IAEA-TECDOC-1074

Safety measures to address the year 2000 issue at medical facilities which use radiation generators and radioactive materials

March 1999

The originating Section of this publication in the IAEA was:

Radiation Safety Section International Atomic Energy Agency Wagramer Strasse 5 P.O. Box 100 A-1400 Vienna, Austria

SAFETY MEASURES TO ADDRESS THE YEAR 2000 ISSUE AT MEDICAL FACILITIES WHICH USE RADIATION GENERATORS AND RADIOACTIVE MATERIALS IAEA, VIENNA, 1999 IAEA-TECDOC-1074 ISSN 1011–4289

© IAEA, 1999

Printed by the IAEA in Austria March 1999

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.

The IAEA Secretariat convened a group of consultants who met in Vienna from 14 to 18 December 1998 and produced this report. The consultants decided that the report should cover not just "medical facilities which use radioactive materials" but also medical facilities which, while perhaps not using radioactive materials, use ionizing radiation produced by radiation generators such as accelerators.

The reports issued together are: Achieving Year 2000 Readiness: Basic Processes; Safety Measures to Address the Year 2000 Issue at Medical Facilities Which Use Radiation Generators and Radioactive Materials; and Safety Measures to Address the Year 2000 Issue at Radioactive Waste Management Facilities. This report addresses means of dealing with the Y2K problem at medical facilities which use radiation generators and radioactive materials.

The IAEA is grateful to G. Ibbot (United States of America) for his contribution to the preparation of this report. The responsible IAEA officer 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.

The mention of names of specific companies or products (whether or not indicated as registered) does not imply any intention to infringe proprietary rights, nor should it be construed as an endorsement or recommendation on the part of the IAEA.

CONTENTS

1. INTRODUCTION	1
2. APPROACH TO THE YEAR 2000 PROBLEM	2
 2.1. Initial assessment 2.2. Detailed assessment (including testing) 2.3. Remediation (including testing) 2.4. Alternatives to replacing or upgrading the system	4 5 5 6
2.4.2. Stop using the system2.5. Contingency planning	
3. PROBLEMS COMMON TO ALL AREAS	
3.1. Radiation dose calculations	
3.2. Patient scheduling	
3.3. Problems related to dates other than 1 January 20003.3.1. Leap year	7
3.3.2. September 1999	
3.3.3. Future years	
4. EXTERNAL BEAM RADIATION THERAPY	8
4.1. Treatment planning and dose calculations for isotope teletherapy units 4.1.1. Assessment	
4.1.2. Testing	9
4.1.3. Remediation	
4.2. Accelerator control systems	
4.3. Assessment	
4.3.2. Remediation	
4.4. Quality control systems	
4.4.1. Assessment	11
4.4.2. Testing	
4.4.3. Remediation	
4.5. Record and verify systems	
4.5.1. Assessment	
4.5.2. Testing 4.5.3. Remediation	
4.6. Radiotherapy simulators and computed tomography (CT) simulators	
4.7. Calculations of biological effectiveness	
5. BRACHYTHERAPY	14
5.1. Dose calculation	15
5.1.1. Assessment	
5.1.2. Testing	
5.1.3. Remediation	
5.2. Inventory of sources	
5.3. Treatment schedules for fractionated brachytherapy	
5.4. Radioactive waste	17

6. NUCLEAR MEDICINE (IMAGING)	17
6.1. Assessment6.2. Testing6.3. Remediation	
7. THERAPY WITH UNSEALED SOURCES	19
8. ENDOVASCULAR BRACHYTHERAPY	19
9. DOSIMETRY EQUIPMENT AND RADIATION MEASUREMENTS	20
9.1. Assessment9.2. Testing9.3. Remediation	20
10. CONCLUSIONS AND RECOMMENDATIONS	21
10.1. Conclusions	
ANNEX: CRITICAL DATES	23
REFERENCES	24
CONTRIBUTORS TO DRAFTING AND REVIEW	25

1. INTRODUCTION

Passage into the year 2000 has the potential to disrupt a number of computer services, in manners ranging from the mundane to the potentially life threatening. That the year 2000 (Y2K) issue exists at all is a result of efforts by computer programmers to reduce the space required to store dates. For many years it was customary to store only two digits to represent a year (e.g. 84 for the year 1984), with the understanding that dates always fell in the range 1900 to 1999. It was generally assumed that "someone" would implement a solution before the year 2000. As is now generally well appreciated, this has not been the case, and computer users all over the world are therefore facing the task of assessing the extent of the problems associated with the Y2K issue in their own lives and businesses — implementing solutions provided by manufacturers of computers and computer based systems or developing their own solutions.

There are further date problems associated with the application of computer based systems (see Annex). It may happen that the year 2000 is not correctly identified as a leap year with the risk of failure on 29 February 2000 or 31 December 2000, which is the 366th day of that year. Other critical dates are even earlier, for example, 22 August 1999 or 09 September 1999 (9/9/99). The first date may be important for systems involving the Global Positioning System (GPS), for example, in the transport of radioactive waste. The second date is important for systems handling the year with two digits because 99 (or 9999) was used as an end-of-file marker or "STOP" code. Such date related problems are simply referred to as "year 2000" or "Y2K" problem.

Many industries are finding that they are inadequately prepared for the year 2000, and predictions have been made of disastrous consequences. Some of these predictions are exaggerated, of course, but many are not.

It is expected that some countries will experience failures of their electrical power systems, for example, because of computer errors that will occur after 31 December 1999. At medical facilities, the potential for harm is no less serious. Many medical procedures are controlled or assisted by computers, proper medical care often being dependent on the correct interpretation of dates.

The IAEA was requested by a resolution of the General Conference in September 1998 [1] to deal with the Y2K problem and act as a focal point of contact for Member States to exchange information regarding diagnostic and remedial actions being taken at nuclear power plants, fuel cycle and/or medical facilities which use radioactive materials to make these facilities year 2000 ready. The IAEA, among other activities, is developing a set of reports [2, 3] including the present report.

The Y2K issue, sometimes referred to as the 'millennium bug', stems from a computer's inability to make the transition properly from 31 December 1999 to dates further in the future. In its simplest manifestation, the resulting problem may appear as the interpretation of "00" as representing the year 1900 rather than the year 2000. A program that calculates a patient's age by subtracting the birth date from the current date might behave unpredictably on 1 May 2000 when calculating the age of a patient born on 23 March 1949, for example. More insidiously, a similar error might result in the accidental exposure of a patient to radiation or in the delivery of an incorrect dose — either too small or too large.

