AAPM REPORT NO. 56

Medical Accelerator Safety Considerations

Published for the
American Association of Physicists in Medicine
by the American institute of Physics

AAPM Report No. 56

Medical Accelerator Safety Considerations

REPORT OF AAPM NUCLEAR
MEDICINE COMMITTEE TASK GROUP 35

Members

James A. Purdy, Chairman
Peter J. Biggs
Charles Bowers
Edgar Dally
Walter Downs
Benedick A. Fraass
C. J. Karzmark
Faiz Khan
Paul Morgan
Robert Morton
Jatinder Palta
Isaac I. Rosen
Ted Thorson
Goran Svensson
Joe Ting

Reprinted from MEDICAL PHYSICS, Vol. 20, Issue 4, July/August 1993

February 1996

Published for the
American Association of Physicists in Medicine
by the American Institute of Physics

Further copies of this report may be obtained from:

American Association of Physicists in Medicine
American Center for Physics
One Physics Ellipse
College Park, MD 20740-3843

(301) 209-3350

International Standard Book Number: 1-888340-01-0
International Standard Serial Number: 0271-7344

Published by the American Institute of Physics
500 Sunnyside Blvd., Woodbury, NY 11797-2999

Printed in the United States of America

Medical accelerator safety considerations: Report of AAPM Radiation Therapy Committee Task Group No. 35

James A. Purdy, Chairman, Peter J. Biggs, Charles Bowers, Edgar Dally, Waiter Downs, Benedick A. Fraass, C. J. Katzmark, Faiz Khan, Paul Morgan, Robert Morton, Jatinder Palta, Isaac I. Rosen, Ted Thorson, Goran Svensson, Joe Ting
AAPM Task Group No. 35

(Received 24 March 1992; accepted for publication 26 February 1993)

TABLE OF CONTENTS

I. INTRODUCTION

Several recent radiation accidents resulting in overexposures of radiotherapy patients have focused attention on the serious consequences of equipment failures in linear accelerator treatment units. Descriptions of these incidents have been reported in American Medical Association (AMA) periodicals.[1-5] The potential hazard is particularly great in multimodality treatment units. This task group report discusses the safety considerations stemming from the increased use of computer logic and microprocessors in the control systems of treatment units. It suggests how procedures and operator responses can be improved to lessen or avoid risks associated with hardware and software failures in radiotherapy equipment.

Examination of radiation overexposures in general suggests that equipment failures and faulty procedures, as well as poor operator responses, are frequently involved. A report on the 1986 reactor accident at Chernobyl places heavy blame on the reactor staff for six actions identified by Soviet authorities as violations of operating procedures.[6] In an early study of radiation exposure accidents in the U.S. Nuclear Energy Program, Catlin found that the primary cause of accidents was operator error followed by equip-

 0094-2405/93/20(4)/1261/15/$1.20

ment, procedure, and other failures.[7] Overexposures can result solely from equipment failures; inadequate, inappropriate, or undocumented procedures; or operator error. Often, two or all three factors are involved. Because humans are fallible, and radiation therapy is carried out in a stressful environment, it is essential to clearly delineate response procedures for operators when radiation safety is involved.

II. MULTIMODALITY ACCELERATOR TREATMENT MACHINES

The technical complexity of multimodality treatment units presents potential hazards usually not present in single modality units.[8] Multimodality treatment units are being adopted by an increasing number of treatment centers because they provide increased flexibility in treating a wide range of cancers. Such units usually provide a low-energy x-ray beam of 6 MV and a high-energy x-ray beam of 10-20 MV or higher along with five to ten electron beam energies typically ranging from 6 to 20 MeV, but in some cases from 3 to as high as 50 MeV.[9,10] Additional modalities such as electron arc therapy, x-ray arc therapy, and high dose rate total skin electron therapy are available on some units. This ensemble of modalities is an impressive armamentarium for a single treatment unit. Among the advantages of such units is that patients can be treated using two modalities without being moved to another treatment unit. Also, multimodality accelerators provide backup for other, more limited treatment units. However, the treatment flexibility that they facilitate is accompanied by a significantly increased technical complexity, and hazard. Electrical, mechanical, and radiation safety considerations. therefore, must he more elaborate. To address this increased complexity, digital logic, and microprocessors have been incorporated into accelerator control and monitor functions because of their versatility, reliability, and low cost.

