**IAEA-TECDOC-1108** 

# Report of the International Workshop on Safety Measures to Address the Year 2000 Issue at Medical Facilities Which Use Radiation Generators and Radioactive Materials, Vienna, 28–30 June 1999

# (Supplement to IAEA-TECDOC-1074)

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#### FOREWORD

In resolution GC(42)/RES/11 on "Measures to Address the Year 2000 (Y2K) Issue", adopted on 25 September 1998, the General Conference of the International Atomic Energy Agency (IAEA) — inter alia — urged Member States "to share information with the Secretariat regarding diagnostic and corrective actions being planned or implemented by operating and regulatory organizations at their … medical facilities which use radioactive materials to make those facilities Year 2000 ready", encouraged the Secretariat "within existing resources to act as a clearing-house and central point of contact for Member States to exchange information regarding diagnostic and remediation actions being taken at … medical facilities which use radioactive materials to make these facilities Year 2000 ready", urged the Secretariat "to handle the information provided by Member States carefully" and requested the Director General to report to it at its next (1999) regular session on the implementation of that resolution.

In March 1999, the IAEA published and distributed IAEA-TECDOC-1074 to all Member States to describe possible effects of the year 2000 issue (Y2K) on safety in medical facilities which use radiation generators and radioactive materials. The IAEA-TECDOC-1074 was prepared prospectively and provided identification of areas that could be affected as well as methods to address the issue.

To foster exchange of information and experience and to develop more specific advice based on this experience, the IAEA, in co-operation with the World Health Organization, conducted an International Workshop on Safety Measures to Address the Year 2000 Issue at Medical Facilities Which Use Radiation Generators and Radioactive Materials, held in Vienna, 28–30 June 1999.

Whereas the focus in IAEA-TECDOC-1074 had been on identifying what might go wrong as a result of Y2K problems and on proposing methods to address them, the focus of the International Workshop was on sharing the experience gained in implementing the proposed methods — an approach consistent with the role of the Secretariat as "a clearing-house and central point of contact for Member States to exchange information regarding diagnostic and remediation actions".

The recommendations included here were contributed by the participants in the International Workshop (see the list of contributors) and drafted by G.S. Ibbott, Chairman of the Workshop. The Scientific Secretary was P. Ortiz-López of the Division of Radiation and Waste Safety.

#### DISCLAIMER

It is the responsibility of each Member State to ensure that all its equipment is Y2K compliant or ready. In these circumstances, it is for each Member State to evaluate the information received from the IAEA and make its own independent judgement as to the value and applicability of that information with respect to Y2K compliance or Y2K readiness in that Member State. Accordingly, the IAEA cannot accept any responsibility or liability with respect to the use by a Member State of any information received from the IAEA relating to the Y2K issue.

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#### 1. INTRODUCTION

A consultants meeting was held in December 1998 in order to consider the potential problems of the year 2000 (Y2K) issue in relation to medical radiation sources. This resulted in the secretariat preparing a Technical Document on "Safety Measures to Address the Year 2000 Issue at Medical Facilities which use Radiation Generators and Radioactive Materials" (IAEA-TECDOC-1074) [1], which should be read in conjunction with this report.

An International Workshop on Safety Measures to Address the Year 2000 Issue at Medical Facilities which use Radiation Generators and Radioactive Materials was held in Vienna, 28–30 June 1999. The recommendations in this report are a result of the workshop.

Whilst some medical facilities and national authorities have already taken the initiative to evaluate and mitigate the Y2K problem, some countries have made little or no preparation. This report, therefore, contains specific recommendations and advice for conducting an inventory of equipment that might be affected, setting up a task force, performing a preliminary assessment, establishing priorities, allocating resources, evaluating equipment that might be affected, testing for Y2K compatibility, implementing remediation efforts, and verifying proper operation. It also contains suggestions for developing concrete contingency plans for equipment that cannot be made Y2K compatible. As the Y2K problem revolves around the inability of some computer systems to handle not only the date 1 January 2000 but other dates as well, examples of other critical dates are given in Appendix I.

The significance and urgency of the issue cannot be overstated; if adequate preparations are not made, the risk exists for patients to receive incorrect treatments (overdoses or underdoses) or incorrect diagnoses, resulting in compromised medical care or even injury.

It is believed that adequate time exists for hospitals to prepare for the transition and to take preventive measures to avoid accidental exposures, but if preparations are not already under way, they should be started immediately.

The report is intended for use by health authorities, hospital administrators, radiation oncologists, radiologists, nuclear medicine physicians, medical physicists, radiation protection specialists, and regulators. Professional associations may also find it useful, and should participate by ensuring that their members receive these recommendations.

Other IAEA publications related to the Y2K problem which may be of interest are given in Refs [2, 3].

# 2. RECOMMENDATIONS COMMON TO ALL AREAS OF APPLICATION OF RADIATION IN MEDICINE

#### 2.1. Setting up a task force

At the time of writing this report, fewer than six months remain for preparations for Y2K compliance. It is imperative that institutions that have not completed Y2K compliance efforts begin immediately. It should be recognized that compliance may require obtaining solutions from the manufacturer of the equipment, possibly comprising replacement hardware or upgraded software. Some time may be required for ordering, assembly, delivery, and installation of such solutions.

On the other hand, hospitals should be aware that Y2K testing is not necessarily complicated or time-consuming. Hospitals should have adequate time to address the Y2K issue, at least for those systems having high clinical significance or a high likelihood of Y2K problems. It is estimated that the testing of a standalone PC may require only 30 to 60 minutes. More complicated systems, and systems that are networked may require more time. Hospitals should be encouraged to begin efforts at the earliest opportunity.

Hospitals should establish a task force to address the Y2K issue. Members should include a representative of hospital management, the chairs of affected departments, the radiation protection officer, the chief medical physicist, a clinical engineer, and a medical information systems representative. Individuals should be assigned responsibility for specific tasks based on expertise. Hospital management may need to adjust the responsibilities assigned to the task force members to assure that adequate time is available to address Y2K issues. A timetable should be established for conducting the remaining tasks. A flow diagram, which includes a suggested timeline for implementing these tasks, appears in Appendix II. As indicated in the Introduction, facilities using radiation generators and radioactive materials that have not yet begun assessment and mitigation procedures should begin at the earliest opportunity. While little time remains before the transition date, hospitals should be able to address the health and safety issues associated with Y2K.

# 2.2. Reporting progress

Hospital management should establish requirements for reporting on progress made by the task force. It is suggested that reports be made, at least, on a monthly basis. However, these reports should not be lengthy as extensive detail will detract from attention to the problem itself. Instead, they should simply indicate the progress made by the task force in each of the areas below. Management should use these reports to monitor the progress of the task force, and their adherence to the deadlines established earlier.

#### 2.3. Inventory

The first step taken by the task force in addressing the Y2K problem should be to prepare an inventory of equipment and systems that might conceivably be affected by the year 2000 issue. At this point, all equipment used in diagnostic radiology, radiation therapy and nuclear medicine should be considered at risk. Some suggestions for equipment that might be considered are presented in Appendix III. The reader is cautioned that this list is not intended to be all-inclusive.

A database should be constructed that contains information about each system and piece of equipment. A recommendation for the information to be collected is contained in Appendix IV. A sample database, including the necessary software, is available for downloading from the US National Institute of Standards and Technology (NIST) Website at <a href="http://y2khelp.nist.gov/">http://y2khelp.nist.gov/</a>. While not extensive, the database may be useful as a starting point for medical facilities.

A number of Websites are available at which information is provided on Y2K issues. Some of these sites are listed in Appendix V. No endorsement is implied by the inclusion of a site in this list, nor is the exclusion of a site to be interpreted as a judgment of the quality of the site. The reader is reminded that many of these sites are commercial and the information contained must be evaluated with care.