In medicine, Y2K problems may put patients' lives at risk, as well as cause confusion and inefficiency, because of errors associated with:

- the use of dates for the calculation of correction factors such as radioactive decay;
- the use of dates for storing, retrieving or displaying data.

In both cases, the errors resulting from the Y2K issue can be very serious, and one cannot assume that any computer system is immune until it has been tested thoroughly.

This report addresses the likely impact of the Y2K issue in medicine. In particular, the fields of radiotherapy, nuclear medicine and medical physics have been considered. A large variety of computer systems and subsystems of many manufacturers are in use in medicine; in addition, many computer systems for treatment or imaging have been developed in-house. Consequently, it is impractical for a report such as this to give specific advice or instructions. A recipe or protocol might be suitable for some types of equipment, but unsuitable — or even misleading — for others. Instead, general methods are provided for the assessment and identification of problems, the performance of initial testing and the development of appropriate remediation.

In this report, dates are presented in several different formats intentionally in order to illustrate the variety of formats used throughout the world. An indication is given of the potential for error should the intended date be misunderstood. The term 'computer system' is used to describe a combination of computers and other devices supporting a specific application. A 'computer network' is the hardware and software that ties two or more computers or computer systems together, over either a short or a long distance.

2. APPROACH TO THE YEAR 2000 PROBLEM

Essential to any Y2K investigation is a thorough analysis of the extent of the problem. It is tempting to dismiss Y2K problems as those that will be experienced only by governments, banks, big industrial concerns and the like. However, preliminary assessments have shown that serious problems can occur in medicine as a result of the 'millennium bug'. In many cases, of course, manufacturers of medical equipment will by now have ensured that their equipment is Y2K compliant, but in some cases the manufacturer may require customers to purchase upgraded hardware or software. In some cases, the manufacturer may no longer be in business, or for other reasons may not be willing or able to provide a solution.

It is incumbent upon hospital directors, department administrators and medical practitioners:

- to evaluate the problem thoroughly, by identifying departments and procedures that can be affected and by anticipating the consequences of the problem;
- to conduct comprehensive tests of all systems with the potential to be affected;
- to determine whether the manufacturer has developed a programme for Y2K remediation or, for some reason, is not able to address the problem;
- to develop and implement solutions for each affected computer and computer system;
- to conduct final testing to evaluate the effectiveness of the solution.

Above all, the following questions should be asked: Could a patient or employee receive an accidental radiation exposure? Is it possible for a patient to receive an incorrect treatment? Could a patient receive substandard, incomplete or incorrect medical care? Could there be a loss of or damage to patient records? This report recommends a strategy for Y2K readiness based on that set out in Ref. [2], but elaborated to accommodate the specific variety of activities performed in medical uses of radiation generators and radioactive materials. The Y2K strategy emphasises the essential elements, explains their importance and provides guidance for accomplishing the programme. The programme consists of four principal phases:

- Initial assessment;
- Detailed assessment (including testing);
- Remediation (including testing); and
- Contingency planning.

Regulatory authorities are responsible to monitor and ensure compliance with Regulations [4], and should therefore ensure that licensees are aware of the Y2K issues and are responding effectively. The licensee is responsible for the implementation of the Y2K programme.

2.1. Initial assessment

The purpose of this initial assessment is to establish an inventory of items that are required to be reviewed, determine the importance of each item to the facility and schedule those items that require further analysis during detailed assessment. Initial assessment is the first step toward accomplishing the Y2K readiness of each item.

The first step in the initial assessment phase is to establish a "Preliminary Inventory". This Preliminary Inventory establishes, by careful examination of the equipment and software whether there are any items that are date sensitive. At the end of this initial review it should be clear which facilities do or do not have computer-based systems in them and potential hazards identified.

Once this first step has been initiated and information becomes available on the equipment and software in the facility, each item that is potentially date sensitive can be "classified". Classification determines whether an item is to be included. At the end of the classification a grouping is recommended into categories that are related to the consequences.

In a medical facility, computer systems can be classified into the three categories listed below (this will prepare the facility for the next stages — testing of the equipment for modes of failure, the implementation of remediation processes and ongoing testing to ensure future Y2K compliance):

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

2.2. Detailed assessment (including testing)

The purpose of detailed assessment is to obtain or generate sufficient information about an item to determine its expected behaviour on critical dates. Detailed assessment results are used to make decisions regarding remediation and/or contingency planning.

There are two main steps to completing the detailed assessment. Firstly, information should be sought from the vendors on the item with regard to its date sensitivity. The vendor's willingness and qualification to support the facilities Y2K programme should be evaluated, with the aim being to determine whether the vendor will participate in the evaluation and provide certification of an item's performance. A vendor's unwillingness or inability to support the Y2K programme may have significant implications for the way in which investigation tests or remediation can be carried out.

The second step in the detailed assessment is an evaluation of the item's sensitivity to the critical dates. In the situation where the vendor has provided information a verification of the validity of the information, as it relates to the specific item, should be arranged by the operator of a facility or activity. Where this is carried out by the vendor, it should be checked by the operator.

Where the hospital is not able to obtain information from the vendor or involve the vendor in conducting the evaluation the hospital should carry out a formal evaluation and arrange for this to be tested.

As described above, the 'millennium bug' results from a computer's inability to correctly recognize or interpret dates beyond 31 December 1999. Testing for Y2K compatibility therefore generally requires that attempts be made to enter dates in the year 2000 and beyond. As a general rule, computers and other devices are *not* Y2K compliant if they have no capability for displaying — or allowing the entry of — dates with four digits to identify the year (for example, 31/12/1999) because they cannot distinguish between the year 2000 and other increments of 100 years — for example, the year 1900.

For the most part, computers that restrict the representation of a year to two digits make the assumption that the year falls within the 20th century.¹ Therefore, a date entered as "00" will be interpreted as 1900, "50" means 1950 and "99" means 1999. This is not always the case, and one must be aware that some computers interpret "00" in other ways. Some early desktop systems use "00" to represent the date 4 January 1980 and may revert to this date after 31 December 1999, or if the internal battery runs down.

It is not always as easy as one might think to test a computer's ability to recognize dates beyond 2000. When dealing with individual desktop computers that are not connected to a network, the test may be straightforward. Experiencing a failure when attempting to set the system clock to any date in the year 2000 may indicate that the system software is not Y2K compliant. Simple tests can be devised to simulate the effect on a computer of a date change from 1999 to 2000. For example, by setting the system clock to a date in January 2000, one can instruct the computer to calculate the elapsed days from a date in December 1999.

