records of software updates provided to or installed by each USER. (b) If use of data from the previous version could cause incorrect results, either: (1) the design shall convert the data to the new format; or (2) the design shall prevent use of the data. (c) If installation of a new version of the software may delete machine set-up or other patient TREATMENT data, the OPERATOR shall be warned and required to backup the data before proceeding with installation of the new version.	Yes ☐	No ☐

TABLE 4. TYPE TESTS PER IEC 62274 ED.1.0 [20] (cont.)

Clause	Requirement	Compliance?	
	(d) If data created on the currently installed version of the software are to be used on the next successive version of software, the INSTRUCTION FOR USE shall provide instructions on how to restore data created with the current version onto the next version, unless these services are performed solely by the MANUFACTURER. (e) The INSTRUCTIONS FOR USE shall provide instructions on how to restore the RVS to the condition it was in prior to the installation of a new version of software. *Compliance is checked by testing (b and c), and by inspection of the ACCOMPANYING DOCUMENTS (a, b, c, d, e).*		
13	**Human errors in use** The INSTRUCTIONS FOR USE shall provide comprehensive instructions to the USER of all information needed for safe operation, including, but not limited to, the specific information in other clauses and subclauses of this standard. The INSTRUCTIONS FOR USE shall provide a cautionary notice to the USER that the USER should ensure that individuals authorized to enter and accept machine set-up or other patient TREATMENT data are appropriately trained for the functions they perform. *Compliance is checked by inspection of the ACCOMPANYING DOCUMENTS.*	Yes ☐	No ☐

This is to certify that version _____ of the RVS software
Software version

produced by _____
Name of manufacturer

is compliant with the standard as indicated in Section 4 of, and in the Appendix to, the IAEA report on Record and Verify Systems for Radiation Treatment of Cancer: Acceptance Testing, Commissioning and Quality Control.

Company representative _____ _____ _____
Name Signature Date

As per the note at the beginning of Section 4, the type tests described above were explained to my satisfaction:

User/purchaser representative _____ _____ _____
Name Signature Date

5. SITE TESTS — ACCEPTANCE TESTING OF RVSs

'Site tests' refer to those tests that are to be carried out by the installer and the user together to establish compliance with specified criteria, i.e. acceptability of the RVS. The tests to be performed are a subset of the 'type tests' described in Section 4, and should be performed at the user's site immediately after the RVS has been fully installed. In addition, these tests should be repeated after installation of a new version of the software (see Section 6). The tests serve two important purposes. Firstly, the tests will provide an educational opportunity for the user to participate in the operation of the RVS. Secondly, the tests will demonstrate to the user that the results using the hardware and software as installed at the user's site are consistent with the type tests performed by the manufacturer at the factory. The user needs to verify compliance or the lack thereof by the 'yes' or 'no' answers in the site tests summary below (Table 5).

A detailed description of the procedures to perform site tests is given in the Appendix to this publication.

A copy of Section 5 with the list of 'site tests' is attached to this report on a CD-ROM, and should be used for documenting the testing results and signing by the manufacturer and the user at the hospital.

TABLE 5. SITE TESTS PER IEC 62274 ed.1.0 [20]

Clause	Requirement	Compliance?	
4.2	**Testing during installation** The MANUFACTURER shall provide an installation test document as part of the technical description that includes a demonstration that the RVS performs according to the operational description provided in the ACCOMPANYING DOCUMENTS as required in Clause 5. *Compliance is checked by inspection of the ACCOMPANYING DOCUMENTS.* ***IAEA Note:** Table 1 of clause 5 of IEC standard 62274 ed.1.0 is a list of the types of document (instructions for use or technical description) that are required for each clause. This publication should be used as a replacement of table 1.*	Yes ☐	No ☐
6.1	**RADIATION quantities** All values of RADIATION quantities requested, displayed or printed shall include their units. Units of RADIATION should conform to the SI convention. Units (e.g., "monitor units" (MU)) describing dose delivery shall be consistent with those used by the TREATMENT machine. *Compliance is checked by inspection of the DISPLAY and output information.* ***IAEA Note:** Incorporated in tests described in the Appendix to this publication.*	Yes ☐	No ☐
6.2	**Date and time** When the date is displayed or printed, correct interpretation shall not depend upon the OPERATOR's interpretation of format, and a DISPLAY of the year shall be in four digits. *Compliance is checked by testing and by inspection of the DISPLAY and output information.* ***IAEA Note:** Incorporated in tests described in the Appendix to this publication.*	Yes ☐	No ☐
	When the time is requested, displayed or printed, it shall be represented on a 24-hour clock basis, or if a 12-hour clock is used it shall be unambiguously indicated whether it is a.m. or p.m. Measurements of time shall include units (hr, min, sec.). *Compliance is checked by testing and by inspection of the DISPLAY and output information.* ***IAEA Note:** Incorporated in tests described in the Appendix to this publication.*	Yes ☐	No ☐
	When time is entered, displayed or printed, each denomination of time shall be labelled. To prevent confusion with numbers, single-letter abbreviations of time denomination shall not be used (e.g., h, m, s). *Compliance is checked by testing and by inspection of the DISPLAY and output information.* ***IAEA Note:** Incorporated in tests described in the Appendix to this publication.*	Yes ☐	No ☐
6.3	**Coordinate systems and scales** It shall be possible for the OPERATOR to perform all RVS functions with the scales and coordinates of RADIOTHERAPY TREATMENT EQUIPMENT displayed according to the IEC 61217 convention. If, in addition, any convention other than IEC 61217 is employed for scales and coordinates, the conventions shall be identified. The units shall be the same as are used in the RADIOTHERAPY TREATMENT EQUIPMENT. *Compliance is checked by testing and by inspection of the DISPLAY, output information and ACCOMPANYING DOCUMENTS.* ***IAEA Note:** Compliance tests are described in the Appendix to this publication.*	Yes ☐	No ☐