The radiation safety hazard of high electron beam currents in an early dual modality treatment unit was identified over two decades ago." In x-ray therapy, the electron beam is intercepted by a thick target followed by the x-ray flattening filter. In electron therapy, the electron beam is either spread out by a scattering foil(s) or magnetically scanned over the treatment field. In the electron therapy mode, the beam current through the exit window is about 1/1000 of the beam current at the x-ray target for a similar energy x-ray therapy mode. For example, at 4 Gy/min at 100 cm, in the 6 MV x-ray mode, the average beam current at the x-ray target for a typical medical accelerator is of the order of 100 μA. At the same dose rate in the 6 MeV electron mode, the average beam current at the electron foil is about 0.1 μA. Similarly, an average beam current of 20 μA is typical for 25 MV x-ray therapy while 0.02 μA is common for 25 MeV electron therapy. If the hardware or software fails, a large electron beam current intended for x-ray operation can emerge without being intercepted by the x-ray target or the x-ray flattening filter. With the scattering foil(s) in place or the scanning operable, an estimated dose comparable to a typical 2 Gy dose fraction can be delivered to the patient in about 0.03 sec at 4000 Gy/min. This is far too fast for an operator to react, so patient protection depends totally on fast monitoring and radiation-terminating electronics.

A combination of electronic and mechanical malfunctions with a failure of the software to respond properly to an operator action appears to have been responsible for the aforementioned overexposures, wherein a large electron beam current emerged as an unscattered, unscanned, and almost unmonitored beam from the radiation head. The hazard is increased if the electron scattering foil(s) or scanning system can fail at the same time. O'Brien, *et al.* have measured a dose of 1-2 Gy per pulse from 25 MeV electrons at the normal treatment distance under such abnormal operating conditions.[12,13] The electron beam distribution will then be sharply peaked at the level of the patient, and the electron dose rate can be of the order of 15 000 Gy/min delivering a normal 2 Gy dose fraction to a small volume of tissue in a single pulse of the accelerator. Clearly, the safety electronics must include the ability to monitor the radiation beam on a pulse-by-pulse basis and to terminate radiation within one interpulse period (approximately 0.002 sec).

III. CLASSIFICATION OF POTENTIALLY DANGEROUSPROBLEMS

To consider in detail the types of problems that can affect accelerator safety, one must first determine (a) the likelihood of each type of problem, (b) the possible consequences of that kind of failure, and (c) procedures that would decrease the likelihood of the event in question. In this section, we define several types of hazards associated with medical accelerators and analyze the problems that fall into each major hazard category. General estimates of risk probabilities for equipment failures, and patient injury are also discussed. The principles in this section have been adopted, with some modification, from those used for the starting point of safety analysis of a commercial accelerator.[14]

A. General hazard classifications

FDA regulations define a class I hazard as one that could cause death or serious injury. Class II includes hazards where the risk of serious injury is small. Obviously, a more quantitative definition, coupled with a probability factor, is required to determine the suitability of a medical accelerator for clinical use. Yet no such definitions are available in any published literature.

B. Medical accelerator hazards

Hazards associated with medical accelerators can originate from many sources. To generate a practical definition of accelerator hazards, a limited number are considered here. The following list contains most of the causes of potentially life-threatening problems.

1. Incorrect radiation dose

Numerous patient complications can result from an incorrect dose being delivered to the targeted tissue. An excessive dose can cause (a) death, (b) increased levels of

complications, (c) genetic effects, and (d) induction of new cancers. Underdosage can compromise the possibility of cure or tumor control.

2. Dose delivered to the wrong region

Dose delivered to the wrong region of the patient can cause many of the same problems listed above. This error can occur for many reasons, including operator error, incorrect setup of the patient, and patient motion during treatment. Accelerator-related causes include an unwanted motion (powered or free) of some part(s) of the machine and geometrical misalignments (x-ray beam-light field coincidence, for example). Additionally, the newer generation medical accelerators typically provide some type of computer-controlled setup, which could be a cause of irradiating the wrong volume of tissue.

3. Collision between machine and patient

Collisions between the treatment machine and the patient can cause significant injury or death. For example, this kind of problem can occur during simple arc therapy. With the new generation of computer-controlled machines, multiple mechanical motions are made with the technologist outside the treatment room, and investigation of collision hazards is even more important in this setting.