Similar tests must be conducted with each piece of software. However, with computers that are connected to other equipment, either directly or across networks, the procedure may

¹ For the purposes of this report, the term '20th century' is used to describe dates between 1900 and 1999.

be more complicated. Resetting the date on a single PC may not reset the clock on a network server, and may not test the Y2K compliance of the entire system. Other system components may confuse or mask the behaviour. The communication protocol being used by the network should be considered. In medical imaging networks, the use of DICOM-3 or DICOM-RT may demonstrate the Y2K compliance of the image transfer processes, but it may not ensure that all computers and functions associated with image manipulation handle dates correctly.

The user should ensure that tests that involve changing the system date also evaluate the computer's retention of the data. It is possible that the computer may properly recognize dates in the 21st century until it is switched off or rebooted. Therefore, after changing the system date, the user should switch the computer off, then back on, and then repeat the Y2K compliance tests.

With some computer systems, the entry of a date beyond 31 December 1999 may cause irreversible damage to or a loss of data. Before any tests are conducted, a backup of all software should be made so that the system can be restored if necessary. Comprehensive testing should be performed as much as possible 'off-line' so that important hospital functions are not disrupted.

2.3. Remediation (including testing)

The purpose of remediation is to address the failure modes identified in the detailed assessment. During remediation the Programme Manager should track the timeliness of purchased material delivery and the progress of conversions, replacements, deletions, retirements and vendor efforts. Remediation efforts that are not timely require Programme Manager attention.

Once an item has been determined to be susceptible to Y2K failures or that there is a likelihood of failure, a remediation strategy should be selected. Once a computer system has been found to be — or is suspected of being — susceptible to Y2K problems, the first step should always be to contact the manufacturer. In many cases, the manufacturer will be able to provide a certificate of compliance for the system or its components. Many manufacturers of medical computing systems have anticipated the Y2K issue and have already developed software updates. Another benefit of dealing with the system manufacturer is that he is best able to consider the interactions between different components of the system.

The manufacturer of the system may not be able to address Y2K problems, either because he is no longer in business or because he no longer supports the system. In this case, it may be necessary to contact the manufacturers of individual system components. However, these manufacturers may not know of problems that result from interactions among components. In this case, the hospital must confirm that upgrades and 'bug fixes' are compatible and that the desired result is achieved.

2.4. Alternatives to replacing or upgrading the system

Finally, there may be economic reasons or other constraints that prevent the hospital from obtaining a solution from the developer of the computing system or the manufacturer of the components. It is the normal policy of manufacturers to support products for a reasonable period after production, say ten years. However, cases are known of manufacturers who have

simply notified their customers that existing systems (even recently released ones) are known not to be Y2K compliant, have been declared obsolete and will not be supported. In these circumstances, the hospital must use its own resources in seeking solutions to Y2K problems. Such solutions fall into the following categories:

2.4.1. Implement a 'work-around'

Although work-around is not a preferred remediation strategy it may be the only pragmatic reality. The hospital should analyse any work-arounds to ensure they are achievable and safe. Consideration should include failure modes, interaction effects and consequences of failure upon staff resources.

There may be administrative solutions that can be implemented as alternatives to replacing or upgrading the affected system. For example, under circumstances in which dates are used only prospectively, the hospital might institute a policy that all dates represent the 21st century. In other words, '00' would always mean 2000 and '99' would always mean 2099. Of course, this procedure precludes any further use of dates in the 20th century, but it may be satisfactory in some cases.

Extreme caution should be used if this method is implemented, as unforeseen difficulties may result. For example, failure to follow the new policy may lead to re-emergence of the problem, perhaps with catastrophic consequences. In its documentation, Microsoft states that Windows 95 is Y2K compliant 'with minor issues'. This indicates that under some circumstances, possibly with third party software, dates may not be handled correctly. The use of a 'work-around' as recommended here should not be attempted without a full investigation of such 'minor issues'.

2.4.2. Stop using the system

In some cases, the manufacturer may not be available or may be incapable of making a correction, or the system may be so out of date that a correction is not possible. Under some circumstances, there may be economic barriers to effecting a solution. In these situations, there may be no option but to stop using the system. Naturally, this may mean reverting to manual techniques or dispensing with a procedure entirely.

2.5. Contingency planning

Contingency planning is an integral activity to the Y2K programme. Contingency planning is a process that may begin at any time subsequent to the initial assessment and may continue throughout the programme.

If a system can not be made Y2K compliant, and therefore its use has to stop, specific provisions will have to be planned and implemented to dispense with the system. This may involve the use of manual procedures or dispense with a procedure, which in turn, may need to change the strategy in patient management. Any of these decisions need careful planning, provision of resources, detailed procedures and protocols, formal documentation and testing to ensure that safety is not compromised when implementing the contingency plan.

3. PROBLEMS COMMON TO ALL AREAS

Some of the problems associated with the Y2K issue are limited to specific procedures or activities, and they are addressed individually in the sections which follow. However, some Y2K problems may occur in many — if not all — departments of a hospital. The problems common to several or many activities involving the use of radiation and radioactive materials are addressed here.

3.1. Radiation dose calculations

Calculations of radiation dose are most likely to be affected by the 'millennium bug' when they involve the calculation of elapsed time. In particular, this will occur when corrections are being performed for the decay of a radionuclide. For example, systems that recognize the two-digit year '00' as 1900 are unlikely to account for decay correctly between 1999 and 2001, and may calculate the elapsed time to be –98 years rather than +2 years. In the treatment of cancer patients with a cobalt-60 unit, such an error could result in the incorrect calculation of a treatment time, with the result that the patient receives the wrong dose. Similarly, the rate of decay of radioactive waste could be overestimated, leading to radioactive releases exceeding authorized levels.

3.2. Patient scheduling

An almost unlimited number of potential problems associated with patient scheduling may result from Y2K incompatibility. These all stem from the inability of computer systems either to correctly represent dates beyond 1999 or to correctly calculate the elapsed time between dates. Some possible problems:

- Appointments after 31 December 1999 cannot be scheduled.
- Patients to whom radiopharmaceuticals have been administered for uptake studies are not given future appointments for the evaluation of uptake. The procedure may have to be repeated, resulting in the administration of a radiation dose from which the patient receives no medical benefit.
- The synchronization of procedures to be applied in combination may not be accomplished properly. For example, many patients receive combined radiation therapy and chemotherapy in accordance with a schedule. Failure to arrange for an appointment for one of the procedures may compromise the treatment.
- Automatically generated reminders of future appointments fail to materialize, and patients are not informed. Patients may miss recommended periodic visits for checkups.
- Appointments for follow-up visits (e.g. to re-evaluate suspicious findings) are not made. Patients may experience an undetected progression of the disease.

3.3. Problems related to dates other than 1 January 2000

Other date related problems that are peripherally connected with the Y2K issue can occur with computer systems used in medicine.