# 2.4. Preliminary assessment

Y2K compliance is not an issue for devices that operate without a real-time clock and do not store or calculate date and time data.

- 1. Devices that incorporate a real-time clock used for date stamping but perform no calculations related to time and date. Y2K compliance is important as patient appointment scheduling, medical record storage and record retrieval may be based on the date.
- 2. Devices that incorporate a real-time clock used for time based calculations, such as the calculation of elapsed time or of radioisotope decay. Y2K compliance is important, as patient treatments may be based on such calculations.

# 2.5. Establishment of priorities and allocation of resources

It may not be possible or practical for a facility to assess and mitigate the Y2K problem for all pieces of radiological equipment prior to the transition date. Instead, and to assure that critical equipment is not overlooked, a list of priorities should be established. Each system and piece of equipment should be classified in terms of its clinical significance (critical, secondary, or low) and the probability of susceptibility to Y2K (high or low) [4]. *Critical significance* refers to serious events such as unintended radiation exposure, injury, or incorrect diagnosis. *Secondary significance* refers to events such as scheduling errors, record keeping errors, or losses of data. *Low significance* refers to minor events such as the erroneous display of date information. Equipment should then be ranked as follows:

- 1<sup>st</sup> priority critical significance, high probability
- 2<sup>nd</sup> priority secondary significance, high probability
- 3<sup>rd</sup> priority critical significance, low probability
- 4<sup>th</sup> priority secondary significance, low probability
- 5<sup>th</sup> priority low significance, high probability
- 6<sup>th</sup> priority low significance, low probability.

Once all systems and equipment are prioritized, available resources can be allocated to ensure that the following tasks are accomplished in the most effective manner.

# 2.6. Evaluation

Information useful to conducting the assessment should be collected. This might include published advice, manufacturers' recommendations, and the experiences of other facilities and practitioners. A large amount of information is available over the Internet. A list of a number of Web pages with Y2K information appears in Appendix V. Hospitals should view such information critically. The Workshop is aware of commercial entities that purport to offer Y2K solutions that are inadequate or may be inappropriate for the systems for which they are marketed. There is the risk that solutions may be purchased that are not needed, resulting in unnecessary expenditure. The experiences reported by other users of similar equipment may not be helpful, as the same piece of equipment may function differently in different environments.

The following steps should be followed in evaluating each system and piece of equipment:

- 1. If available, obtain a "Certificate of Y2K Compliance" from the manufacturer for the specific model and configuration of equipment. In addition, obtain recommended testing procedures from the manufacturer of the equipment. However, careful attention must be paid to verifying that the manufacturer's statement applies to the correct piece of equipment, with the correct software version, and in operation under the correct circumstances.
- 2. Perform a backup of the computer or system, to ensure that it is possible to restore the original operating conditions.
- 3. Test each system and piece of equipment according to the manufacturer's recommendations. Be aware that the manner in which the equipment is used may affect the validity of the testing; in some cases, procedures recommended by the manufacturer may be applicable only for specific modes of operation.
- 4. If procedures are not available from the manufacture, they must be devised by the facility. The following procedures are recommended, but additional or modified tests may be necessary for certain pieces of equipment. Be aware that it may not be possible to conduct some or all of these tests if the equipment does not allow the user to modify the date.
  - Build a test environment, to avoid modifying or interfering with existing data. In some cases, it may be simplest to perform a full backup of the system, which can be restored after testing is completed.
  - Test that the system rolls over to year 2000 with the power on.
  - Test that the system retains the year 2000 when the power is switched off and back on.
  - Test that the system rolls over to the year 2000 with the power off.
  - Test that the system permits entry and changing of year 2000 dates.
  - Perform tests before and after 29 February 2000
  - Check that the day of the week is computed correctly from the date in year 2000.
  - Test that the system rolls over to the year 2001 with the power on and off, and retains year 2001 dates.
  - Test operation of the application software in a simulated future environment.
  - Test the synchronization of dates across networked systems.
  - Test the system operation around additional critical transition dates (refer to IAEA-TECDOC-1074).
- 5. Categorize the degree of compliance of each system and piece of equipment:
  - System operates properly when data include dates before and after 1 January 2000.
  - System operates properly before and after 1 January 2000.
  - System operates properly at time of transition between 1999 and 2000.
  - Dates incorporating 4 digits for the year are input and output correctly.
  - Software calculates day of the week correctly.
  - System recognizes that 2000 is a leap year.
  - System sorts by date properly.
  - System calculates days elapsed between dates properly.

- 6. Remove files created as part of the testing process, and restore the system date to the current date.
- 7. If necessary or appropriate, restore the entire system from the backup.

# 2.7. Precautions

Facilities should be aware of a number of pitfalls that can be encountered when testing equipment for Y2K compliance. These include:

- 1. The chance that by resetting the date stored in a computer one might trigger the expiration of the software license.
- 2. Resetting the date may trigger a security lock and prevent further use.
- 3. Resetting the date may initiate maintenance procedures prematurely.
- 4. It may not be possible to recover after a failure involving dates after 1 January 2000.
- 5. Tests devised by the user may indicate inaccurate results (false positive).
- 6. The testing methods may not indicate real problems with the system (false negative).
- 7. The test may be completed successfully, but may cause errors once operation is returned to normal.
- 8. Data may be lost as a result of testing, or because advancing the date may trigger automatic purging of a database.
- 9. Resetting dates in one system may cause errors with subsystems in which dates are not reset.
- 10. Testing may cause errors due to misinterpretation of dates or date formats.
- 11. Equipment may perform properly in a standalone mode, but may fail when connected to a network.
- 12. Other users must be prevented from using the system during testing. This is particularly important in the case of networked systems.

#### 2.8. Implement remediation efforts

If the tests described in Section 2.6 (steps 3 and 4) indicate failure to comply to Y2K requirements, remediation or other action will be required. The priorities established in Section 2.5 should be followed to establish the sequence in which remediation efforts are applied. When available, the manufacturer's recommendations should be followed. These recommendations may involve the replacement of software or hardware, or be as simple as merely editing the date after 1 January 2000.

In some cases, remediation must be performed by the manufacturer, in which case documentation should be provided to indicate that the work has been done and tested. If remediation is not available from the manufacturer, and in-house changes are implemented, these should be documented carefully so that they may be understood if questions arise in the future.

Changes made as part of Y2K remediation, whether done in-house or by the manufacturer, should be incorporated into the quality assurance (QA) programme.

With some equipment, remediation may not be possible. If the equipment is classified with low clinical significance, it may be possible to implement a contingency plan or work-around (see Section 2.10). Otherwise, the equipment (and the associated functions) may have to be retired.

#### 2.9. Conduct verification testing

If remediation is required, the system must then be tested to ensure that the intended changes were made and the system complies with Y2K requirements. Testing must also be conducted to demonstrate that the system continues to function as expected. Therefore, verification testing should consist of the following two steps:

- The tests described in Section 2.6 (steps 3 and 4) should be repeated, to demonstrate that the system passes Y2K tests which previously were failed, and that it continues to pass tests that were passed previously.
- The system should be subjected to comprehensive quality assurance tests, to ensure that Y2K remediation has not introduced new errors or changes in performance.

Verification testing should be conducted immediately after remediation efforts and prior to clinical use.

Testing should also be performed after transition to the year 2000, but prior to clinical use, **whether or not** remediation was required, to ensure that the transition has not introduced unanticipated errors.

# 2.10. Develop contingency plans

Regardless of how carefully testing and remediation are conducted, it is possible that some aspect of Y2K performance may be missed. There are also likely to be systems in use that cannot be tested adequately or remediated successfully. Therefore, it is necessary to develop contingency plans, in the event that systems cannot be used clinically after the transition date. Such contingency plans should anticipate failures of the following types:

- Equipment failures
- External system connectivity failures
- Infrastructure failures
- Supply delivery failures
- Failures at other institutions leading to referral of large numbers of patients
- Commuting problems for employees
- Inability to process payments, receipts, and payroll
- Other long term financial problems.