4. Incorrect beam energy or modality

Delivering radiation of the wrong beam energy or modality (for example, electrons instead of photons) would likely present an extreme hazard. The two most likely results are (a) an incorrect dose delivered to the patient because of incorrect calibration or massive failure of the machine dosimetry system due to extremely high dose rates (e.g., unfiltered electron beam delivered to the patient when a photon beam current was programmed); or (b) an incorrect area irradiated because of the different depth dose or other characteristics of the beam of the incorrect energy. Therefore, although this energy/modality hazard is an important one, its effects have already been covered above.

5. Other electrical and/or mechanical problems

Electrical hazards are well covered by such groups as the Underwriter's Laboratories and the Canadian Standards Association. Mechanical problems (for example, the patient falling off the treatment table, or other such incidents) are similar to general hazards for any hospital-based procedure, and are not discussed here.

C. Proposed classification of hazards

Medical accelerators are used to treat patients who have cancer. This fact is one of the most difficult things to fold into the analysis of hazards for these machines, because the treatment that is delivered by the medical accelerator is implicitly hazardous already. The patient is typically being treated for a fatal disease. The radiation treatment, even when prescribed appropriately and when delivered exactly as prescribed, has some probability (1%-5%) of serious treatment-related complications, and that complication rate is accepted by both patient and physician as the price that must be paid for the possible higher tumor control response rate due to therapy. Therefore, all risks associated with the use of the accelerator must be viewed in relationship to these relative high rates of complication, which are due entirely to clinical issues rather than machine quality assurance issue.

A single definition for all class I hazards is not practical because the range of hazards that can be considered dangerous or possibly fatal is very broad. Two levels of class I hazards (type A and type B) are defined here. In order to give quantitative examples of the hazards involved, the following estimate of normal clinical practice will be applied to the discussion: 30 fractions, each delivering a dose of 200 cGy to the center of the patient's tumor, will be used. This course of treatment will be given five days/week, so the total treatment time per patient is six weeks. A one week period between each episode of maintenance and physics testing is assumed.

1. Type A hazards

Type A hazards are considered to be the most dangerous type of hazard, and are clearly serious, and can likely be directly responsible for life-threatening complications for the patient. For the examples below, assume that a type A hazard will be created by an overdose equivalent to 25% or more of the total prescribed dose. The rationale for this choice is related to the observation that a 25%-to 50% increase in total dose will often place the patient in the range of the LD50/5 (the probability of 50% lethal complication within five years) numbers quoted in the literature.[15-17] The further assumption that weekly quality assurance checks on the machine will find errors of this size limits the possibilities of long term overdoses to one week of treatment. Therefore, the total dose error threshold for a type A hazard is on the order of 10-15 Gy.

(a). Radiation overdose caused by a faulty machine. This hazard can be generated in the following ways.

(1) By an undiscovered fractional dose error, in which 200% or more of the prescribed dose per fraction is delivered to any part of the radiation field and in which there is no indication of a malfunction that would cause immediate corrective action.

(2) By the delivery of a large single dose before the malfunction is identified, with a single fraction dose of 10 Gy or more being delivered to any part of the radiation field.

(b) Dose outside the intended radiation field. This hazard is most likely to produce severe clinical complications when a critical organ (for example, the spinal cord) is near a radiation field margin. The allowable errors are dependent upon the organ and tumor prescription dose. For a tissue volume that is not supposed to be in the high dose region, the total dose to that volume must be similar to that stated above to qualify as a type A hazard, with a high likelihood of causing a fatal or serious complication. Therefore, the failure must be such that the organ in question will receive at least the full daily prescription tumor

dose, compared to a typical dose several cm outside a radiation portal (approximately 5%) . The dosimetric error during one week is thus very large, perhaps an increase in a factor of 100-1000 in the dose at that point outside the field.

(c) Patient/machine collision. Any collision between treatment machine and patient should be viewed as a risk that is potentially fatal.

(d) Incorrect beam energy or modality. Irradiation with an electron beam when a photon beam was intended or a photon beam when an electron beam was intended may result in one of the dosimetric error conditions stated above being fulfilled, and so can be classified as a type A hazard in some circumstances.

2. Type B hazards

There are several errors that increase the probability of unacceptable outcome (complication or lack of tumor control), but usually do not pose a threat to life. These are classified as type B hazards, and examples are discussed below.