3.3.1. Leap year

The year 2000, which is a leap year, is unusual in that some of the standard tests used by computers to identify leap years will fail. Even systems that are reported to be Y2K compliant may not properly recognize the existence of 29 February 2000, and may not correctly calculate intervals between dates spanning this date.

3.3.2. September 1999

Some programers used the date 9/9/99 as a special indicator or as a code for other purposes. As a result, this date may not be accepted by the computer software or may cause unexpected results.

3.3.3. Future years

As discussed earlier, the Y2K issue is largely a result of programmers' efforts to save memory by reducing the memory required for storing dates. Two-digit dates were used because less memory was required than for four digits. Similarly, the representation of dates beyond a certain point may be subject to memory limitations. For example, some Unix systems store the date and time as the number of seconds elapsed from 1 January 1970. The elapsed time is stored in a 32 bit register, which means that overflow of this register will occur some time in the year 2038. While this limitation will not affect many medical functions, it should be recognized as an indication that further problems may occur even after 1 January 2000 has passed.

4. EXTERNAL BEAM RADIATION THERAPY

The equipment associated with external beam therapy (teletherapy) includes treatment units, simulators, treatment recording and verification systems, and treatment planning computers. Much of the equipment used today for teletherapy employs computer systems, and in many cases the computers use dates for calculation, record storage, data retrieval and analysis.

Unlike many other forms of medical care, teletherapy almost always takes place daily over a period of weeks. Accurate record keeping is mandatory, to permit evaluation of the treatment. Accuracy is critical, as errors either in the placement of the radiation or in the magnitude of the dose can have severe consequences. The use of treatment planning computers is common in radiotherapy, to facilitate the determination of beam shapes and orientation and to compute parameters that govern the dose to be delivered.

A critical component of a radiotherapy programme is a quality assurance (QA) programme. A comprehensive QA programme should address all aspects of patient care and include a programme of equipment quality control (QC). Specific recommendations for QC are given in the scientific literature; they include recommendations for periodic tests of equipment performance. QC programmes should include tests that are performed at frequencies ranging from daily to annually, and they should address all aspects of equipment operation that affect patient treatment.

4.1. Treatment planning and dose calculations for isotope teletherapy units

Isotope teletherapy units — such as cobalt-60 teletherapy units and caesium-137 teletherapy units (still in use in some parts of the world) — and dedicated radiosurgery units — such as the Gammaknife® — rely on the accurate measurement of time to deliver the prescribed dose. As the sources decay, the treatment time must be adjusted so that the correct dose is delivered reliably. Computers are often used to perform calculations of source decay. In many cases, commercial dose calculation systems or treatment planning systems (TPSs) are used, but frequently such software is developed in-house.

In either case, decay calculation errors result directly in dose delivery errors. Large errors in delivered dose can be catastrophic and lead to the death of the patient. Relatively small errors can result in detectable changes in survival rates. Therefore, careful attention to Y2K problems is of paramount importance.

4.1.1. Assessment

It is tempting to assume that decay correction errors will always be obvious. They will probably be obvious in cases where the year 2000 is interpreted by a computer to be 1900 and the decay is calculated for -100 years rather than +1 day. However, several factors may conspire to produce results that seem reasonable even though they are wrong. For example:

- Computers may not interpret "1/1/00" as 1 January 1900, but instead convert this value to some other date (such as 4 January 1980). For a long lived isotope such as caesium-137, the erroneous calculation may still appear acceptable.
- Erroneous calculations may be transformed into apparently reasonable values by conflicting malfunctions. One such possibility is that an erroneous decay correction yields a value that exceeds the capacity of a storage register. The value may overflow or be truncated or otherwise modified into a value that is similar to the expected value. Such errors can be completely unpredictable.
- Overworked or distracted staff may rationalize substantial errors into acceptable values. For instance, the computed result 0.04 min may appear when a value of 0.4 min is expected. A staff member may not recognize the order of magnitude error and conclude that the result confirms the expected value.
- National conventions may mask erroneous results. Software developed for use in the United States of America uses a dot ('full stop' or 'period') to indicate a decimal separator and a comma to indicate multiples of 1000. In some European countries, however, a comma is used instead of a decimal point. A calculation that yields a value of the order of 1,000 min (one thousand minutes) when a value of approximately 1 min is expected could be interpreted as correct, owing to confusion over the use of the comma.

4.1.2. Testing

Prior to testing, a backup should be made of all software and data storage. The possibility should be considered that testing for Y2K compliance will produce unexpected results, including corruption of software and data. Tests should then be performed to detect occurrences of the kind mentioned in the previous section, it being borne in mind that the list is not exhaustive.

Testing may be accomplished by resetting the system clock of the computer to a date in the 21^{st} century. Calculations of radioactive decay can then be performed with initial activities specified on a date in the 20^{th} century. Tests in the reverse direction should also be conducted. The tests should take into account a variety of unexpected possibilities, such as the possibility that calculations will be performed correctly when the date is entered in one format, say 1/1/00, but incorrectly if another format is used, such as 1/1/2000. Tests should not be limited to 1 January; they should ensure that the use of subsequent dates (5 May, 4 July or 25 December, for example) does not cause errors.

The tests should be compared with calculations performed manually. It is advisable that a pocket calculator not be used for calculations involving the entry of dates until the calculator itself has been tested for Y2K compliance.

4.1.3. Remediation

If possible, the manufacturer should be requested to provide updated or modified software that is known to be Y2K compliant. In the case of in-house software, or in circumstances where the manufacturer refuses or is not available to provide revisions, other possibilities exist:

- Software that is not Y2K compliant, and cannot be brought into compliance by the developer, may have to be abandoned.
- Software that is not Y2K compliant but behaves in a predictable fashion may be usable under certain circumstances. For example, it may be possible to confirm that dates entered using two digits (e.g. '00' to '99') are always interpreted as dates in a single century. This might mean that the two-digit dates correspond equally well to the range 1900 to 1999 or to the range 2000 to 2099. An isotope teletherapy unit can perhaps be calibrated on 1 January 2000 and the new output entered into the computer with the date specified as '1/1/00'. After careful and thorough testing, it may be possible to demonstrate that accurate decay calculations are performed provided the dates are considered always to fall between 2000 and 2099.

Regardless of the form of remediation chosen, it is imperative that a comprehensive programme of regular QA procedures include systematic tests of date handling.

4.2. Accelerator control systems

Many modern medical accelerators are controlled by computers that use dates for several purposes. For example, the date may be used to archive records of internally controlled daily QC procedures, and would be displayed on the printout of such records. Many accelerators are equipped with software to record the delivery of treatments, and the records may be archived by date. However, some accelerators — particularly older ones — do not use the date in any way; this section does not apply to them.