Contingency planning in most cases will amount to the institution of manual procedures to replace computerized procedures that may be made inoperable due to Y2K issues. For example, manual operations may include:

- Requests
- Medical orders
- Reporting
- Financial operations
- Patient scheduling
- Dosimetry calculations and treatment planning
- Calculation of administered activities in nuclear medicine
- Medical records database operations.

In some cases it may be possible to institute "work-arounds" to replace functions formerly conducted by computer. For the most part, these will consist of reverting to paper records and manual calculations. It may also be possible to adopt administrative solutions to overcome computer limitations. For example, in circumstances where dates are only used prospectively, the hospital may adopt a policy that all dates using two digits for the year represent the 21<sup>st</sup> century. The entry "00" would always mean 2000, and "99" would mean 2099. Such a policy would not permit calculations of elapsed time across the transition date, but may be acceptable for some functions.

Some computer software considers years expressed as "00" to "49" to fall into the 21<sup>st</sup> century, while dates expressed as "50" to "99" fall in the 20<sup>th</sup> century. Such operation would not apply in cases where calculations of elapsed time are performed across a larger range of dates, but may be acceptable in most cases. For example, such software may compute the decay of radioactive sources properly, because it is unusual for sources to have calibration dates before 1950. However, the calculation of patient ages may fail because many patients have birth dates before 1950.

The implementation of a work-around should be done with care and with careful planning to avoid the introduction of other modes of failure into the system. The hospital should also consider the increased likelihood of human error when changes to existing procedures are introduced. Training sessions should be provided if needed to explain the manual procedures to employees. Systems for error checking should be amended to consider the introduction of contingency plans. In addition, emergency procedures may need to be modified to accommodate contingency plans. Employees will need training in these modified procedures.

# 3. EXTERNAL BEAM RADIATION THERAPY

Systems used in external beam therapy are usually quite complex and consist of more than one component. To demonstrate this fact, components of representative treatment planning systems, "record and verify" systems and linear accelerators are listed below.

- 1. Treatment planning system:
  - computer unit (PC, dedicated workstation, mainframe, etc.)
  - operating system
  - application software
  - peripheral devices.
- 2. "Record & verify" (R&V) system:
  - server
  - workstations
  - server operating system
  - workstations operating system
  - network software
  - application software
  - commercial database
  - peripheral devices.

# 3. Linear accelerator

- built-in control system
- control computer
- peripheral devices.

It is very important to take this complexity into account when designing test procedures for Y2K compliance. It may happen that a particular workstation has been declared by its producer to be Y2K compliant, but the whole network system will collapse due to the non-compliance of another component.

The following approach should be taken for complex systems: If one component fails or is declared by its producer as non-compliant, then the whole system shall be considered to be non-compliant.

# 3.1. Prepare inventory of equipment

The following is a list of equipment that might be found in a radiation oncology department, that should be considered for Y2K compatibility:

- 1. Photon and electron accelerators
- 2. Advanced features found in linacs (multileaf collimators (MLC), on-line portal imaging systems, intensity modulation radiotherapy (IMRT), etc.)
- 3. Radionuclide teletherapy units (Co-60, Cs-137, etc.)
- 4. Other accelerators (protons, heavy ions, etc.)
- 5. Superficial and orthovoltage X ray units
- 6. Treatment simulators (conventional)
- 7. Computed tomography (virtual) simulators
- 8. Treatment planning systems
- 9. Systems for calculation of radiobiological effects
- 10. Treatment verification and recording systems
- 11. Block cutters
- 12. Compensator milling machines
- 13. Film processors
- 14. Computer hardware and software used for treatment time/monitor unit (MU) calculation or verification (spreadsheet based application, etc.).

*Note*: the above is not intended as a complete list as other equipment such as local network systems and dosimetry systems may be in use. This issue is addressed in a separate section (see Section 6).

# 3.2. Potential hazards of Y2K non-compliance

Medical systems used in radiation therapy may fail in a number of ways related to the Y2K issue. The hazards may involve problems in the correct identification of a patient and therefore may involve the wrong patient, the wrong examination or treatment to a given patient.

Hospitals should be aware of the following modes of failure:

- 1. Incorrect calculation of treatment dose.
- 2. Incorrect delivery of intended dose (overexposure, underexposure).
- 3. Incorrect calculation of time interval between specified periods (with the possibility of errors in calculations of biological effects, etc.).
- 4. Malfunction of control computers (loss of control of equipment incorrect positioning, unintended irradiation, inability to interrupt the radiation by using normal operating procedures, unintended movement of equipment during treatment, wrong positioning of the flattening filter or scattering foils, etc.).
- 5. Incorrect identification of the day of the week (this is important for scheduling/fraction determination, and for combination of treatment with other modalities).
- 6. Incorrect date/time stamping of patient records or data.
- 7. Errors in scheduling of patient appointments.
- 8. Disruption of interfaces (communication with hospital network and other devices).

# **3.3. Establishing priorities**

Based on the above, establish the priority for each of the tests. The most critical equipment shall be tested immediately. For the affected equipment, implementation of the Y2K solution shall be implemented with the highest priority before the end of 1999.

Readers are reminded that the classification in terms of clinical significance and probability of errors (Section 2.5) can vary from one institution to another due to differences in clinical practice and differences in equipment available. The final classification is ultimately the responsibility of the user.

This report therefore cannot give any specific recommendation regarding the classification of equipment. To help with the classification Table I gives examples of potential problems.

Hospitals should be aware that some linear accelerators cannot be operated without a "R&V" system. When establishing the priority for such equipment both entries in Table I (for accelerators as well as for "R&V" systems) shall be considered.

# **3.4.** Testing procedures

*Warning:* before starting the test procedures, refer to Section 2.6.

It may not be possible to conduct all the test listed in the examples below. Perform the tests as described in Section 2.6 (steps 3 and 4) in conjunction with QA programmes already implemented. If an appropriate QA programme has not yet been implemented, serious consideration should be given to developing procedures for checking the proper operation of the unit. These tests do not necessarily cover all the problems that may occur.

# TABLE I. GUIDE FOR SETTING PRIORITIES FOR Y2K TESTING OF RADIATION THERAPY EQUIPMENT

| Equipment  | Incorrect<br>calculation<br>of dose | Delivery of<br>unintended<br>dose | Incorrect<br>calculation<br>of interval | Malfunction<br>of control<br>computers | Incorrect<br>identification<br>of the day of<br>the week | Incorrect<br>date/time<br>stamping | Errors in<br>patient<br>scheduling | Disruption of interfaces |
|--|-------------------------------------|-----------------------------------|---|--|--|------------------------------------|------------------------------------|--------------------------|
| Linear accelerators                                | no                                  | yes                               | no                                      | yes                                    | no   | yes                                | no                                 | yes                      |
| Advanced features in linacs                        | no                                  | yes                               | no                                      | yes                                    | no   | yes                                | no                                 | yes                      |
| Radionuclide<br>teletherapy units                  | no                                  | yes                               | no                                      | yes                                    | no   | yes                                | no                                 | yes                      |
| Other accelerators                                 | no                                  | yes                               | no                                      | yes                                    | no   | yes                                | no                                 | yes                      |
| Superficial and<br>orthovoltage X ray<br>units     | no                                  | yes                               | no                                      | yes                                    | no   | no                                 | no                                 | yes                      |
| Treatment simulators (conventional)                | no                                  | yes                               | no                                      | yes                                    | no   | yes                                | no                                 | yes                      |
| CT* (virtual)<br>simulators                        | no                                  | no                                | no                                      | yes                                    | no   | yes                                | no                                 | yes                      |
| Treatment planning systems                         | yes                                 | no                                | yes                                     | yes                                    | no   | yes                                | no                                 | yes                      |
| Systems for calculation of radiobiological effects | yes                                 | no                                | yes                                     | no                                     | yes  | yes                                | no                                 | yes                      |
| Treatment record and verify systems                | yes                                 | no                                | yes                                     | yes                                    | yes  | yes                                | yes                                | yes                      |
| Block cutters                                      | no                                  | no                                | no                                      | yes                                    | no   | yes                                | no                                 | yes                      |
| Compensator milling machines                       | no                                  | no                                | no                                      | yes                                    | no   | yes                                | no                                 | yes                      |
| Film processors                                    | no                                  | no                                | no                                      | yes                                    | no   | yes                                | no                                 | no                       |
| Other computer hardware and software               | yes                                 | no                                | yes                                     | yes                                    | yes  | yes                                | no                                 | yes                      |

\* Computer tomography.