(a) Radiation overdose caused by a faulty machine. This hazard can be generated in the following ways.

(1) An undiscovered fractional dose error, in which 120% or more of the prescribed dose per fraction is delivered to any part of the radiation field when there is no indication of a malfunction clear enough to cause immediate corrective action.

(2) The delivery of a large single dose before the malfunction is identified, with a single fraction dose of 4 Gy or more being delivered to any part of the radiation field.

(b) Dose outside the intended radiation field. Unintended treatment with the primary beam of areas more than 2 cm from the prescribed field edge as the result of machine error is a reasonable example of a type B hazard.

(c) Incorrect energy or mode. Most incorrect energy or mode errors constitute at least a type B hazard if not detected within the first few fractions.

(d) Underdose. Most underdose situations fall into the type B category, because the patient's likelihood of control or cure will usually be reduced to some extent. For example, the delivery of no dose to the target volume for one week of treatment, the worst case allowed under the model being used here, is a dose difference of only 10 Gy. This may decrease the tumor control rate, but it is unlikely to cause direct life threatening complications.

D. Accelerator hazard rates

A definition of hazards in itself is not sufficient for making appropriate quality assurance decisions. The question of probabilities must also be addressed. That is, how frequently is an accident likely to occur? Until this question is answered, quality assurance questions cannot be completely resolved. We were unable to find published accident frequencies for radiation therapy devices.

General risk levels for medical procedures such as prescription drugs, surgical anesthesia, and general medical treatment are **on** the order of 10^{-4}-10^{-6} per patient or per procedure.[18-20] Another relevant area is the aircraft industry, as they have a formal method of categorizing accident types by severity, and they discuss discrete failure probability guidelines to establish the transition points between categories.[21] The class I type of risk is in the range of 10^{-6}-10^{-8} per flight hour, and divisions of order 10^{-2} are used between categories. These numbers are mentioned only as reference, because airline passengers are not suffering from a life-threatening disease.

To determine the appropriate failure levels, we continue to use the treatment model suggested above. If there are 40 patients treated per day, and 250 treatment days per year, then the total number of patient treatments per year is 40 X 250 = 10 000 per machine per year. For a machine lifetime of 15 years: this is 150 000 patient treatments per machine. If there is to be less than one type A failure for a machine in its lifetime, then the error rate must be less than 5×10^{-6} per patient treatment.

With the above background, the risk level for a type A risk should be maintained at less than 10^{-6} per machine type and patient. This kind of error level can be used when analyzing the severity of possible machine errors. Similarly, an error rate for faults leading to type B problems should be set at about 10^{-4}.

IV. PROCEDURES FOR MEDICAL PHYSICISTS IN RESPONDING TO POTENTIAL SAFETY HAZARDS

Incidents of lethal overexposure involving medical accelerators have made it highly desirable to prepare and adopt a set of procedures for medical physicists to follow if faced with a similar situation. In practice, most machine breakdowns or malfunctions that require engineering attention do not generally require dosimetric checks or recalibration by the physicist. The anticipated change in the calibration factor is typically quite small (usually less than 5%). The greatest concern is the rare situation of a previously unnoticed condition that causes large output increases, while the machine appears to be functioning relatively normally. Because one cannot anticipate the seriousness of any new problem, each situation should be treated in the same way until fully resolved. It is important to differentiate between problems that have been seen many times with predictable outcomes and those that are entirely new. In the former case, strict adherence to the proposed recommendations is unnecessary, whereas in the latter case, careful attention to these procedures is recommended. The purpose of these guidelines is to enable the physicist or engineer to take appropriate action to aid in diagnosing the problem and to ensure that the radiation oncologist and other users are alerted as soon as possible if a serious problem exists. Also, while this report is primarily directed to the medical physicist, it is understood that in the occurrence of significant unprescribed radiation exposures to the patient, the radiation oncologist must take an active primary role in (a) the immediate evaluation of the affected patient; (b) informing the patient of the occurrence and potential for acute and late effects; (c) informing the other physicians in respective specialties responsible for the patient's care; (d) the termination or

alteration of the fraction size from the intended regimen of radiation therapy; and (e) implementing a rigorous timeline for followup patient care to assess the occurrence of acute and late effects.