4.3. Assessment

The first procedure should be to consult with the manufacturer regarding Y2K compliance. If a compliant version of the software exists, this should be installed and tested. If

not, the manufacturer may supply guidelines for ensuring proper operation in the year 2000. If no guidelines exist or the manufacturer can no longer be contacted, thorough testing of the equipment should be carried out in order to determine whether and under what conditions it can still be used after 1 January 2000.

4.3.1. Testing

The tests should include procedures to determine whether and how the entered date is used and whether it is transferred to other systems networked to the accelerator. For example, the date may be transferred to a record and verify (R&V) system or to an independent QA system. In many cases, the date may be used to archive internal records of treatments and QA procedures. Even with such simple systems, significant errors can occur in documentation, leading to the misinterpretation of treatment records and possibly to incorrect decisions regarding treatment. If dates are used in any fashion, the method of date representation must be assessed and its ability to indicate dates beyond 1 January 2000 determined. As before, the possibility exists that, even if 1 January can be represented properly, dates beyond that will not be.

4.3.2. Remediation

In most cases, the preferred method of remediation is to install the update or upgrade supplied by the manufacturer. Very few radiation therapy departments are equipped to modify such systems themselves. In some cases, depending on the application software design and the system software version, remediation can be accomplished by entering the correct date when the system is used for the first time after 1 January 2000. In at least one case, this is the procedure recommended by the manufacturer.

Under some circumstances it may be acceptable to adopt a policy for the interpretation of two-digit dates that allows '00' to indicate 1900 internally but to represent 2000 to the users of the device. Again, unforeseen problems may arise. A comprehensive QA programme should therefore include frequent testing of date handling should such a policy be adopted.

4.4. Quality control systems

Independent systems are available that automate the performance, storage and analysis of equipment QC procedures for teletherapy units. The only systems available at present appear to be stand-alone devices that can interface with a detector system for in-beam measurements. There appear to be no systems that interface directly with accelerators or other radiation producing devices.

The incorrect handling of dates in 2000 and beyond may not directly impact patient treatments, but could lead to confusion in record keeping. Unintended consequences could include the loss or misplacement of QC records and service reports, leading to delays in preventive maintenance and to malfunction or failure.

4.4.1. Assessment

These systems must be tested for Y2K compliance. In some cases, the manufacturer may provide a statement of compliance or recommend procedures for assessing compliance. If the

necessary information is not available from the manufacturer, the hospital should conduct its own assessment. The questions to be considered include:

- the ability to enter dates beyond 31 December 1999;
- the correct representation of dates in archived records;
- the correct use of dates for the generation of reports, trend graphs and so on;
- the correct display of dates on printouts and displays.

4.4.2. Testing

Unless instructions are received from the manufacturer, the user should endeavour to carry out tests covering all the questions listed above.

4.4.3. Remediation

The manufacturer should be consulted about procedures to ensure Y2K compliance, and any recommendations made by the manufacturer should be followed. If the manufacturer makes no recommendations, a decision should be taken regarding internal policies to allow the continued use of two-digit dates. This may be acceptable provided that it is clearly understood that, for example, '00' represents the year 2000 and that dates prior to 1/1/2000 cannot be represented or used.

4.5. Record and verify systems

Record and verify (R&V) systems have evolved over the years to function in several different ways:

- Verify only systems, which simply compare the actual geometrical and dose delivery parameters of the treatment unit with the prescribed parameters and prevent treatment unless there is agreement, or the operator decides to override the system;
- Automated setup systems, which transfer the prescribed setup to the treatment machine and automatically set some or all parameters;
- R&V systems, which combine the above functions with a recording capability for the documentation of each treatment delivered and accumulation of the dose to target points;
- Patient information systems, which may include all the functions of an R&V system and either interface with other systems or include capabilities for storing patient demographics, scheduling functions, billing, report generation, transcription and electronic charting.

The application software of an R&V system may use other software packages, such as the computer's operating system, other application software, a database software package and networking software. All of these software packages must be Y2K compliant.

4.5.1. Assessment

These different systems function in somewhat different ways, but — with the possible exception of the verify only system — all use date functions. Systems with a recording capability generally record each treatment together with the date and time of the treatment.

This information is used in several ways: to display treatments in chronological order; to calculate functions such as the elapsed time for a course of treatment; and to compute biologically effective doses and thereby facilitate comparison of different fractionation schemes. Thus, Y2K compliance is essential for the correct functioning of these systems.

4.5.2. Testing

If at all possible, the manufacturer should be consulted in order to determine the compliance status of the software. In many cases, this may involve contacting the manufacturers of several hardware and software components. Testing such systems may be complicated by the fact that most are networked to other systems, such as treatment planning computers, simulators and treatment units. In addition, it may not always be clear how or where the date is stored and whether changing the date at any workstation affects the date stored on the file server or other devices.

In all circumstances, a backup should be made of the complete system, including application software and data storage, before testing is performed. The possibility should be considered that testing will produce unexpected results, including corruption of data and software.

However, if possible before the year 2000 (and definitely at the first opportunity after 1 January 2000), tests should be performed at least for the following:

- correct recording of treatment dates;
- correct display of treatments and other appointments (in chronological order);
- correct accumulation of delivered dose to target points;
- ability to schedule future appointments in the same department and in other departments (and accurate printout of appointment slips);
- ability to schedule dose break points, treatment parameter changes and combination therapy (e.g. chemotherapy);
- ability to schedule twice-a-day treatments (if ability existed before 31 December 1999);
- proper generation of patient charges, invoices and past-due reminders;
- correct calculation of date sensitive functions such as patient age, survival time and other time spans.

4.5.3. Remediation

The manufacturer should be consulted and the manufacturer's recommendations should be followed; these may include recommendations regarding upgrades to ensure Y2K compliance. The use of other methods to work around the problem is specifically not recommended for commercial R&V systems.

In the case of in-house R&V systems, the user must accept responsibility for making appropriate modifications to ensure Y2K compliance.

4.6. Radiotherapy simulators and computed tomography (CT) simulators

Modern radiotherapy simulators generally incorporate computers to facilitate their operation and expand their capabilities for mimicking many treatment units. It is rare that

simulators themselves use date functions to store or retrieve data, as these operations are generally conducted in conjunction with an R&V system. However, the user should be aware of the potential for the use of dates in the storage or manipulation of data files that control simulator operations — for example, by retrieving communications protocols, or geometric co-ordinate and angle conventions.