TABLE 5. SITE TESTS PER IEC 62274 ed.1.0 [20] (cont.)

Clause	Requirement	Compliance?	
6.4	**Protection against unauthorized use** Means shall be provided to prevent unauthorized changes. Where changes to the data are permitted by authorized persons, means shall be provided to prevent a person making changes he/she is not authorized to make. *Compliance is checked by testing and by inspection of the ACCOMPANYING DOCUMENTS and INSTRUCTIONS FOR USE.* ***IAEA Note:** Compliance test (incorporated in tests described in the Appendix to this publication): create several authorized users with different levels of access (e.g. different for treatment prescription and machine configuration). Verify that each authorized user has no more than the level of access intended by the specified authorization.*	Yes ☐	No ☐
	Where network connection is permitted by the design, the following requirements apply. (a) Access to the RVS shall be provided only to EQUIPMENT or individuals who are authorized (for example, by a password under the control of the USER). *Compliance is checked by testing and by inspection of the ACCOMPANYING DOCUMENTS.* ***IAEA Note:** Compliance test (incorporated in tests described in the Appendix to this publication): if a network connection is provided, connect the RVS to the network and confirm that access to the RVS is limited to only authorized users; for example, those provided with a PASSWORD. Confirm that the RVS cannot be accessed from another computer on the network other than by an authorized user.*	Yes ☐	No ☐
	(b) Access to TREATMENT prescriptions and other data containing the PATIENT identification information through the network shall be restricted to prevent unauthorized access. *Compliance is checked by testing and by inspection of the ACCOMPANYING DOCUMENTS.* ***IAEA Note:** Compliance test (incorporated in tests described in the Appendix to this publication): Confirm that the RVS cannot be accessed from any computer on the network, other than by an authorized user.*	Yes ☐	No ☐
6.6	**Data acceptance** Means shall be provided such that the TREATMENT machine set-up data and other patient TREATMENT data shall be available for TREATMENT use only after the OPERATOR has acknowledged that they have been reviewed for correctness and completeness. *Compliance is checked by testing and by inspection of ACCOMPANYING DOCUMENTS.* ***IAEA Note:** Compliance tests incorporated in the tests described in the Appendix to this publication.*	Yes ☐	No ☐
	Where design allows, machine set-up data and other patient TREATMENT data shall be reviewed or approved by entry of an authorized identification: (a) any modification to the data shall result in invalidation of the authorized identification; (b) after modification of the approved data a new authorized identification shall be required; (c) the RVS shall provide a means for preserving the history and the record of the authorized identification; and (d) the INSTRUCTIONS FOR USE shall describe how these features are to be properly and safely used. *Compliance is checked by testing and by inspection of ACCOMPANYING DOCUMENTS.* ***IAEA Note:** Compliance tests incorporated in the tests described in the Appendix to this publication.*	Yes ☐	No ☐

TABLE 5. SITE TESTS PER IEC 62274 ed.1.0 [20] (cont.)

Clause	Requirement	Compliance?	
6.7	**Deleting and editing data** Means shall be provided to restrict the ability to edit TREATMENT history data to persons who are authorized to carry out this function. A record of the change details shall be retained. The fact that the TREATMENT history has been modified shall be apparent to a person using it e.g., by a visual indicator. *Compliance is checked by testing.* ***IAEA Note:*** *Compliance test incorporated in the tests described in the Appendix to this publication.*	Yes ☐	No ☐
6.8	**Backing up data** Means shall be provided for backing-up data onto a separate medium from the primary storage, such that it can be restored in the case of a failure of the primary data storage device. NOTE Usually a backup provides a means to restore data in the case of system failure. *Compliance is checked by testing and by inspection of ACCOMPANYING DOCUMENTS.*	Yes ☐	No ☐
6.9	**Archiving data** Means shall be provided for archiving sets of data for long term storage, such that the data can be accessed at a later date. NOTE Archiving is the process of moving or copying sets of data from the primary storage to a separate storage media. Standardizing the archiving process is highly desirable. By using established standards such as DICOM or HL7, archiving would be vendor and media independent. *Compliance is checked by testing and by inspection of ACCOMPANYING DOCUMENTS.*	Yes ☐	No ☐
7	**TREATMENT machine set-up verification**		
7.1	**Prevention of TREATMENT** The RVS shall provide a means by which the operation of the TREATMENT machine shall be prevented in the event that the machine set-up does not correspond to the prescribed data within prescribed tolerances. *Compliance is checked by testing.* ***IAEA Note:*** *Compliance test incorporated in the tests described in the Appendix to this publication.*	Yes ☐	No ☐
7.2	**Override** If an override capability is provided, the USER shall: — acknowledge the override parameters; — provide authorized identification. The fact that an override has been made shall be recorded. *Compliance is checked by testing.* ***IAEA Note:*** *Compliance test incorporated in the tests described in the Appendix to this publication.*	Yes ☐	No ☐
8	**TREATMENT recording and reporting** For each patient the RVS shall provide a means by which the OPERATOR can retrieve and report all recorded TREATMENT machine parameters used in the previous TREATMENT sessions. NOTE The guides and contents of the record and report may be found in ICRU publications 50 and 62 for photon beam therapy and 58 for BRACHYTHERAPY. *Compliance is checked by testing.* ***IAEA Note:*** *Compliance test incorporated in the tests described in the Appendix to this publication.*	Yes ☐	No ☐