#### 3.4.1. Examples for testing external beam equipment

#### 3.4.1.1. Radiation treatment planning systems (RTPS)

- 1. Check the treatment time or monitor unit (MU) calculation against a manual calculation at the reference point for a prescribed dose of 2 Gy with the following settings:
  - Isotope calibration date in 1999; current date after January 2000; leave a time gap of at least 3 months for cobalt-60.
  - Isotope calibration date in 2000; current date after 2000; leave a time gap of at least 3 months for cobalt-60.
  - Isotope calibration date in 2000; current date after 2001; leave a time gap of at least 3 months for cobalt-60.
- 2. Treatment dose calculation for a test phantom. Monitor unit or treatment time calculation to the reference point of 2 Gy for a standard reference setting. Perform the calculation on the last working day of 1999 and repeat the test at the beginning on the first working day of 2000 prior to any treatment plan calculation. Compare both values.

#### 3.4.1.2. Linear accelerator

Before starting any treatment after 1 January 2000 a set of tests should be conducted to verify the normal operation of the unit. An example of the test set is given below.

- Check the functionality of emergency buttons and door interlocks.
- Check the dose on the central axis at the reference point for every energy.
- Check that the treatment unit motion can be interrupted with radiation on and off.
- Check that it is possible to switch off the beam before reaching prescribed setting.

# 3.4.1.3. Verification system

- 1. Create a new patient using R&V system tools, then without changing the system date, try to schedule an appointment:
  - starting in 1999 and continuing after 1 January 2000.
  - starting after 1 January 2000.
  - check that the system works correctly.
- 2. Change the system date to the date after 1 January 2000, and create a new patient using "R&V" system tools:
  - check that the system works correctly.
  - check that appointments can be scheduled.
  - check that the patient is offered the treatment according to the prescribed fractionation.
  - check that the system can schedule a treatment for 29 February 2000 and 1 March 2000.

# 3.4.1.4. Calculation of biological effectiveness

Check that the calculation of the time interval (or predicted value of biological effectiveness) is correct for the following situations:

- starting date of treatment in the year 1999, date to which the value is calculated, is after 1 January 2000.
- starting date of treatment after 1 January 2000, date to which the value is calculated, is any later date.

#### 3.5. Problems related to work-around solutions

Examples of potential hazards for some work-arounds are mentioned in this section. The IAEA reminds readers that this is not intended to be a comprehensive list.

- 1. Reset date to an earlier date. Before starting implementation and testing of this workaround the following hazards should be considered:
  - Is there a danger of losing the database consistency?
  - How will the system handle a patient treated previously (with the date earlier than the current one) when returning for re-treatment?
  - Is it possible to select a year which will fit year 2000 in terms of matching days of the week?
  - If the day of the week is not calculated correctly, there is a danger of not treating or double-treating the patient.
  - If scheduling functions fail completely, there is a danger that staff will be stressed and patients may be mistreated.
- 2. Discontinue use of the old database and develop a new one:
  - Does a 20<sup>th</sup>-century year exist that will fit year 2000 in terms of matching day of the week?
  - If the day of the week does not fit, there is the danger of not treating or double-treating the patient.
  - If scheduling functions fail completely, there is the danger that staff will be stressed and patients may be mistreated.

- If patient histories are discontinued, there exists the potential danger of incorrect dose administration for re-treated patients.
- 3. Reset date on the treatment planning computer and change radionuclide calibration data (dose rate and calibration date) accordingly:
  - Requires very careful QA not to introduce extra errors due to incorrect input data.
  - When an old plan is reloaded and recalculated, a miscalculation of treatment time or source activity may occur.
  - When an old plan is reloaded and recalculated, a potential danger exists of the system crashing due to dates being out of range.

# **3.6.** Contingency plan

Any contingency plan shall take into account all the procedures performed and the typical workflow of the department. The items listed below can be used to create an individual contingency plan for a particular location:

- 1. Prioritize procedures.
- 2. Make personnel aware of the contingency plan.
- 3. Review and update emergency procedures before the end of the year, and verify that the procedures are consistent with the Y2K contingency plan. The procedures should consider that the likelihood of power failures may increase after the transition date. Train staff in any necessary changes to emergency procedures.
- 4. Construct a list of contact information for essential personnel.
- 5. Make sure staff know the exact location of the main/emergency switch (in case of machine malfunction, etc.).
- 6. Ensure that survey meters are prepared.
- 7. Prepare for transfer of patients among centres (send and receive).
- 8. Prepare protocols for manual recording of patient treatment.
- 9. Prepare procedures for manual calculation of treatment plans; ensure that all necessary data are available and valid.
- 10. Prepare procedures for manual patient contouring if the CT scanner is down.
- 11. Prepare pre-calculated standard plans, where applicable.
- 12. Ensure that all necessary documents (manuals) are easily accessible.
- 13. Develop and conduct training to manage manual procedures introduced in the contingency plan.
- 14. Do not start any new treatment techniques during the transition period (at least December–January).

# 4. BRACHYTHERAPY

Brachytherapy makes use of a variety of dose computation tools for calculating dose distributions. and treatment time needed to fulfill the clinical prescription. In all cases, the treatment is based on an accurate knowledge of the activities of the radioactive sources and in most cases simple methods are used. Often in-house software is used in brachytherapy.

Several techniques have been developed in order to use different devices to bring a sealed radioactive material into the patient for a given time or permanently (interstitial, intracavitary and intraluminal brachytherapy, surface plaque technique, intravascular and intracoronary brachytherapy).

The variety of radioactive materials and available activities present a large number of treatments including gamma and beta emitters and half lives ranging from tens of hours to tens of years. Brachytherapy applications involve single or multiple fractions of treatment lasting from a few minutes (high dose rate (HDR) and pulsed dose rate (PDR) treatments) to several days (low dose rate treatments). Calculations of treatment time may be performed by a treatment planning system, taking into account the current activity of the source(s). In some cases, especially HDR equipment, treatment planning systems are part of the remote afterloading device and calculations are based on the nominal or initial source activity, and on corrections made by the remote afterloading device to account for source decay. Because treatment times are often short in HDR, an error in the calculated treatment time may not be detected before the end of the treatment causing a severe injury or even death. Moreover, the radioactive sources can be placed manually or through the use of automatic equipment (remote afterloading).

The large variety of combinations makes it extremely difficult to develop a comprehensive checklist of all possible equipment to assist the user in making an inventory of equipment and systems that may be affected by the Y2K issue. In principle, the simplest planning for a brachytherapy treatment foresees the use of certified radioactive sources and methods to evaluate accurately their activities at the time of treatment using a device to calculate the physical decay (pocket calculator or PC).