A difficulty in developing safety procedures is the question of the resources available in different types of radiation therapy facilities. In a large teaching hospital, there are typically experienced physicists and engineers on the staff. In small hospitals, however, there may be no staff engineers. In the private clinic, there may be no full time physics personnel at all. The large institutions can therefore respond to a given situation more rapidly, and radiation therapy technologists will, in general, report all malfunctions. For the smaller institutions, however, where outside help usually must be sought, problems take longer to solve, and there is pressure to continue treating patients as long as the machine still functions. The procedural rules should therefore reflect these differences in resources. Local or regional efforts or agreements may be needed to assist the smaller institutions.

A. Reporting of incidents, malfunctions or machine breakdowns

Machine related problems can occur at the start of the day, during the warmup period, or during the treatment day. Obvious dosimetry problems, such as miscalibration of the beam or lack of symmetry/flatness, are readily apparent only during the morning checks (assuming the standard daily procedure includes the appropriate tests). The most frequent problems can be classified into three categories: (a) clear breakdowns-no beam, (b) machine suffers frequent interlock interrupts-beam available if radiation therapy technologist continually resets interlock; and (c) machine gives occasional problems that can easily be overridden by radiation therapy technologist.

Once the fault has been diagnosed and corrected for category (a) failures, the decision as to whether to recalibrate or rescan the beam can easily be made.

The immediate concern with categories (b) and (c) is to ensure that the radiation therapy technologist reports such problems promptly. If full time engineering or physics personnel are available, these problems would be reported to them for resolution. If only physics personnel are on hand, the severity of the problem can be assessed and, if necessary, the manufacturer's service personnel contacted. The most difficult situation is when there is no technical backup available to the technologist. Frequently, the vendor's service personnel are not immediately available, and the technologist is left to decide what action to take. It is obviously more convenient to try to continue with treatment, since this avoids lengthy downtimes. However, seemingly benign faults that are easily reset can be misleading. For example, even "UNDERDOSE" faults can be indicative of severe overdoses. Thus, if the radiation therapy technologists are able to finish the treatment, regardless of how many times the reset and start buttons are pressed, there is the temptation to do so. It should be made clear to the technologists that this response is not acceptable, because it can lead to potentially serious overdoses. However, two questions arise: at what frequency of fault appearances should the radiation therapy technologist report the machine as malfunctioning, and, more importantly, should patients continue to be treated on the machine? If a fault occurs more than two or three times during a treatment day, the appropriate service personnel should be notified. It may or may not be possible to duplicate the fault, but by observing the treatments for an hour or so the engineer may be able to see the fault firsthand. However, in cases where the problem has been encountered before, is well understood, no change in the dosimetry is anticipated, and the corrective action is simple, all this may be unnecessary. However, where faults are occurring at the rate of one or more per treatment, then immediate service action is required and treatments should be suspended.

B. Reporting by radiation therapy technologists

Because the radiation therapy technologists are the machine operators, they are the ones who supply the information regarding machine malfunction during treatments. It is essential that radiation therapy technologists be adequately trained in the operation of medical accelerators so that they can recognize unusual situations and can coherently explain to the physicists or accelerator engineers the sequence of events leading up to the fault. Their training should emphasize the need to be vigilant and attentive when the machine is moving or producing radiation and to report any changes in machine performance. There must be a well-defined mechanism for feedback between technologists, physicists, accelerator engineers, and radiation oncologists.

C. Simulating the faults

After reporting by the radiation therapy technologist, the physicist should then try to duplicate the error; it may be best to let the technologist demonstrate how the fault occurred, since he or she has firsthand knowledge. If the error is intermittent, this may require many attempts. It may also be impossible to duplicate the error within a reasonable time. If one proceeds under the assumption that the fault can be simulated, albeit intermittently, the physicist should attempt to calibrate the machine during these duplication efforts. This calibration should be performed under standard conditions used at the specific institution.

Important additional information can also be obtained from the patient. This was very valuable in the case of the recent incidents referred to earlier. However, patients are unlikely to volunteer information in less dramatic events. Also, patients should not, for obvious reasons, be unnecessarily alarmed. Polite questions, such as "How did the treatment go today?," will probably elicit information if there is a serious problem.

D. Basis for clinical release of machine

If the calibration is found to be in error, the physicist must decide whether the magnitude of the change is within expectations for the given problem, in which case the cal-

ibration can be adjusted. If that is not the case, then a second calibration system should be used to check the results.