TABLE 5. SITE TESTS PER IEC 62274 ed.1.0 [20] (cont.)

Clause	Requirement	Compliance?	
9	**Accuracy** The MANUFACTURER shall state the accuracy of the RVS for all of the TREATMENT parameters recorded. *Compliance is checked by testing as described in the ACCOMPANYING DOCUMENTS.* ***IAEA Note:*** *This test can be interpreted as testing the precision to which the treatment parameters are recorded in and displayed by the RVS. Compliance test incorporated in the tests described in the Appendix to this publication.*	Yes ☐	No ☐

This is to certify that version _____ of the RVS software
Software version

produced by _____
Name of manufacturer

has passed the acceptance tests as described in Section 5 of, and in the Appendix to, the IAEA report on Record and Verify Systems for Radiation Treatment of Cancer: Acceptance Testing, Commissioning and Quality Control.

Company representative _____ _____ _____
Name Signature Date

User/purchaser representative _____ _____ _____
Name Signature Date

6. COMMISSIONING AND ONGOING QUALITY CONTROL OF RVSs

As explained in Sections 2.3 and 2.4, the parameterization of an RVS is actually part of the installation, and it should have been performed, jointly with the vendor, before the acceptance document was signed. The clinical use of the RVS starts very soon after the acceptance testing has finished, and it is recommended that a vendor representative be present for assistance during the treatment of the first patients (typically at least half a day). Therefore, in principle, there is no formal additional 'commissioning'. However, there should be a step where the person responsible for the RVS, as defined in Section 2.2, takes the formal responsibility of starting the clinical use of the system, after having checked that the relevant procedures have been defined and explained, and that the staff members who will use the system have well understood what to do.

The details of the departmental organizational aspects are out of the scope of this report, but they are essential to warrant safe use of RVSs [19, 22]. In all cases, there will be a transitional period where everybody becomes familiarized with the system. During this period, under the guidance of the person responsible for the RVS, the daily use of the system should be monitored closely. Table 6 lists the more important checks to be carried out during this period. Actually, these systematic checks must be maintained for all patients after the transitional period, but they could be somewhat adapted, depending on the problems encountered, as the staff expertise increases.

The general QA of an RVS is very much based on a prospective analysis of the RVS related risks complemented by a reactive adaptation to the pitfalls discovered during the transitional period. The difficulty is to permanently maintain an awareness of these risks among the staff and to adapt the training accordingly.

In spite of the implementation of RVSs, which could seem to protect them from most types of errors if comprehensive commissioning and ongoing QC are achieved, the users must be aware of the potential dangers of such systems and conscious that they are still fully responsible for the safety of patient treatments.

TABLE 6. ONGOING QC OF RVSs

1	Formal approval (electronic signature), by an authorized person, of each prescription, plan and beam entered or transferred to the RVS after comparison between the data stored in the RVS and the data output from the TPS, and complemented, by any formal document related to the treatment prescription
2	Critical review (preferably formalized) of the RVS data by the staff in charge of treatment delivery (radiation therapists) before the first fraction and after each treatment modification. Complementary information (e.g. information on patient positioning or use of special accessories) might be added to the RVS records at this step
3	Special attention during patient set-up and treatment delivery about any unexpected value or message displayed by the RVS, with emphasis on presence and orientation of accessories, MLC setting, MU values and beam and sessions sequencing
4	Special attention to alerts and any treatment modification, such as changes in beam parameters, number of fractions, dose per fraction, treatment schedule, replanning on another machine, etc.
5	Regular inspection (typically weekly), for all patients, of the recorded cumulative dose at the reference points (see Section 3.3.1.1) to check consistency with prescribed and expected dose values
6	Systematic closure of patient files by an authorized person immediately after the last session, with production of a summary of the main treatment characteristics used as a reference for and possibly transferred automatically to the medical record (e.g. site, dose, number of fractions, number of days between start and end of treatment)
7	Regular survey (typically daily) of all unexpected situations detected and recorded by the RVS, e.g. overrides or abnormal treatment terminations
8	Traceability of all encountered problems in log books and regular analysis of these problems to adapt procedures and training

Note: MLC — multileaf collimator; MU — monitor unit; RVS — record and verify system; TPS — treatment planning system.