# 4.1. Inventory

The user should undertake the following activities:

1. Review all the brachytherapy sources in use in the department. A list of the most frequently used radionuclides is provided in Table II.

| Nuclide | Mean energy | Half-life   |
|---------|-------------|-------------|
| Cs-137  | 662 keV     | 30 years    |
| Ir-192  | 360 keV     | 74.2 days   |
| I-125   | 28 keV      | 59.0 days   |
| Pd-103  | 22 keV      | 17.0 days   |
| Am-241  | 60 keV      | 432.2 years |
| Sm-145  | 43 keV      | 40.0 days   |
| Co-60   | 1250 keV    | 5.27 years  |
| Yb-169  | 93 keV      | 32.0 days   |
| Au-198  | 420 keV     | 64.7 h      |
| Ta-182  | 700 keV     | 115 days    |
| Ra-226  | 780 keV     | 1600 years  |
| P-32    | 694 keV     | 14.3 days   |
| Sr-90   | 546 keV     | 28.7 years  |
| Y-90    | 2270 keV    | 64.0 h      |
| Ru-106  | 3400 keV    | 369 days    |
| Cf-252  |             | 2.64 years  |

# TABLE II. RADIOACTIVE SOURCES COMMONLY OR OCCASIONALLY USED FOR BRACHYTHERAPY

- 2. Consider the equipment and all the devices involved in their use, including the software. A possible general list of equipment is the following:
  - Manual afterloading system
  - Low dose rate remote afterloading system
  - High dose rate remote afterloading system
  - Pulsed dose rate remote afterloading system
  - PC
  - Pocket calculator
  - Treatment Planning System
  - Electrometers with ion chambers
  - QC equipment (phantoms, radiation field scanner)
  - Survey meters
  - In vivo dosimetry system.
- 3. Analyse the potential Y2K vulnerability of each item.
- 4. Obtain specific information about the affected devices and equipment. The list should include for each item:
  - The department allocation
  - The name of the responsible persons (clinical application and radiation protection and QA)
  - The type and manufacturer of the equipment
  - The model number, the software and operating system version
  - The vendor name and the maintenance service
  - The maintenance contract
  - The network connection of the system (if existing)
  - The classification of the equipment
  - The decision to retire, repair or remediate
  - The priority level
  - An estimate of the time to remediate and the cost.
- 5. Establish the priorities and the location of resources (refer to Section 2.5).

# 4.2. Potential hazards

Potential hazards may involve problems in the correct identification of a patient and therefore may involve the wrong patient, the wrong examination or treatment to a given patient or the wrong source activity. Potential Y2K problems include:

- Incorrect calculation of the source activity.
- Incorrect calculation of the treatment time.
- Incorrect treatment plan from the treatment planning system (TPS).
- Computer malfunction controlling source position.
- Computer malfunction controlling treatment dwell time.
- Incorrect input of data to and from the TPS.

- Incorrect identification of the day of the week (this is important for scheduling/fraction determination, and for combination of treatment with other modalities).
- Incorrect date/time stamping.
- Disruption of interfaces (communication with hospital network and other devices).
- Incorrect calculation of radiobiological indexes ((relative biological effectiveness (RBE), extrapolated response dose (ERD), time dose fraction (TDF)).

# 4.3. Detailed assessment

The purpose of the detailed assessment is to obtain information about the equipment to determine its behaviour on the critical dates and beyond them. The user should:

- 1. Acquire information from the vendor and/or manufacturer of the equipment with regard to its date sensitivity.
- 2. Ask the vendor and/or manufacturer to supply the equipment with a testing procedure.

The user must be aware that manufacturers generally do not confirm that third party equipment that interfaces with their products are Y2K compliant.

# 4.4. Remediation and testing

The purpose of the remediation and testing is to modify the equipment to remove the Y2K problems and to perform a test of the functionality of the equipment on the critical dates. The remediation procedure should be taken from the vendor/manufacturer, keeping in mind that the procedure must be appropriate for the specific configuration and use of equipment and software.

Before the testing procedure, the user should take precautions not to lose data. It is recommended that a backup of all files be created (see Section 2.6).

A QA programme should be performed on a regular basis in brachytherapy in order to administrate an accurate and consistent treatment. Whenever possible, the measured source strength should be compared with the calculated strength to determine the accuracy of the calculated activity in a simple geometry [5].

Testing after the remediation action should consist of repeating the seven step procedure described in Section 2.6 (steps 3 and 4), performing QC tests after changing any date, checking standards plans output before and after the transition date, and performing a check of decay factors and treatment time calculations against a hand calculation.

# 4.5. Contingency plan

Any contingency plan shall take into account all the procedures performed and the typical workflow of the department. Items listed below can be used to create an individual contingency plan for a particular location.

- 1. Prioritize procedures.
- 2. Make personnel aware of the contingency plan.
- 3. Review and update emergency procedures before the end of the year, and verify that the procedures are consistent with the Y2K contingency plan. The procedures should consider that the likelihood of power failures may increase after the transition date. Train staff in any necessary changes to emergency procedures.

- 4. Prepare a list of contact information of essential personnel.
- 5. Know exactly the location of the main/emergency switch (in case of machine malfunction, etc.).
- 6. Develop procedures for returning sources immediately to emergency storage containers in the event of a power failure.
- 7. Make sure survey meters are prepared for use.
- 8. Prepare for transfer of patients among centres (send and receive).
- 9. Prepare protocols for manual recording of patient treatment.
- 10. Prepare manual calculation of treatment plans; ensure all the necessary data are available and valid.
- 11. Prepare pre-calculated standard plans, where applicable.
- 12. Ensure all the necessary documents (manuals) are easily accessible.
- 13. Training to manage manual procedures introduced in the contingency plan.
- 14. Schedule source calibration procedures to occur shortly before the transition date, rather than after it.
- 15. Schedule HDR source exchange to occur shortly before the transition date, rather than after it.

# 5. DIAGNOSTIC IMAGING, INCLUDING NUCLEAR MEDICINE AND DIAGNOSTIC RADIOLOGY

If a computer or microprocessor forms part of a system within a department of nuclear medicine or diagnostic imaging, then the question needs to be asked whether calculations that are performed are dependent on the date and time.

If the answer is YES then it needs to be established whether this system will suffer from the Y2K problem.

Of paramount interest is whether the Y2K problem will lead to increased radiation hazard to patients and/or staff such as:

- wrong examination or treatment
- wrong activity to the patient
- handling of wrong activities due to incorrect measurements
- discharge of radioactive waste with wrong activity.

The following specific areas must be addressed concerning Y2K compliance:

- Administrative routines
- Equipment in nuclear medicine and diagnostic radiology
- Potential Y2K hazards
- Radiopharmaceuticals
- Hardware and software for image processing
- Networks.

# 5.1. Administrative routines

Routines that may lead to increased radiation hazard to the patient may involve problems in the correct identification of a patient and therefore may involve the wrong patient, the wrong examination or treatment to a given patient or the wrong administered activity.

Administrative procedures that may give rise to shutdown of specific equipment or even the entire department may cause delays, stress or even chaos but will not lead to increased radiation hazard.

# 5.2. Inventory of equipment

- 1. Nuclear medicine equipment
  - Gamma cameras
  - positron emission tomography (PET) systems
  - Activity meters (dose calibrators)
  - Monitoring instruments
  - In vitro counting systems
  - Image processing and picture archiving systems (PACS).
- 2. Diagnostic imaging equipment
  - Magnetic resonance imaging (MRI)
  - Ultrasound
  - Radiographic and fluoroscopic systems
  - Image processing and PACS.

