Y2K & MEDICAL FACILITIES USING RADIATION SOURCES

PROTECTING PATIENTS

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At hospitals, clinics, and other health care facilities, the Y2K bug is potentially life-threatening. It could endanger patients if vital medical equipment is allowed to fail, or errors are made during diagnosis or treatment.

Special areas of concern are medical care involving radiation applications. The health care of millions of patients each year includes the use of radiopharmaceuticals, or radiation technologies for diagnosis and treatment of illness. In the treatment of cancer patients with a cobalt-60 unit or in brachytherapy, for example, incorrectly calculating the radionuclide's decay could result in the patient receiving the wrong radiation dose.

For all types of medical care, the Y2K bug could cause an almost unlimited number of potential problems associated with patient scheduling. Some possible problems:

- Patients receiving radiopharmaceuticals may miss, or not be given, follow-up appointments. 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 cancer 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.
- Appointments for follow-up visits (e.g. to re-evaluate suspicious findings) are not made. Patients may experience an undetected progression of the disease.

Not all medical applications involving radiation sources will be affected by the bug. As part of the Y2K assessment process, medical authorities will need to properly inventory and categorize devices to assess potential problems and move to prevent them.

Basically, the devices fall into three categories: (1) those 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);
(2) those 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); and (3) those 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).

To a large extent, the Y2K issue has commanded the attention of national regulators and manufacturers of medical devices for a number of years. An important step now is to share experience to ensure that health practitioners and their patients are not placed at risk by the millennium bug.

As part of its activities, the IAEA has issued a guidance document for governments and health practitioners on Y2K-related safety measures at medical facilities using radiation sources. As part of follow-up work, in late June 1999, the IAEA and World Health Organization (WHO) jointly organized an international workshop for the international nuclear medical community. It helped to foster the exchange of information on approaches to dealing with the Y2K issue at medical facilities which use radiation generators and radioactive materials. A particular focus was placed on experience already gained; identifying potentially affected systems; assessing the problems; testing systems; remediation activities; and contingency planning.

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Participants included regulatory authorities responsible for monitoring compliance with radiation protection regulations at medical facilities; authorities responsible for health care in hospitals using radiation generators and radioactive materials; hospital administrators; medical and technical staff working in radiotherapy, nuclear medicine and radiology, medical physics and radiation protection; and experts at professional societies active in these areas.

POTENTIAL TROUBLE AREAS

Y2K problems can compromise the safety of several types of medical applications involving the use of radiation. They include:

External Beam Radiation Therapy. Much of today's teletherapy equipment employs computer systems, and in many cases the computers use dates for treatment dose calculation, record storage, data retrieval and analysis. Unlike many other forms of medical care, teletherapy almost always takes place in daily fractions delivered over a period of weeks. Accurate recordkeeping of all treatment parameters and doses throughout the whole course of the treatment is essential for evaluation.

Accuracy is critical, because errors either in the placement of the radiation or in the magnitude of the dose can have severe consequences, by either failing to control the tumor, or by causing severe, even life threatening, complications to normal tissue. 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.

Radionuclide teletherapy units mostly use cobalt-60, though caesium-137 still is in use in some parts of the world. Also used are dedicated radiosurgery units, such as the *Gammaknife.* They all rely on the accurate calculation of the treatment time needed to deliver the prescribed dose. As the sources decay, the treatment time must be adjusted accordingly 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 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, or in severe complications. Therefore, careful attention to Y2K problems is of paramount importance.

Brachytherapy. This treatment involves placing radioactive sources in contact with or near a tumour. The dose to be delivered to the tumour is controlled 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.

The dose to the patient is dependent on accurate calculations of activity and treatment time, and treatment schedules for fractionated brachytherapy. Errors can be serious. In high-dose-rate brachytherapy applications, an error may not even be detected within the time required for treatment; a lethal dose could be delivered.

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.

All equipment (computers, pocket calculators), graphs and charts used for planning brachytherapy treatments must be checked for the existence of Y2K problems. In addition to the patient dose calculation, other functions in brachytherapy -- such as inventory of sources (radionuclide and activity corrected for decay), and management of radioactive waste -- can be also affected.

Nuclear Medicine Imaging. For the purposes of this report, the practice of nuclear medicine is considered to consist of the imaging of the distribution of radioactive materials within the patient's body, that have been previously ingested or injected. 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 total 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 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 imaging process. Some correction 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, since the wrong imaging may lead to the wrong diagnosis and the wrong treatment.

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

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 to correct a stenosis such as percutaneous transluminal balloon angioplasty.

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 radioactive liquid also has been considered.

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 Y2K problem must be addressed.

Dosimetry Equipment. Dosimetry systems of various types are used in radiology, nuclear medicine, and radiotherapy. They are used for acceptance testing and commissioning of new equipment, in periodic quality assurance procedures, and for *in vivo* measurements on individual patients.

Many dosimeters and dosimetry systems used in medicine are not dependent on date and time functions. However, there is increasing use of more sophisticated dosimetry systems in a number of areas, which involve automatic application of date sentitive correction factors. 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. Dosimetry errors may lead to the delivery of wrong radiation doses to patients.

ADDRESSING THE PROBLEM

Once an item has been determined to be susceptible to

Y2K failures or that its failure is likely, a remediation strategy should be selected. The first step should always be to contact the manufacturer. Many manufacturers of medical computing systems have anticipated the Y2K issue and have already developed software updates. Another benefit of dealing with system manufacturers is that they are best able to consider the interactions between different components of the system. Not all Y2K problems benefit from this approach, however, either because the manufacturer is no longer in business or because it no longer supports the system.

When assistance from the manufacturer is not available, alternatives may consist of 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.

Testing of computer systems may be done by resetting the clock to a date in the 21st century. Calculations of radioactive decay can then be performed with initial activities specified on a date in the 20th century. In the case where 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, which in some systems may pose difficulties or may not even be possible.

Some solutions appear straightforward: in cases where 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. This procedure precludes any further use of dates in the 20th century. It may be satisfactory in some cases, but needs extreme caution and an effective quality assurance, as failure to follow the new policy may lead to re-emergence of the problem, perhaps with severe consequences.

Contingency Plans. In some cases, there might be no option but to stop using a system. This will imply the need to revert to manual techniques or even dispensing with a medical procedure temporarily. This will require a change of strategy in patient management, and in all cases will imply changing procedures, protocols, forms and staff time. Any of these decisions need, therefore, careful planning, provision of resources, formal documentation, training of staff in the new procedures, testing and monitoring to ensure that safety is not compromised when implementing the contingency plan.

IAEA Guidance. As part of its assistance to Member States on Y2K issues, the IAEA has prepared a report -- *Safety Measures to Address the Year 2000 Issue at Medical Facilities Which Use Radiation Generators and Radioactive Materials* (TECDOC-1074) -- for the attention of State authorities.

The report highlights that:

- 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 medical exposures with severe consequences.
- A variety of uses of radiation generators and sealed and unsealed sources could be affected, together with ancillary and auxiliary equipment and systems.
- 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, 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 to the very simple, are tested for Y2K compliance and that remedial measures are taken where necessary.

The mid-1999 international workshop organized by the IAEA and WHO helped to promote even greater awareness of steps that should be taken to prevent the Y2K bug from seriously affecting the health care community. ❑