If the RVS is used as a replacement of manual patient charts, it is of utmost importance to check regularly that the records are accurate and complete. This can be facilitated by extracting statistical information from the system at regular intervals, using pertinent indicators (e.g. number of patients, number of fields, planned MUs versus recorded MUs, inadvertent events) and trying to estimate if they are reasonable.

There are some special circumstances when specific QC procedures must be imperatively followed:

— Update of TPS software or data used in it (if there is direct data exchange with the RVS):
  • Modification of the machine library or available beam data;
  • New software release.
— Update of RVS software or data used in it:
  • Modification of internal configuration;
  • Changes in the RVS parameterization;
  • New software release.
— Modification of treatment machine or simulator:
  • Addition or removal of a machine;
  • Definition of new capabilities or new accessories on existing machines;
  • Removal of existing capabilities or accessories on existing machines;
  • Treatment console software update.
— Any modification of any application sending data to, or receiving data from, the RVS.
— Alteration of the network infrastructure.

Deciding which tests must be performed is very much an appreciation of what could have been changed. For new software releases, the user must obtain from the vendor a detailed list of the changes pertaining to the new version and review it carefully to spot what could have a consequence on the existing use of the RVS. However, it must be kept in mind that inadvertent changes might also occur as an indirect consequence of some local software changes. Practically, ‘dummy patient’ files or ‘test cases’ should be prepared, incorporating a large variety of possibilities used clinically (i.e. field shapes, beam orientations, wedge filters, etc.), and end-to-end tests, similar to the description given in the Appendix to this publication, should be repeated.

Appendix

DETAILED DESCRIPTION OF SITE TESTS

The tests described in this Appendix are split into three different categories. The tests in Section A.1 are related to the RVS as a whole, independent of any specific data transfer between the RVS and a given machine. Conversely, the tests in Section A.2 are specific to the local TPS and treatment machines. They are named 'end to end' tests since they are intended to validate the full process that will be followed for patients from the time of finalizing a treatment plan until just before and during treatment. Many of the 'site tests' recommended in this report (Section A.1) are detailed in Section A.2. Section A.3 describes tests related to the special situation where patient data must be transferred from one machine to another. Section A.4 discusses the typical time requested to carry out RVS acceptance testing and commissioning for one accelerator.

A.1. GENERAL TESTS OF RVSs

These tests focus on the general requirements of the RVS and should be performed at all of the treatment units in the department, or at least on each treatment unit type that has a distinct interface.

Demographics

Demographic patient data can be entered manually and/or imported from the HIS. A unique identification of a patient should be possible, e.g. using a unique patient ID number.

(1) Enter a new patient in the RVS with a unique identification (patient ID number). No problem should occur.
(2) Log off the system and log in again. Check that you can recall the patient who you just entered and verify that all demographic data that you entered are still available.
(3) Attempt to enter a new patient in the RVS without entering a unique identification (patient ID number). The RVS should display an error, indicating that this is not possible.
(4) Attempt to enter a new patient in the RVS who has the same unique identification (patient ID number) as another patient who is already in the system. The RVS should display an error, indicating that this is not possible.

Treatment prescription and delivery

A treatment prescription could either be entered manually in the RVS, or imported from an external system. Treatment should only be allowed after the treatment prescription has been approved by an authorized user. When modifying the treatment prescription, an existing approval should disappear.

(1) Try to enter the RVS system as an unauthorized user by entering a wrong password. Check that access to the system and to any patient data and treatment prescriptions in the system is not possible (clause 6.4, Section 5).
(2) Now log in to the system as an authorized person.
(3) Enter a patient in the RVS system and define a plan with one treatment field. (Note: One of the fields used in Section A.2 may be used for this purpose.) Enter a total dose for the treatment corresponding to the accumulated dose that will be delivered in four fractions, or indicate that the field should be used during four fractions. Do NOT approve the treatment field yet.
(4) Try to transfer the (unapproved) field to the treatment console. An error should pop up, mentioning that treatment is only possible after the treatment field has been approved (clause 6.6, Section 5).
(5) Try to approve the treatment field as an unauthorized person, by entering (on purpose) a wrong password. This should not be possible (clause 6.4, Section 5).
(6) Let an authorized person approve the field.