If a change in calibration of 5% or more is found, a check with a second dosimetry system is mandatory. If the two dosimetry systems disagree, the difference in readings may be due to one of the dosimetry systems being faulty and not a change in the accelerator's calibration. In this case, a third dosimetry system should be used.[22] Unfortunately, for many institutions, particularly the smaller ones, triplicate dosimetry systems are a luxury beyond reach. Such institutions should anticipate this need and attempt to arrange for assistance from a larger institution before such an event occurs. Assistance could, and perhaps should, be formalized on a local or regional basis. If the calibration from two dosimetry systems is consistent and indicates a large change in calibration, then further investigation is warranted and treatments should be suspended until the problem has been diagnosed and corrected.

If no apparent fault has occurred but the patient complains of pain during the treatment or tells the technologist that the machine "sounded" different, the physicist should perform the necessary calibrations on the treatment unit and, in the first case, the patient should be examined by the radiation oncologist. If a dosimetry problem is discovered, treatments should be suspended until normal operation has been restored. If no fault is found, despite detailed dosimetric investigation, the accelerator should be returned to clinical use but with additional monitoring by the physicist and/or engineer. In such cases, after clinical release of the machine by the physicist, the decision as to the resumption of actual patient treatments should ultimately be made by the radiation oncologist.

E. Documentation of problem

Documentation of malfunctions and problems is essential to the safe operation of the machine. Technologists should be encouraged to report all types of incidents, regardless of their perceived severity, to the responsible physicist. It is essential to establish a written reporting and documenting mechanism. These reports should be reviewed and discussed with the technologists regularly.

A written record of an incident will help minimize possible omission of important details. The report should be completed as soon as possible after the event occurs. It is equally important that the technologist leave the machine in its "fault" state to help service personnel diagnose the problem. Clearly, if a fault occurs frequently and has no dosimetric consequences, the engineer or physicist need not record any details. After several years experience with a particular machine, an operator may become aware of several, infrequent, low risk, operational faults.

F. Problem reporting

When a treatment unit fails a quality assurance (QA) test criterion or fails during treatment, the failure should be reported in accordance with the requirements of the facility's comprehensive QA program. If the failure is hazardous to patients or staff and/or could occur again at the facility or elsewhere, one should warn others that have this model of accelerator. At least two agencies in the United States, the Nuclear Regulatory Commission (NRC) and the U.S. Pharmacopeia (USP), receive reports of radiation overexposures. This route is sufficient for most problems. In the extreme case of a life-threatening problem, however, this method of reporting is too slow and ineffective. For radiotherapy units with a large installed base, the user should report problems directly to the manufacturer. At that point, the manufacturer is required by law to contact all other users of the machine directly and promptly.

The Medical Device and Laboratory Product Problem Reporting Program was initiated m 1973. The program's objectives are to improve product quality and to inform industry and government about health hazards caused by medical devices. The program is coordinated by the United States Pharmacopeia (USP), an independent nongovernmental body, and funded by the Food and Drug Administration, Center for Devices and Radiological Health (CDRH) . The Problem Reporting Program (PRP) for Radiation Therapy was first introduced to the radiation therapy community in December 1979, by the CDRH and the AAPM. The PRP for radiation therapy is cosponsored by the American Association of Physicists in Medicine, the American Society for Therapeutic Radiology and Oncology, the American Society for Radiologic Technologists, the American Association of Medical Dosimetrists, and The American College of Radiology.

Those reporting problems are encouraged to supply as much information as possible. Of particular significance are the following.

(a) Equipment identification numbers (model, serial, etc.). This information helps to identify problems that are recurring in a particular model and enables the FDA to resolve problems rapidly.

(b) Complete name of the device(s) and the company name that appears on the label. Note, if possible, whether the company is identified as a distributor or manufacturer.

(c) Whether the directions for use were properly followed, and if not, whether the directions could have been improved.

The FDA is always interested in reports of death, serious injury, or any malfunction that could result in hazards or injuries. Problems with medical devices, *in vitro* diagnostics, and radiological health products should be reported when the following occurs.