#### 5.3. Potential Y2K hazards

#### 5.3.1. Nuclear medicine equipment

#### 5.3.1.1. Gamma cameras

Old analogue gamma cameras will not suffer from Y2K problems. Similarly, very modern digital gamma cameras are expected to be Y2K compliant. However, cameras manufactured during the transition period from analogue to fully digital and cameras upgraded by fitting a computerized acquisition unit should be given highest priority in testing.

#### 5.3.1.2. PET systems

No Y2K problems are anticipated for this equipment. However, users of PET equipment should verify that this is the case.

#### 5.3.1.3. Activity meters

All activity meters shall be checked preferably according to manufacturers recommendations and protocols. If not available, the routine QC programme should be used.

#### 5.3.1.4. Monitoring instruments

Monitoring instruments are used for contamination monitoring and for monitoring patients who have received therapeutic amounts of activity. No Y2K problems are anticipated here.

#### 5.3.1.5. In vitro counting systems

Computer- or microprocessor based systems should be checked as they often involve corrections based on elapsed time.

# 5.3.1.6. Image processing and picture archiving systems

This includes film processors, image display systems, printers, computerized image processing stations and archiving and retrieval systems.

Incorrect processing of image and patient data in any of the processes or stages listed above may lead to the repetition of the imaging procedure and hence will increase the radiation burden.

In nuclear medicine the use of unsupported computers may give increased Y2K problems. If as a consequence the use of such a computer is discontinued, the examination will have to be repeated. Similarly because of data incompatibility amongst computers in nuclear medicine, software produced in house or of unknown origin which may malfunction in the year 2000 will also lead to examinations to be repeated.

Modern applications software from major commercial manufacturers are expected to be Y2K compliant but should be tested according to the manufacturers recommendations.

# 5.3.2. Equipment in diagnostic radiology imaging

Equipment in diagnostic imaging that does not involve a computer or microprocessor will not yield any Y2K problem. However, due to the complexity of modern diagnostic imaging equipment, the full co-operation of the manufacturer is essential.

#### 5.3.2.1. X ray based equipment

This includes conventional radiographic equipment, fluoroscopic and image intensifier systems, CT and modern digital X ray systems.

It is unlikely that any Y2K problem will be experienced pertaining to the duration and amount of X rays emitted.

#### 5.3.2.2. Magnetic resonance imaging (MRI) and ultrasound

Malfunction can cause a breakdown of the equipment and hence inconvenience to the patient but will not lead to any radiation hazard. Only if the MRI or ultrasound examination is replaced by an X ray examination would there be an additional radiation dose.

#### 5.3.2.3. Image processing and picture archiving

This includes film processors, image display systems, printers, computerized image processing stations and archiving and retrieval systems.

Incorrect processing of image and patient data in any of the processes or stages listed above may lead to the repetition of the imaging procedure and hence will increase the radiation burden.

# 5.3.3. Radiopharmaceuticals

#### 5.3.3.1. Production and transportation

It is anticipated that there will be no Y2K problems with the production of radioactive generators and other radiopharmaceuticals by reputable manufacturers. However, a key issue, not within the control of the nuclear medicine user, is the transportation of the radiopharmaceuticals to the nuclear medicine department. If they do not arrive on time there will be inconvenience and delay to the patient and frustration to the staff but no radiation hazard.

#### 5.3.3.2. Handling of unsealed sources

The only possible problem that can be anticipated in this area would be due to a failure in the supply of electricity and water to the facility for the handling and preparation of radiopharmaceuticals, e.g. a breakdown of the air conditioning system.

# 5.3.3.3. Administration of radiopharmaceuticals

The only area of concern would be a malfunction of the activity meter/dose calibrator. In such a case, manual decay based calculations will have to be performed in accordance with the body weight of the patients.

# 5.3.3.4. Radioactive waste

Usually, discharges of waste are, in practice, controlled by using a simple monitor, which is related to the activities of the radionuclides involved. Therefore, no significant Y2K problems are anticipated for the handling of radioactive waste in nuclear medicine. In case of doubt, the time of temporary storage should be extended.

#### 5.4. Radionuclide therapy with unsealed sources

In view of the possible effects of the Y2K problem on administrative routines discussed above, it will be essential to correctly identify the patient prior to the administration of the therapy dose and to confirm that the dose is correct. If in any doubt, the procedure must be postponed until Y2K issues have been resolved.

#### 5.5. Communication with other imaging modalities

When different computers and/or imaging modalities are connected in a network, and one or more components experience a Y2K problem, this will cause a disruption in the network ranging from complete breakdown to incorrect or confused processing of data. For example in multimodality imaging, images of different patients, or images taken on different dates, may be wrongly compared.

#### 5.6. Contingency planning

An increasing awareness of and training in the manual procedures in nuclear medicine and diagnostic imaging is recommended as we approach and enter the new century, so that these procedures can be implemented if the automatic/computerized procedures should fail due to a Y2K problem.

Greater emphasis should increasingly be placed on checking and confirming patient information, image data, calculated parameters and reports.

If in any doubt, it is recommended as a general rule that the procedure or examination be postponed until all necessary data are confirmed correct.

A backup and/or hard copies of relevant records such as an inventory of radioactive sources and radioactive waste in the nuclear medicine department should be done.

# 6. DOSIMETRY EQUIPMENT AND RADIATION MEASUREMENTS

# 6.1. Prepare an inventory of equipment

- 1. Electrometers with ion chambers (standard and field dosimeters, well chambers, etc.).
- 2. TLD systems (reader, annealing system, printer, registration software).
- 3. In vivo dosimetry system (solid state detectors, etc.)
- 4. QC equipment (daily dose monitors, phantoms for energy stability checks, etc.)
- 5. Radiation beam scanners (water phantom, in-air scanner, etc.)
- 6. Survey meters
- 7. Radiation monitors and connected data loggers
- 8. Personal dosimetry system (direct ion storage, etc.)
- 9. Film densitometer
- 10. Film processor
- 11. Source calibrator.

*Note:* the above is not intended as a complete list as some other equipment may be used.

#### 6.2. Potential hazards of Y2K isues

- 1. Incorrect dose measurement (due to sensitivity correction based on reference source measurement, incorrect temperature and pressure correction due to microchip malfunction, incorrect TLD measurement due to incorrect annealing process controlled by chip).
- 2. Incorrect machine calibration (as a result of the defective dose measurement and/or data misinterpretation).
- 3. Incorrect date/time stamping.
- 4. Disruption of interfaces (communication with other devices).
- 5. Incorrect presentation of the measurement (registry overflow).

#### 6.3. Establish priorities for testing

Based on the above, establish the priority for the test. The most critical equipment shall be tested immediately. For the affected equipment, implementation of the Y2K solution shall be implemented with the highest priority before the end of 1999.

Readers are reminded that the classification in terms of significance and probability (Section 2.5) can vary from one institution to another due to a different clinical practice and

different equipment available. The final classification is ultimately the responsibility of the user.

This report therefore cannot give any specific recommendation regarding the classification. To help with the classification, Table III gives examples of potential problems.

| Equipment                                     | Incorrect dose<br>measurement | Incorrect machine calibration | Incorrect date/time stamping | Disruption of<br>interfaces | Incorrect presentation of the measurement |
|---|-------------------------------|-------------------------------|------------------------------|-----------------------------|---|
| Electrometers with ion chambers               | yes                           | yes                           | no                           | yes                         | yes                                       |
| TLD systems                                   | yes                           | no                            | yes                          | yes                         | yes                                       |
| In vivo dosimetry system                      | yes                           | no                            | yes                          | yes                         | yes                                       |
| QC equipment                                  | yes                           | no                            | yes                          | yes                         | yes                                       |
| Radiation beam scanners                       | yes                           | yes                           | yes                          | yes                         | yes                                       |
| Survey meters                                 | no                            | no                            | yes                          | yes                         | yes                                       |
| Radiation monitors and connected data loggers | no                            | no                            | yes                          | yes                         | yes                                       |
| Personal dosimetry system                     | yes                           | no                            | yes                          | yes                         | yes                                       |
| Film densitometer                             | yes                           | no                            | yes                          | yes                         | yes                                       |
| Film processor                                | no                            | no                            | yes                          | no                          | yes                                       |
| Source calibrator                             | yes                           | yes                           | yes                          | yes                         | yes                                       |

TABLE III. ADVICE FOR DEVELOPING PRIORITIES FOR TESTING DOSIMETRY EQUIPMENT

# 6.4. Testing procedures

Warning: before starting any test procedure, please read carefully Section 2.6.