(7) Transfer the approved field to the treatment console. Now the transfer should be successful (clause 6.6, Section 5).
(8) Set up the field correctly.
(9) Check, for all parameters of the treatment field (i.e. gantry angle, collimator angle, couch positions, etc.), that the actual values and scales in the RVS and at the treatment console are identical (clause 6.3, Section 5).
(10) Treat the field (fraction 1).
(11) Check that the units describing dose delivery in the RVS (generally 'monitor units' (MUs)) are consistent with those used by the treatment machine (clause 6.1, Section 5).
(12) Recall the treatment field again. Adjust one of the parameters of the field outside tolerance (e.g. by rotation of the gantry by 10°), and check that treatment is not allowed (clause 7.1, Section 5).
(13) Try to force an override for this parameter, by entering (on purpose) a wrong password. This should not be possible (clause 6.4, Section 5), indicating that treatment is still prohibited.
(14) Now let an authorized person force an override for this parameter. Check that treatment may be started afterwards (clause 6.4, Section 5).
(15) Treat the field (fraction 2).
(16) Modify the treatment description in the RVS, e.g. by manually changing the prescribed gantry angle for the treatment field. Check that the previous approval for the treatment field disappears (clause 6.6a, Section 5). Do NOT approve the treatment field yet.
(17) Try to transfer the unapproved field to the treatment console. An error should pop up, mentioning that treatment is only possible after the treatment field has been approved (clause 6.6b, Section 5).
(18) Let an authorized user approve the treatment field and transfer it to the treatment console again. Now the transfer should be successful (clause 6.6, Section 5).
(19) Check that the RVS indicates that the treatment prescription has been changed since the last treatment and which changes were involved (clause 6.7, Section 5).
(20) Set up the field correctly and start treatment (fraction 3, part 1).
(21) Terminate the treatment halfway. Write down the number of MUs that were delivered.
(22) Exit the patient from the RVS and recall the patient again.
(23) Continue with the previous treatment.
(24) Check that the right number of MUs remains (i.e. it is equal to the original number of MUs minus the number of MUs that have already been delivered). This may require an override from an authorized user.
(25) Treat the remainder of this treatment field (fraction 3, part 2).
(26) Make a manual treatment of the plan (fraction 4).
(27) Try to set up the treatment field at the treatment console again. Check that the RVS gives a warning that the prescribed total dose and/or the prescribed number of treatment fractions will be exceeded in that case (clause 6.6, Section 5).
(28) Check that treatment is not possible after an unauthorized person tries to give an approval, by entering (on purpose) a wrong password (clause 6.4, Section 5).
(29) Check that treatment can be started after an authorized person gives an approval (clause 6.4, Section 5).
(30) Treat the field (fraction 5).
(31) Verify in the RVS that, in addition to the prescription of the latest approved treatment field, also the prescription of the original treatment field can still be made visible (treatment history). Check for both prescriptions that the authorized person who approved them can be identified (clauses 6.6c and 6.7, Section 5).
(32) Print a summary of the treated fields and check that:
— All recorded values correspond to the actual treatment parameters during treatment (clause 9, Section 5).
— The overrides in fractions 2 and 5 are clearly indicated (clause 7.2, Section 5).
— The recorded values in fraction 4 (manual treatment) correspond to the prescribed settings.
— The dose accumulation is correct. At this stage, it should contain data for five fractions in total. If the system allows for dose accumulation in more than one point, check that the dose accumulation is correct in each point (clause 8, Section 5).
— The radiation quantities include SI units (Gy or cGy) (clause 6.1, Section 5).
— For each fraction, the date and time should be displayed in agreement with the IEC standard (clause 6.2, Section 5).

Delete a patient from the RVS

It should not be possible to delete a patient who has already been treated from the RVS.

(1) Delete a patient from the RVS who was not yet treated and for whom none of the treatment fields have yet been approved. This should be possible without any problem.
(2) Attempt to delete a patient from the RVS who has already been treated. The RVS should display an error, indicating that this is not possible (clause 6.7, Section 5).

A.2. END-TO-END TESTS: FROM A TPS TO TREATMENT DELIVERY WITH AN RVS

Preferably, the configuration of the treatment machines in the TPS and the RVS are identical. If any differences exist, there should be proper conversion of data when transferring data from the TPS to the RVS.

During commissioning of an RVS and after installation of new software versions on the RVS, TPS or treatment units, one must confirm that the information that is transferred from the TPS is correctly imported in the RVS. The tests, mentioned in Table 7, should, in principle, be performed for each treatment machine in a department. But when a department has more treatment units of the same manufacturer and type, with the same console software version and which also have the same treatment unit configuration and the same parameterization in the RVS, it is sufficient to perform these tests on one of the machines only. The tests can be combined into one plan that is transferred from the TPS to the RVS and then analysed. The list of tests in Table 7 may be reduced by the users of a TPS with basic planning capabilities according to the non-availability of specific options (e.g. MLCs, compensators, etc.).

Note: When an interface between the TPS and the RVS is not available, digital transfer of the treatment plan is not possible, and all treatment fields should be entered manually in the RVS.

(1) Generate a treatment plan in the TPS, based on either a flat water phantom or a CIRS phantom (or other phantom). This plan should include different fields, testing all relevant geometric settings of the treatment unit that are applied clinically (see Table 7 for an example). Some of the fields that are used in the site tests of the TPS, described in IAEA-TECDOC-1540, may be used for these site tests as well. Use an SSD of 100 cm for each field. For these site tests, the dose delivered by each field is not critical, so, e.g., 100 MUs may be entered.
(2) Plot the beam's eye view projection at the isocentric plane (generally 100 cm from the focus) for fields 1, 3 and 4.
(3) Transfer the plan from the TPS to the RVS.
(4) Generate a patient in the RVS with the same unique identification as used during treatment planning.
(5) Import the plan, which was exported from the TPS, in the patient. (Note: In case there is no interface between the TPS and the RVS, digital transfer of the treatment plan is not possible, and all fields should be entered manually.)
(6) Verify that the entered treatment plan is consistent with the data that you entered in the TPS before. If the data are correct, approve the treatment fields.
(7) Transfer the plan to the treatment console.
(8) Set up the treatment fields one after another and check:
    - By visual inspection the correspondence of all treatment parameters with scales and units of the treatment unit;
    - By visual inspection the direction of motion for the gantry, collimator and couch, i.e. the position of the machine should agree with the TPS representation;
    - By visual inspection the correspondence of the light field projection with the BEV plots of TPS for fields 1, 3 and 4 (Note: For this test, the couch top should be positioned at isocentric level, generally 100 cm from the isocentre on a linear accelerator);
    - For fields 5 and 6, the wedge direction, by visually comparing if the position of the thickest part of the wedge corresponds with the setting during planning, and/or by performing (relative) dose measurements at 2.5 cm to the left and right of the central axis to define the thickest part of the wedge.