CT simulators, on the other hand, use date and time stamping to store and identify patient images. Many CT simulators are built around CT scanners that were developed before full awareness of the Y2K issue became widespread. The user should take steps to evaluate the possible Y2K impact on the acquisition, analysis, use and transfer of CT images and simulation parameters.

As has been recommended for other major pieces of radiological equipment, the user's first step should be to contact the manufacturer of the equipment and to ascertain whether an upgrade or software modification is available for correcting Y2K problems. The installation of a more recent operating system may be necessary; if so, it should be carried out under the manufacturer's supervision.

However, it may be necessary for a medical facility to develop its own solution to the problem, which may follow the lines of earlier recommendations. If, for example, date and time stamping is used only to identify images internally within the CT software and is not transmitted to other systems, it may be reasonable to adopt policies within the facility to guide the recognition of dates as being in the 21st century. Caution should be exercised when the simulator or CT simulator is connected via a network to an R&V system or to a treatment planning system. In such arrangements, it is quite possible that date information may be passed from the simulator to other equipment, creating the potential for misinterpretation or erroneous calculations.

4.7. Calculations of biological effectiveness

Some commercial treatment planning systems are now being delivered with the ability to implement models of biological effectiveness. Some models (for example, the linear–quadratic model) can be used to demonstrate the effect of different doses per fraction or of protraction of the treatment course over a longer period. It is rare for the algorithms to use the entry of dates to perform these calculations, but not out of the question.

In addition, many departments use pocket calculators, in-house software or programs available over the Internet to do biological effectiveness calculations.

Such calculations should be tested for Y2K compliance in the same manner as the treatment planning system itself.

5. BRACHYTHERAPY

Brachytherapy is the practice of placing radioactive sources, such as iridium-192 and caesium-137, into or near a tumour (or, in the case of endovascular brachytherapy, the site of hyperplasia). Treatment in this manner allows a high dose to be delivered to the tumour or target tissue, while the surrounding normal tissue is largely spared from radiation. Brachytherapy is divided into the following types of procedures:

- Interstitial brachytherapy, in which radioactive needles or seeds are implanted directly into the tissue. The term "*afterloading*" describes the introduction of radioactive sources into needles or catheters which have been previously placed in the tissue. Afterloading techniques are used almost universally for brachytherapy procedures. Some interstitial implants are *permanent*, meaning that the radioactive sources remain in place while they decay and deliver the dose to the patient. Radioisotopes with a short half-life (up to about 60 days) are used in permanent implants. Other implants are *temporary*, and the sources must be removed at the end of the procedure. In most cases, the patient must remain in the hospital during the use of temporary implants.
- Intracavitary brachytherapy, in which sources are placed into a body cavity, such as the cervix or uterus. Generally, an applicator is first inserted and carefully positioned within the cavity, and the radioactive sources are *afterloaded* later.
- Surface plaques, in which the radioactive material is placed against the skin surface, or against the surface of the organ to be treated (e.g. the eye).
- Intraluminal brachytherapy, in which the sources are introduced into the lumen of an organ (such as the bronchus) or a blood vessel (addressed in Section 8 Endovascular brachytherapy).

Brachytherapy can be further divided into *manually afterloaded* procedures and *remote afterloaded* procedures. Remote afterloading is conducted though the use of a machine in which the radioactive source(s) is stored and which can be programmed to drive the source(s) through a tube and into a catheter or applicator that has been placed in the tissue or body cavity to be treated.

Remote afterloaders themselves are subdivided into high dose rate (HDR) units, low dose rate (LDR) units and — in some institutions — pulsed brachytherapy (PDR) units. HDR and PDR units have a single source with an activity as high as 10 Ci (370 MBq). In order that the desired dose distribution may be achieved, the source is programmed to stop briefly ('dwell') at a number of locations within the implanted catheters or applicators. This procedure typically lasts only a few minutes, and it is generally repeated at intervals of a few days or a week. LDR units are intended to substitute for conventional low dose rate brachytherapy with manually afterloaded sources, and they typically contain a number of sources that can be assembled into 'trains' that mimic the conventional source arrangements. The devices can be programmed to insert the source trains into the applicators or catheters, and they offer the benefit that the sources can be retracted when the patient requires medical attention or has visitors who warrant interruption of the treatment.

5.1. Dose calculation

5.1.1. Assessment

One controls the dose to be delivered to the tumour by monitoring the treatment time or, in the case of permanent implants, the activity of the implanted source. In either case, calculations must be performed in advance to determine the activity of the sources at the time of the implant. For permanent interstitial implants, and for some temporary implants with short lived sources, the radioactive decay over the course of the implant must be determined.

Decay calculations may be done manually, from precalculated tables or graphs, with the assistance of a calculator, or through the use of a treatment planning computer. Often, a correction factor is determined for decay over an elapsed period of time, and this factor is

applied to the initial activity. In other cases, the calculation is based on the entry of dates, such as the date of calibration of the sources and the date of the implantation procedure. For such calculations, the handling of dates is critical and must be tested.

Clearly, the dose to the patient (and — with some treatment facility designs — the dose to other persons) is dependent on accurate calculations of activity and treatment time. Errors can result in a misadministration or even in injury to or the death of the patient. In the case of HDR brachytherapy, the dose rate is so high that a lethal dose can be delivered in a very short time. An error may not be detected within the time required for treatment.

All equipment (computers, pocket calculators), graphs and charts used for planning brachytherapy treatments must be checked for the existence of Y2K problems.

5.1.2. Testing

Testing may be accomplished by resetting the date of the calculator or computer used to perform the calculations. When a pocket calculator is used to determine the days elapsed between two dates, the calculation is easily tested by entering dates on either side of 1 January 2000 and comparing the result to calculations done by hand. Testing of a treatment planning computer may not be so straightforward; it will require at least that the system clock of the computer be changed to a date in the 21st century.

5.1.3. Remediation

Treatment planning computers for brachytherapy are generally quite sophisticated, even those developed in-house. Modifications may be dependent on the operating system in use, in which case it is best to request the manufacturer to provide updated software that is certified to be Y2K compliant.

When assistance from the manufacturer is not available, alternatives may include the avoidance of decay calculations involving the date. For example, decay calculations may be done by hand in advance of treatment planning, so that the source activities can be entered as if the sources were calibrated on the date of the implant procedure.

One can check for correct remediation by determining the product of treatment time and source activity. Implant treatment calculations that involve the same product of time and activity can be performed for time intervals before, during and after 1 January 2000. These calculations should all yield the same dose if the dates are handled correctly. Other tests specific to the institution's own treatment procedures should be conducted.