It may not be possible to conduct all the tests listed in the examples below.

Perform the tests as described in Section 2.6 in conjunction with QA programmes already implemented. If an appropriate QA programme has not been implemented yet, it is strongly recommended that such procedures be created to check the correct operation of the unit. These tests do not necessary cover all the potential problems which may occur.

# Examples

- 1. Film dosimetry. Expose a film with known dose distribution. Perform the evaluation at the end of the year 1999 and repeat it after 1 January 2000. Compare the results, look for differences.
- 2. Any system using time/date stamping. Check if the system can correctly sort data by date (does it recognize that the year 2000 follows the year 1999).
- 3. Dosimeters with built-in correction capabilities. Take a reading with the reference source and compare the result with a tabulated data. If systems perform a correction for temperature and pressure, check the value calculated by the dosimeter versus hand calculation.

# 6.5. Problems related to work-around solutions

Examples of potential hazards for some work-arounds are mentioned in this section. The reader is reminded that this is not intended to be a full list.

- 1. When resetting the date to an earlier one, consider the possibility that:
  - there is a possibility that the veracity of the database will be lost,
  - there may be potential problems in the interfacing with other devices, if the software is detected as being outdated.
- 2. Discontinuing the use of an old database and developing a new one:
  - when data histories are discontinued, there is the potential for misinterpretation of results.

#### 6.6. Contingency plan

A contingency plan shall take into account all the procedures performed and the typical workflow of the department. Items listed below can be used to create an individual contingency plan for a particular location.

- 1. Consider borrowing equipment to use for backup purposes.
- 2. Evaluate all measurements done in 1999 before the end of the year to prevent transition period problems.
- 3. Backup log files before the end of 1999 to prevent data losses if the system fails.
- 4. Plan to conduct calibration procedures shortly before the end of 1999.

# 7. OBSERVATIONS AND RECOMMENDATIONS OF THE WORKSHOP

- 1. Only a few Member States (Argentina, Australia, Bulgaria, China, Cyprus, the Czech Republic, Finland, Greece, Italy, Lithuania, Peru, Sweden and the USA) participated in the International Workshop, and in some of these countries significant preparations have been made for Y2K. Some Member States which did not participate in the International Workshop and which have considerable numbers of computer programs that are not supported by manufacturers and therefore need to take preventive measures may have made little or no preparations for Y2K. The issue is one of great significance and urgency; if adequate preparations are not made, the risk exists of patients receiving incorrect treatments (overdoses or underdoses) or incorrect diagnoses, resulting in compromised medical care or even injury.
- 2. Adequate time exists for hospitals to prepare for the transition and to take preventive measures to avoid accidental exposures, but if preparations are not already under way they should be started immediately.
- 3. It is recommended that hospital administrators set up task forces and schedules based on the International Workshop's report and schedules for reporting progress to responsible hospital officials and to regulatory authorities.
- 4. In order to facilitate the setting of priorities and the allocation of resources, the International Workshop's report contains by way of example lists of possibly affected items used in the various areas of application of radiation in medicine, lists of possible events resulting from the Y2K issue, classifications of items and events according to severity (clinical significance) and probability, suggestions as to procedures to be followed and precautions to be taken in evaluating, remediating and testing, suggestions as to simple generic tests, and a list of subjects to be covered by contingency plans. However, it should be noted that the examples given in the report are only of a generic nature and not exhaustive, and cannot be specific to individual pieces of equipment and software. It is the responsibility of each State to ensure that all its equipment is Y2K compliant.

# Appendix I CRITICAL DATES (from IAEA-TECDOC-1074)

The Y2K problem revolves around the inability of some systems to handle not only the date 1 January 2000, but also the other critical dates listed below:

- **22** August 1999: this date is a problem for system which interface with the Global Positioning System (GPS), for example, the transport of nuclear fuel, where knowledge of its location is important. The original GPS design allocated a 10 bit register to handle the number of weeks elapsed since the base date (or GPS epoch date) of 6 January 1980. The 10 bit week counter will rollover from its maximum value to zero on 22 August 1999.
- 9 September 1999 (9/9/99): as in the case of 1 January 2000, this date is a problem for computer based systems that handle the year of a date with only two digits and that use the number 99 (or 9999) as an end-of-file marker or "STOP" code.
- **1 January 1999**: this date is a problem for computer based systems that handle the year of a date with only two digits because they may misread 00 as the year 1900 instead of the year 2000.
- **29 February 2000**: this date is a problem for computer based systems that do not correctly identify the year 2000 as a leap year and risk failure at 29 February 2000, because it is a leap day.
- **1 March 2000**: this date is a problem for computer based systems that do not correctly identify the year 2000 as a leap year and therefore do not recognize 29 February 2000 as a leap day. 1 March 2000 is the day after the leap day and these systems may carry erroneous data.
- **31 December 2000**: this date is a problem for computer based systems that do not correctly identify the year 2000 as a leap year and risk failure at 31 December 2000, because it is the 366<sup>th</sup> day.
- **1 January 2001**: this date is a problem for computer based systems that do not correctly identify the year 2000 as a leap year and may carry erroneous data on 1 January 2001, because it is the day after the 366<sup>th</sup> day (31 December 2000).

#### Appendix II FLOW CHART SHOWING SUGGESTED TIMELINE FOR IMPLEMENTATION OF ACTION PLAN



#### Notes regarding the flow chart:

- 1. Start contingency planning at an early stage in the Y2K procedure. This will be a dynamic process, as the contingency plan will be updated as the work on testing will progress.
- 2. Send a request for a "Certificate of Y2K Compliance" to the vendors as soon as possible, as it may take some time to receive an answer.
- 3. Keep in mind that a vendor's implementation may be delayed, depending on motivation, your location, and the status of a service agreement.
- 4. It is recommended that the Y2K procedure be completed by the middle of December, 1999, as finalizing work at the end of the year is often difficult.
- 5. The timeline provided here is only an estimate and will vary from one institution to another due to the variety of equipment and clinical practice used.
- 6. The timeline is expressed as a percentage of work completed. The available time from the start of work until the middle of December should be allocated carefully to the project, to avoid postponing work until close to the transition date.