(9) Treat field 6 of the treatment plan.
(10) Interrupt field 6 in the middle of the treatment.
(11) Write down the number of MUs that have been delivered, and the position of the jaws at that stage. (Note: These positions can be derived using the light field projection.)
(12) Exit the patient from the RVS and recall field 6 again. Continue with the previous treatment. This may require an override from an authorized user.
(13) Check that the right number of MUs remains (i.e. equal to the original number of MUs minus the delivered number of MUs), and that the start position of the jaws is correct.
(14) Treat the remainder of this treatment field.

TABLE 7. DEFINITION OF TEST BEAMS

	Field 1	Field 2	Field 3	Field 4	Field 5	Field 6
Test case IAEA- TECDOC-1540	11	9	—	7	4	—
Gantry angle	0°[a]	45°	0°	0°	0°	0°
Collimator angle	0°	0°	30°	0°	0°	0°
Couch angle	0°	0°	30°	0°	0°	0°
X1 (cm)	0	–5	0	−8	−4.5	−4.5
X2[b] (cm)	15	5	15	8	4.5	4.5
Y1 (cm)	0	–5	0	−8	−4.5	−4.5
Y2[b] (cm)	15	5	15	8	4.5	4.5
MLC	None	None	None	Yes[c]	None	None
Wedge	None	None	None	None	Wedge 60°[d]	EDW 60[e]

[a] We assume that at gantry angle 0, the gantry is pointing down (according to the IEC). If not, the gantry angle should be changed accordingly.
[b] In case asymmetric fields cannot be used, X should be set to 15 cm and Y to 15 cm for fields 1 and 3.
[c] The multileaf collimator (MLC) should cover a 12 cm × 12 cm portion from one corner of a 16 cm × 16 cm open field, realizing an L-shaped field.
[d] If a 60° wedge is not available, another wedge should be selected. This field should be omitted in case hard wedges are not available at the treatment unit.
[e] EDW 60 refers to the 60° Varian enhanced dynamic wedge. It could be replaced by another type of digital wedge, but this field should be omitted in case an enhanced dynamic wedge or virtual wedge is not available at the treatment unit.

Field 1 is used to verify if the configuration of zero position of the gantry, collimator and couch angle is consistent in the treatment planning system (TPS) and record and verify system (RVS). In addition, the configuration of the jaw settings is verified.

Field 2 is used to verify if the configuration of the direction of gantry rotation is consistent in the TPS and RVS.

Field 3 is used to verify if the configuration of the direction of collimator and couch rotation is consistent in the TPS and the RVS.

Field 4 is used to verify if the configuration of the MLC is consistent in the TPS and in the RVS.

Field 5 is used to verify if the configuration of a (hard) wedge is consistent in the TPS and in the RVS. A separate treatment field (i.e. fields 5.1, 5.2, etc.) should be generated and tested for each direction of use that is allowed in the TPS. For each situation, the thick part of the wedge should carefully be indicated.

Field 6 is used to verify if the configuration of a dynamic/virtual wedge (moving jaw) is consistent in the TPS and the RVS. A separate treatment field (i.e. fields 6.1, 6.2, etc.) should be generated and tested for each direction of use that is allowed in the TPS. For each situation, the thick part of the wedge should carefully be indicated.

A.3. CONVERSION OF TREATMENT PLANS BETWEEN MACHINES

If a department has several machines, tests on data exchange between the RVS and a treatment machine should be performed at all machines that might be used clinically.

Conversion of treatment plans between matched machines

The RVS should allow a treatment to be delivered at all matched treatment machines (e.g. with an identical beam and treatment unit configuration) without modification of the treatment parameters. (Note: The user should be aware that an RVS does generally *not* verify if the output calibration is identical for different machines, i.e. the system will not give a warning when you intend to treat a patient on a machine with a different output calibration!)

(1) Recall fields 1, 2, 3, 4 and 5 of plan 1 (see Table 7), originally designed for treatment unit A, at each of the treatment machines that are matched to A.
(2) Set up the treatment fields one after another and check:
- By visual inspection the correspondence of all treatment parameters with scales of the treatment unit;
- By visual inspection the direction of motion for the gantry, collimator and couch, i.e. the position of the machine should agree with the TPS representation;
- By visual inspection the correspondence of the light field projection with the BEV plots of TPS for fields 1, 3 and 4 (Note: For this test, the couch top should be positioned at isocentric level, generally 100 cm from the isocentre);
- For field 5, the wedge direction, by visually comparing if the position of the thickest part of the wedge corresponds with the setting during planning.