5.2. Inventory of sources

Some institutions use computer programs to calculate the activity of brachytherapy sources as a function of time after receipt or calibration. The calculations may be performed in advance, to generate a table or graph of the results, or they may be performed periodically to comply with regulations concerning the inventory of sealed sources. The software for such calculations should be tested in a manner similar to that described in the previous paragraph.

5.3. Treatment schedules for fractionated brachytherapy

In certain cases, and particularly when HDR treatments are compared with conventional brachytherapy, calculations of biological effectiveness may be performed to account for fractionation and dose rate. Some of the calculations are done by computer and may involve the entry of dates. Clearly, checks must be made for the correct handling of dates as between the 20th and the 21st century and remediation performed if necessary.

5.4. Radioactive waste

When sealed sources with short half-lives (for example, iridium-192 and iodine-125 sources) are used, those removed after a treatment must be either held in storage while they decay or returned to the manufacturer for disposal. If they are held in storage, calculations may be required in order to determine the date on which the activity has fallen to a level allowing disposal. If the sources are returned to the manufacture, it is usually necessary to calculate the present activity so that the shipment is properly documented. In both cases, calculations may require the entry of dates, and the software must therefore be evaluated for Y2K compliance, either by the user or by the software supplier.

6. NUCLEAR MEDICINE (IMAGING)

For the purposes of this report, the practice of nuclear medicine is considered to consist of the imaging of radioactive materials that are ingested by, or injected into, the patient. This includes planar imaging with rectilinear scanners and gamma cameras, and also tomographic imaging such as single photon emission computed tomography (SPECT) and photon emission tomography (PET). These procedures include organ (liver, brain) imaging and body imaging ('bone scanning', for example). Nuclear medicine also includes quantitative studies such as time based measurements of the accumulation of radioisotopes in an organ (uptake) and their removal (washout). The procedures may be conducted using a gamma camera or a simple probe type detector.

Additional procedures in nuclear medicine include in vitro procedures in which the activity incorporated into body fluids such as blood and urine is measured. For these procedures, an automated detector system such as a liquid scintillation counter may be used.

Much of the equipment used in nuclear medicine is computer controlled. In many cases, calibration coefficients, geometric correction factors, and energy and dose rate dependence factors are stored and retrieved for each measurement. Some factors involve the decay of a radioisotope and are date sensitive. Other data may be stored in such a way that the date is important in their retrieval. In addition, patient related parameters are very likely to be archived by date. Consequently, the Y2K compliance of the imaging or measurement system must be tested and ensured.

6.1. Assessment

Many Y2K problems in nuclear medicine will involve calculations of radioactive decay. They can fall into several classes:

- QA procedures that rely on accurate calculations of the decay of a radioactive source. These may include linearity tests of an activity meter (or 'dose calibrator').
- Measurements of the sensitivity of imaging devices used for quantitative measurements. For example, gamma cameras are sometimes used to determine organ uptake or washout in a quantitative fashion. The sensitivity of the camera is determined by comparison with a source whose current activity must be estimated.
- Internal dosimetry estimations using procedures such as those given in the pamphlets of the Medical International Radiation Dose Committee (MIRD) of the Society of Nuclear Medicine. Such calculations require knowledge of the biological half-life and the physical half-life, as well as the time interval between preparation of the radioactive material and its introduction into the patient.
- An inventory of radioactive materials on hand must be maintained. Frequently, in-house software is developed to assist with recording the initial activity, the date of receipt, the date of transfer to waste and the estimate of the activity removed to waste.
- Waste disposal. The activity of the waste must be estimated so that the time of disposal of the waste can be determined.

Y2K problems may also affect the storage and retrieval of patient records and the scheduling of patients for future procedures.

6.2. Testing

In the case of commercial software, the manufacturer should be consulted about recommended tests to determine Y2K compliance. Software developed in-house must be tested by the hospital. The tests necessary to ensure Y2K compliance, which are straightforward, should address the following:

- ability to enter dates beyond 31 December 1999;
- correct calculation of elapsed days between dates;
- correct use of elapsed days for decay calculations;
- correct representation of dates in archived records;
- correct use of dates for the generation of reports, trend graphs etc.;
- correct display of dates on printouts and displays.

6.3. Remediation

In the case of commercial software, the manufacturer should be consulted about procedures to ensure Y2K compliance, and the manufacturer's recommendations should — if forthcoming — be followed. When there are no recommendations from the manufacturer, a decision should be taken whether or not internal policies can be implemented to allow the continued use of two-digit dates. This may be acceptable provided it is clearly understood, for example, that '00' represents the year 2000 and that dates prior to 1/1/2000 cannot be represented or used.

7. THERAPY WITH UNSEALED SOURCES

Radiotherapy with unsealed sources may be performed either in radiotherapy departments or in nuclear medicine departments. It involves the ingestion or injection of relatively large quantities of radioactive material by or into the patient for the purposes of treatment. The aim is to deliver a prescribed dose to a target organ. As in the case of external beam therapy using radioisotope sources or of brachytherapy using sealed radioactive sources, errors in estimating the activity of the source may yield corresponding errors in the delivered dose, or even result in an accidental exposure.

The procedures for assessing the extent of the problem, testing software and computer systems and applying corrective measures are essentially the same as those recommended in the case of external beam therapy, brachytherapy and nuclear medicine imaging.

8. ENDOVASCULAR BRACHYTHERAPY

Endovascular brachytherapy is a relatively new procedure in which a radioactive source in solid or liquid form is introduced into a blood vessel to irradiate the vessel wall. The procedure has been developed in an attempt to prevent restenosis of blood vessels, notably the coronary arteries, following invasive procedures such as percutaneous transluminal balloon angioplasty (PCTA). The treatment is based on the hypothesis that the proliferative response of the endothelial tissue making up the arterial wall can be slowed done by the administration of moderate doses of radiation.

Endovascular irradiation has been performed by a variety of techniques, most commonly by moving small sealed radioactive sources through the vasculature until they are at the site of the original stenosis, where they are left for a short time until the desired dose has been delivered. Sources with iridium-192, iodine-125 and strontium-90 have been used, and other sources are under consideration. The use of an angioplasty balloon filled with a radioactive liquid has also been considered.

Another procedure under investigation for endovascular brachytherapy is the use of radioactive stents. Non-radioactive stents are commonly used following angioplasty, in an effort to hold the vessel open and combat both the elastic recoil of the vessel wall and the vascular remodelling — or shrinking — of the vessel in response to PCTA. However, the presence of a stent does not prevent neointimal hyperplasia, the third cause of restenosis, and may in fact exacerbate it. Therefore, radioactive stents are being considered for delivering a radiation dose to the proliferating tissue while, at the same time, mechanically holding the vessel open. A radioisotope with a short half-life is commonly used, as the stent is implanted permanently.