### **Appendix III** LIST OF ITEMS TO INCLUDE IN INVENTORY OF EQUIPMENT

(*Note: this list is not exhaustive*)

#### Large computerized medical examination devices

Computed tomographic Magnetic resonance imaging Ultrasonographic Nuclear medicine Angiographic Digital fluoroscopy Radiotherapy treatment units Radiotherapy simulators HDR treatment units Ancillary systems Computed radiography PACS workstations PACS archive and controller devices Teleradiology systems Contrast media injectors Filming and film processing devices Radiotherapy treatment planning systems Isotope calibrators **Information systems** Radiology information systems PACS Record and verify systems Dictation equipment Billing, payroll, and other financial systems Systems with embedded chips Faxes Photocopiers Infusion pumps (contrast material or medication) Anesthesia systems Physiologic monitoring devices Defibrillators Video recorders Personal computers (Note: processes and tools available online) Hardware Operating systems Software (particularly spreadsheets and databases) Peripherals (e.g., independent bar-coding devices, printers, storage devices) Interdependencies (listed as though they were entities) Radiology information system interfaces to PACS Radiology information system interfaces to medical information systems Treatment planning interfaces to R&V Simulator interfaces to R&V Interfaces to third party payers Electronic links to suppliers

#### Lower risk systems (may have embedded microprocessors)

Non-computerized units Plain, portable radiography Multiviewers X ray treatment units Cobalt teletherapy units

# Systems outside your immediate control

Environmental and safety systems (e.g., security locks) Fire alarm systems (detection, sending, receiving, fire suppression) Telecommunications, phones, paging Networks Power and lighting (including emergency backup generators) Heating, ventilation, and air conditioning Water Natural gas Elevators, uninterruptible power suppliers

#### Appendix IV INFORMATION TO BE COLLECTED FOR EACH PIECE OF EQUIPMENT

Department and other location information **Responsible individual in department** Item type (record interfaces as separate items) Item name Information to collect about each item Model number (include components if upgraded, etc.) Software and operating systems versions Location Network port connections Vendor name Vendor contact name, address, phone, fax, e-mail Vendor compliance claims or status of remediation Maintenance contracts Upgrade or replacement plans Developed or modified in-house? Source code available? Individuals responsible for maintenance? Relevant technical information from other sources Data to assess after collecting above information Risk of year 2000 susceptibility Priority level Estimated cost of remediation Estimated time to remediate Data to record as project proceeds Decision to retire, repair, or remediate Actual remediation costs Testing process applied Testing results Problems encountered Redeployment date Supplier information (collect data on vendor compliance) Film and chemicals Radioactive sources Contrast material Catheters and other interventional devices **Emergency medications** Parts to maintain equipment Other general hospital supplies

#### Appendix V INTERNET WEBSITES FOR Y2K INFORMATION

The following Websites were operational at the time of writing of this report. (Much of this list was taken from United States Nuclear Regulatory Commission Information Notice 99-18.) No endorsement is implied by the inclusion of a site in this list, nor is the exclusion of a site to be interpreted as a judgement of the quality of the site. The reader is reminded that many of these sites are commercial, and the information contained must be evaluated with care.

- 1. The American Hospital Association conducted a survey of hospital Y2K readiness status. The results of the survey can be found at the American Hospital Association's Website: <a href="http://www.aha.org/y2k>">http://www.aha.org/y2k></a>
- 2. The American Medical Association Website has Y2K information for the medical community: <a href="http://www.ama-assn.org/not-mo/y2k/index.htm"></a>
- 3. The National Institute of Standards and Technology (NIST) Y2K webpage includes Y2K test programs for small businesses, free software, Y2K standards, Y2K compliance and testing, Y2K hot lines, and Y2K slide shows: <a href="http://www.nist.gov/y2k">http://www.nist.gov/y2k</a>. At the NIST Website for small business, "The Conversion 2000: Y2K JumpStart Kit" for jump-starting a Year 2000 project is available. Also, action planning, assessment, and remediation project planning workshops are available: <a href="http://y2khelp.nist.gov/">http://y2khelp.nist.gov/</a>
- 4. The Federal Communications Commission Website provides information regarding the effects of Y2K on the communications and broadcasting industry. <a href="http://www.fcc.gov/year2000/>"></a>
- 5. The Food and Drug Administration has placed reports of Y2K-compliant and noncompliant medical devices on its Website. The reports are organized by manufacturer: <a href="http://www.fda.gov/cdrh/yr2000/year2000.html">http://www.fda.gov/cdrh/yr2000/year2000.html</a>
- 6. The General Accounting Office has placed Y2K reports on assessment, testing, and contingency planning on its Website: <a href="http://www.gao.gov/y2kr.htm"></a>
- 7. The Health Care Financing Administration has placed Y2K information for health care claim repayments for Medicare, Medicaid, and Child Health Insurance Programs on it Website. The site also includes the Y2K status of health care facilities, Y2K activities, and Y2K help for health care facilities: <a href="http://www.hcfa.gov"></a>
- 8. The Institute of Electrical Engineers' Y2K Website provides information on embedded systems. The site explains the use of Y2K risk management techniques: <a href="http://www.iee.org.uk"><a href="http://www.iee.org.uk"><a href="http://www.iee.org.uk"><a href="http://www.iee.org.uk"></a>
- 9. The intraVision Website provides links to oncology and radiology commercial sites: <a href="http://www.intravsn.com/vendors.shtml"><a href="http://www.intravsn.com/vendors.shtml"><a href="http://www.intravsn.com/vendors.shtml"></a></a>
- 10. The International Atomic Energy Agency Website provides Y2K information for nuclear safety, waste management, medical facilities, safeguards, and physical protection: <a href="http://www.iaea.org/worldatom/program/y2k">http://www.iaea.org/worldatom/program/y2k</a>
- 11. The North American Electric Reliability Council Website provides information and guidance on the effect of the Y2K on the electricity supply for North America: <a href="http://www.nerc.com"></a>
- 12. The Nuclear Regulatory Commission Website provides the status and findings of NRC's Y2K program which includes nuclear power plant audits, Information Notices, Generic Letters, and Y2K links: <a href="http://www.nrc.gov/NRC/NEWS/year2000.html">http://www.nrc.gov/NRC/NEWS/year2000.html</a>
- 13. The President's Council on Year 2000 Conversion Website has information regarding Y2K and the Federal government's efforts to prepare its computer systems, links to

information on Y2K compliance for crucial sectors of the economy, and other Y2K resources. In addition, the Council has established a Y2K consumer information line at 1-888-USA-4-Y2K, which provides free Y2K information to the public. <<u>http://y2k.gov></u>

14. The Radiation and Health Physics Website provides links to radiation detection device manufacturers and dosimetry companies:

<http://www.sph.umich.edu/group/eih/UMSCHPS/commercial/>

- 15. The Rx2000 Website is devoted to Y2K medical issues. The site has a pay section and a free section. Information found in the free section includes a provider preparedness model and comparator, Rx2000 list server and discussion forum, health care Y2K articles and publications, Rx2000 downloadable presentations, links, and health care Y2K self-help materials: <a href="http://www.rx2000.org">http://www.rx2000.org</a>>
- The Small Business Administration Website provides Y2K help for small businesses. The site includes Y2K materials, Y2K activities, and links to other sites: <a href="http://www.sba.gov/y2k"></a>
- The United Kingdom Year 2000 Website provides Y2K information on software compliance. The reports are organized by manufacturer:
  <a href="http://www.open.gov.uk/bug2000.htm">http://www.open.gov.uk/bug2000.htm</a>>
- 18. The Department of Veterans Affairs (VA) Website provides Y2K information and contingency planning for hospitals and the status of VA Y2K efforts: <a href="http://www.va.gov"></a>
- 19. A Website in New Zealand containing Y2K information is: <a href="http://www.year2000.co.nz"></a>
- 20. A commercial Website with Y2K information is: <a href="http://www/datamation.com"></a>

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# ABBREVIATIONS

| CT<br>ERD<br>HDR<br>IMRT<br>MLC<br>MRI<br>MU<br>PACS<br>PDR<br>PET<br>QA<br>QC<br>RBE<br>RTPS | computer tomography<br>extrapolated response dose<br>high dose rate<br>intensity modulation radiotherapy<br>multileaf collimator<br>magnetic resonance imaging<br>monitor unit<br>picture archiving systems<br>pulsed-dose rate<br>positron emission tomography<br>quality assurance<br>quality control<br>relative biological effectiveness<br>radiation treatment planning system |
|---|---|
|   | 1 0   |
| RTPS  | radiation treatment planning system   |
| TDF   | time dose fraction  |
| TLD   | thermoluminescence dosimetry  |
| TPS   | treatment planning system   |
|   |   |

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