Conversion of treatment plans between non-matched machines

(1) Recall fields 1, 2 and 3 of plan 1 (see Table 7), originally designed for treatment unit A, at each of the non-matched treatment machines that might be used clinically.
(2) If the RVS allows treatment at a non-matched machine, set up the treatment fields one after another and check:
- By visual inspection the correspondence of all treatment parameters with scales of the treatment unit;
- By visual inspection the direction of motion for the gantry, collimator and couch, i.e. the position of the machine should agree with the TPS representation;
- By visual inspection the correspondence of the light field projection with the BEV plots of TPS for fields 1 and 3 (Note: For this test, the couch top should be positioned at isocentric level, generally 100 cm from the isocentre).

(3) Recall field 4 (MLC shaped field) and verify that the RVS does not allow treatment delivery in any case at a treatment unit of another manufacturer (even if the number of leaves and the leaf width are identical) and at a treatment unit of the same manufacturer with a different MLC configuration (e.g. with a different number of leaves and/or a different leaf width). (Note: The RVS may allow modification of the MLC shape so that it fits to the specifications of the other MLC or treatment unit. When applying this conversion, the user should carefully check this. Moreover, it should be required to re-approve the field before treatment delivery is possible.)
(4) Recall field 5 (wedged field) at a treatment unit with a different wedge configuration (e.g. wedge codes). Verify that the RVS does not allow treatment. Try to give an override for the wedge in the RVS. If this is possible and the user has been authorized to do so, the RVS may allow treatment at a non-matched machine. (Note: A user is strongly discouraged to give any override for a wedge! Generally, the wedged profile and transmission will be different, yielding a dose delivery that may deviate significantly from the prescribed dose.)
- If the RVS allows treatment at a non-matched machine, set up the treatment field and check the wedge direction by visually comparing if the position of the thickest part of the wedge corresponds with the setting during planning.

A.4. TYPICAL TIME REQUESTED TO CARRY OUT RVS ACCEPTANCE TESTING AND COMMISSIONING FOR ONE ACCELERATOR

The times indicated in Table 8 have been recorded during a pilot study using the procedures described in the present report. The procedures were carried out by a person experienced in the use of the TPS, the RVS and the treatment machine, including all the transfer processes between these pieces of equipment. The required time would increase significantly if a less experienced person carries out the procedures. It would also depend significantly on the types of TPS, RVS and teletherapy units. It could increase significantly if system integration has not been carried out according to well established standards by experienced computer specialists and if problems were encountered during the process.

In a department with several accelerators, the RVS specific tests described in Section A.1 would be shared by all accelerators, and the overall time would not be directly proportional to the number of treatment machines.

The items indicated in Table 8 do not include the preparation phase, the training period and the complementary checks to be performed when starting the clinical use of the system.

TABLE 8. EXAMPLE OF TIME REQUIRED TO CARRY OUT PRECLINICAL ACCEPTANCE TESTING AND COMMISSIONING OF AN RVS SYSTEM

Item	Description	Time required (h)
Preparation of TPS	Preparation of dummy plans	4
Data transfer	Export from TPS and import in RVS	2
Linac connection	Check networking RVS to linac	2
Linac treatment	Deliver test beams covering different techniques, including IMRT (no dynamic technique was used)	2
Acceptance testing (with vendor)	Go through the whole dedicated procedures prescribed by the vendor of the RVS together with the vendor	2
Acceptance required by the local authority[a]	Carry out an acceptance test according to the IEC together with an authorized medical physicist determined by the authority	2
	Total	14

Note: IEC — International Electrotechnical Commission; IMRT — intensity modulated radiation therapy; RVS — record and verify; TPS — treatment planning system.

[a] This step could be mandatory or not, depending on the local context.

REFERENCES

[1] DUTREIX, A., When and how can we improve precision in radiotherapy? Radiother. Oncol. **2** (1984) 275–292.

[2] KARTHA, P.K., CHUNG-BIN, A., WACHTOR, T., HENDRICKSON, F.R., Accuracy in patient setup and its consequence in dosimetry, Med. Phys. **2** (1975) 331–332.

[3] ROSENBLOOM, M.E., KILLICK, L.J., BENTLEY, R.E., Verification and recording of radiotherapy treatments using a small computer, Br. J. Radiol. **50** (1977) 637–644.

[4] FREDRICKSON, D.H., KARZMARK, C.J., RUST, D.C., TUSCHMAN, M., Experience with computer monitoring, verification and record keeping in radiotherapy procedures using a Clinac-4, Int. J. Radiat. Oncol. Biol. Phys. **5** (1979) 415–418.

[5] MOHAN, R., PODMANICZKY, K.C., CALEY, R., LAPIDUS, A., LAUGHLIN, J.S., A computerized record and verify system for radiation treatments, Int. J. Radiat. Oncol. Biol. Phys. **10** (1984) 1975–1985.

[6] DICKOF, P., MORRIS, P., GETZ, D., Vrx: A verify-record system for radiotherapy, Med. Phys. **11** (1984) 525–527.

[7] FRAASS, B.A., QA issues for computer-controlled treatment delivery: This is not your old R/V system any more! Int. J. Radiat. Oncol. Biol. Phys. **71** (2008) S98–S102.