As is the case with conventional brachytherapy, the dose to the artery depends on both the activity of the source and the treatment time. Therefore, the reader is referred to Section 4 (on brachytherapy) for advice on assessing and dealing with Y2K problems. The use of liquid filled balloons for endovascular brachytherapy is similar to the use of unsealed isotopes for therapy, and the reader is therefore referred to Section 6 (on therapy with unsealed sources).

9. DOSIMETRY EQUIPMENT AND RADIATION MEASUREMENTS

Dosimetry systems of various types are used in radiology, nuclear medicine and radiotherapy. They are used for the acceptance testing and commissioning of new equipment, in periodic QA procedures, and for in vivo measurements on individual patients. Many dosimeters and dosimetry systems belong to the first of the three categories mentioned in Section 2; date and time functions are not used, and this advice is therefore not relevant. However, there is increasing use of more sophisticated dosimetry systems in a number of areas, and medical practitioners must ensure that, where such systems are used, they are Y2K compliant or steps have been taken to eliminate the risk of dosimetry errors related to date handling.

Dosimeters used in medicine may be classified in the following manner:

- ionization chamber based systems that include an electrometer and often a phantom of some sort;
- diode based systems that include an electrometer and a phantom;
- dose integrating systems such as thermoluminescent dosimeters (TLDs);
- radiation field analysers, generally including one or more ionization chambers or diodes, a water phantom and positioning system (or multiple detectors positioned at fixed locations in a solid phantom), and a computer control system;
- liquid scintillation counters.

9.1. Assessment

Y2K problems related to dosimetry systems fall into two broad categories:

- date based calculations, such as corrections for radioactive decay, or the fading of a signal or response;
- date based access to data in connection with for example data storage, archiving, retrieval, and manipulation for display or presentation.

Dosimetry systems known to incorporate date functions for data handling include TLD readers, automated electrometers, radiation field analysers, and liquid scintillation counters. This list should not be considered exhaustive, as new developments occur frequently in dosimetry.

9.2. Testing

The testing of dosimetry systems requires the entry of dates near and beyond 1 January 2000 and the evaluation of calculations that are based on such dates. These calculations may include the following:

- correction of the activity of a radioactive source used for constancy checks of an ionization chamber;
- storage of calibration coefficients and correction factors by date, for use on subsequent dates;
- generation of trend charts or graphs for the evaluation of changes in the output of a treatment unit.

Each type of calculation or output should be examined to ensure that the dates are handled properly and, if they are not, to understand the nature of the error. Attention should be paid to dates beyond 1 January 2000 so as to avoid errors occurring at future dates.

9.3. Remediation

As has been recommended in previous sections, the user should first contact the manufacturer of the equipment to determine whether a software update or system upgrade is available to correct for Y2K problems. If one is provided and installed, at a minimum the tests suggested above should be performed to ensure that the revised software performs date sensitive calculations correctly.

When the manufacturer cannot help, the user again has the option of suspending use of the equipment or developing an own solution. In the case of corrections for the decay of a radioactive source or for the fading of a signal, the solution may be to re-establish a calibration or baseline on or soon after 1 January 2000. Tests should be carried out to ensure that calculations are performed correctly after that date.

When dates are used to control data storage and retrieval, the user may be able to develop procedures for segregating data acquired before 1/1/2000 from data acquired afterwards. Such procedures may include simply archiving data acquired during the 20^{th} century in another storage medium so that the data cannot be accessed without the operator being aware that the dates require interpretation.

Systems that use the date on which data were recorded to generate graphs or charts indicating trends may require special treatment. The analysis or display of data spanning the 1/1/2000 boundary may not be possible unless modifications are made either to the software or to the procedures for interpretation of the data. In such cases, users should examine thoroughly the possible consequences of misunderstanding the data.

10. CONCLUSIONS AND RECOMMENDATIONS

10.1. Conclusions

The Y2K issue poses potentially serious problems in medical radiotherapy with radiation generators and with sealed sources and in nuclear medicine diagnosis and therapy with unsealed sources. A number of medical procedures could be affected in ways that result in accidental exposures with severe consequences.

A variety of radiation generators and sealed and unsealed sources could be affected, together with ancillary and auxiliary equipment and systems such as treatment planning computers, accelerator control systems, recording and verification systems, activity meters and dosimetry equipment.

The problem could be aggravated by the fact that many registrants and licensees of medical facilities are making extensive use not only of radiation generators, radiation sources, and equipment and systems supported by recognized manufacturers, but also of hardware and software installed or produced "in-house" and of equipment and systems no longer supported by the manufacturers.

A systematic approach is needed in order to ensure that all radiation generators, radiation sources, equipment and systems for radiotherapy and nuclear medicine diagnosis and therapy, from the most complex (for example, computer networks) to the very simple, are tested for Y2K compliance and that remedial measures are taken where necessary.

10.2. Recommendations

National authorities throughout the world and competent international organizations should be aware of the identified potential for accidental exposures caused by Y2K problems at medical facilities.

Regulatory authorities worldwide should ensure that registrants and licensees of medical facilities carry out systematic actions to identify radiation generators, radiation sources, and equipment and systems that may be affected by Y2K problems and take remedial measures in line with the guidance provided in the report.

National authorities and registrants and licensees of medical facilities should be encouraged to exchange, in a timely manner, the information acquired and experience gained through such actions.

Annex

CRITICAL DATES

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 systems, 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 which had 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 1999, 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 2000:** 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 366th 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 366th day (31 December 2000).

REFERENCES

- [1] INTERNATIONAL ATOMIC ENERGY AGENCY, Measures to address the year 2000 (Y2K) issue, General Conference Resolution GC(42)/Res/11, September 1998, IAEA, Vienna (1998).
- [2] INTERNATIONAL ATOMIC ENERGY AGENCY, Achieving Year 2000 Readiness: Basic Processes, IAEA-TECDOC-1072, Vienna (1999).
- [3] INTERNATIONAL ATOMIC ENERGY AGENCY, Safety measures to address the year 2000 issue at radioactive waste management facilities, IAEA-TECDOC-1073, Vienna (1999).
- [4] INTERNATIONAL ATOMIC ENERGY AGENCY, International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources, IAEA Safety Series No. 115, Vienna (1996).

CONTRIBUTORS TO DRAFTING AND REVIEW

- Andreo, P. International Atomic Energy Agency
- Höppner, C. Siemens AG, Germany
- Ibbott, G.S. University of Kentucky Medical Center, United States of America
- Immers, A. Nucletron International B.V., Netherlands
- Ortiz-López, P. International Atomic Energy Agency

Consultants Meeting

Vienna, Austria: 14–18 December 1998