[8] INTERNATIONAL ELECTROTECHNICAL COMMISSION, Radiotherapy Equipment — Co-ordinates, Movements and Scales, Report IEC 61217, IEC, Geneva (2000).

[9] INTERNATIONAL ELECTROTECHNICAL COMMISSION, Radiotherapy Equipment — Co-ordinates, Movements and Scales, Report IEC 61217: Amendment 1, IEC, Geneva (1996).

[10] MULLER-RUNKEL, R., WATKINS, S.S., Introducing a computerized record and verify system: Its impact on the reduction of treatment errors, Med. Dosim. **16** (1991) 19–22.

[11] CALANDRINO, R., CATTANEO, G.M., FIORINO, C., LONGOBARDI, B., MANGILI, P., SIGNOROTTO, P., Detection of systematic errors in external radiotherapy before treatment delivery, Radiother. Oncol. **45** (1997) 271–274.

[12] FRAASS, B.A., LASH, K.L., MATRONE, G.M., VOLKMAN, S.K., MCSHAN, D.L., KESSLER, M.L., LICHTER, A.S., The impact of treatment complexity and computer-control delivery technology on treatment delivery errors, Int. J. Radiat. Oncol. Biol. Phys. **42** (1998) 651–659.

[13] BARTHELEMY-BRICHANT, N., SABATIER, J., DEWE, W., ALBERT, A., DENEUFBOURG, J.M., Evaluation of frequency and type of errors detected by a computerized record and verify system during radiation treatment, Radiother. Oncol. **53** (1999) 149–154.

[14] HUANG, G., MEDLAM, G., LEE, J., BILLINGSLEY, S., BISSONNETTE, J.P., RINGASH, J., KANE, G., HODGSON, D.C., Error in the delivery of radiation therapy: Results of a quality assurance review, Int. J. Radiat. Oncol. Biol. Phys. **61** (2005) 1590–1595.

[15] PATTON, G.A., GAFFNEY, D.K., MOELLER J.H., Facilitation of radiotherapeutic error by computerized record and verify systems, Int. J. Radiat. Oncol. Biol. Phys. **56** (2003) 50–57.

[16] AMOLS, H.I., New technologies in radiation therapy: Ensuring patient safety, radiation safety and regulatory issues in radiation oncology, Health Phys. **95** (2008) 658–665.

[17] INTERNATIONAL ATOMIC ENERGY AGENCY, Lessons Learned from Accidental Exposures in Radiotherapy, IAEA, Vienna (2000).

[18] INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION, Prevention of Accidental Exposures to Patients Undergoing Radiation Therapy, ICRP Publication 86, Pergamon Press, Oxford (2000).

[19] INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION, Preventing Accidental Exposures from New External Beam Radiation Therapy Technologies, ICRP Publication 112, Pergamon Press, Oxford (2009).

[20] INTERNATIONAL ELECTROTECHNICAL COMMISSION, Medical Electrical Equipment — Safety of Radiotherapy Record and Verify Systems, Report IEC 62274 ed.1.0, IEC, Geneva (2005).

[21] BAIOTTO, B., BRACCO, C., BRESCIANI, S., MASTANTUONI, A., GABRIELE, P., STASI, M., Quality assurance of a record-and-verify system, Tumori **95** (2009) 467–472.

[22] INTERNATIONAL ATOMIC ENERGY AGENCY, Comprehensive Audits of Radiotherapy Practices: A Tool for Quality Improvement. Quality Assurance Team for Radiotherapy (QUATRO), IAEA, Vienna (2007).

[23] INTERNATIONAL ATOMIC ENERGY AGENCY, Specification and Acceptance Testing of Radiotherapy Treatment Planning Systems, IAEA-TECDOC-1540, IAEA, Vienna (2007).

[24] INTERNATIONAL ATOMIC ENERGY AGENCY, Commissioning and Quality Assurance of Computerized Planning Systems for Radiation Treatment of Cancer, Technical Report Series No. 430, IAEA, Vienna (2005).

[25] INTERNATIONAL ATOMIC ENERGY AGENCY, Commissioning of Radiotherapy Treatment Planning Systems: Testing for Typical External Beam Treatment Techniques, IAEA-TECDOC-1583, IAEA, Vienna (2008).

[26] INTERNATIONAL COMMISSION ON RADIATION UNITS AND MEASUREMENTS, Prescribing, Recording, and Reporting Photon Beam Therapy, ICRU Report 50, ICRU, Bethesda, MD (1993).

[27] INTERNATIONAL COMMISSION ON RADIATION UNITS AND MEASUREMENTS, Prescribing, Recording, and Reporting Photon-Beam Intensity-Modulated Radiation Therapy (IMRT), ICRU Report 83, ICRU, Bethesda, MD (2010).
[28] INTERNATIONAL COMMISSION ON RADIATION UNITS AND MEASUREMENTS, Prescribing, Recording, and Reporting Photon Beam Therapy (Supplement to ICRU Report 50), ICRU Report 62, ICRU, Bethesda, MD (1999).
[29] INTERNATIONAL COMMISSION ON RADIATION UNITS AND MEASUREMENTS, Prescribing, Recording, and Reporting Electron Beam Therapy, ICRU Report 71, ICRU, Bethesda, MD (2004).

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