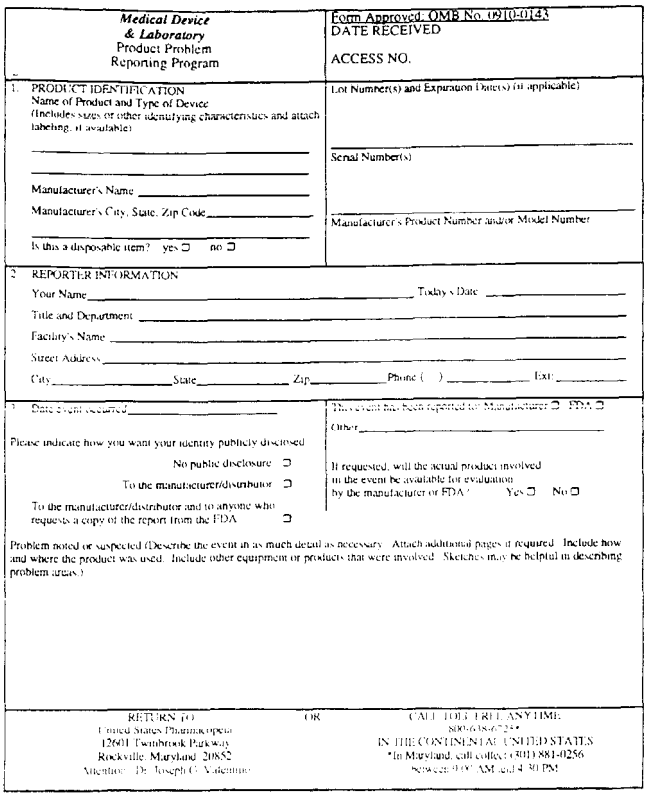
(a) User error is the cause or a contribution. The FDA is especially interested if the design of the device, or unclear or incomplete labeling, contributed to the event.

(b) A decision is made to no longer use a piece of equipment because of a malfunction. It is better to report the event rather than just return the device to the firm.

(c) Repeated repairs do not solve the problem.

(d) A manufacturer's design or repair changes adversely affect the performance, safety, or efficacy of a product.

(e) The problem indicates poor quality control by the vendor.



Medical Device & Laboratory Product Problem Reporting Program

Form Approved: OMB No. 0910-0143
DATE RECEIVED
ACCESS NO.

1. PRODUCT IDENTIFICATION
Name of Product and Type of Device (Includes sizes or other identifying characteristics and attach labeling, if available)
Manufacturer's Name
Manufacturer's City, State, Zip Code
Is this a disposable item? yes ☐ no ☐
Lot Number(s) and Expiration Date(s) (if applicable)
Serial Number(s)
Manufacturer's Product Number and/or Model Number

2. REPORTER INFORMATION
Your Name ____ Today's Date
Title and Department
Facility's Name
Street Address
City ____ State ____ Zip ____ Phone ( ) ____ Ext:

Date event occurred
This event has been reported to: Manufacturer ☐ FDA ☐
Other
Please indicate how you want your identity publicly disclosed
No public disclosure ☐
To the manufacturer/distributor ☐
To the manufacturer/distributor and to anyone who requests a copy of the report from the FDA ☐
If requested, will the actual product involved in the event be available for evaluation by the manufacturer or FDA? Yes ☐ No ☐

Problem noted or suspected (Describe the event in as much detail as necessary. Attach additional pages if required. Include how and where the product was used. Include other equipment or products that were involved. Sketches may be helpful in describing problem areas.)

RETURN TO
United States Pharmacopeia
12601 Twinbrook Parkway
Rockville, Maryland 20852
Attention: Dr. Joseph C. Valentine

OR

CALL TOLL FREE ANYTIME
800-638-6725*
IN THE CONTINENTAL UNITED STATES
*In Maryland, call collect (301) 881-0256
between 9:00 AM and 4:30 PM

FIG. 1. Form used for reporting problems with medical devices and laboratory products.

(f) Incompatibility between different manufacturer's devices results in a serious hazard or injury and the labeling did not warn the user of such potential problems.

(g) A malfunction reduces the patient's opportunity for successful treatment or results in prolonged hospitalization, repeated surgical procedures, or readmission.

If the event you observed does not involve (or have the potential to cause) a death, serious injury, or life-threatening malfunction, it probably should not be reported. These include the following.

(a) Cosmetic changes to a product that do not affect, or have the potential to affect, the performance, safety, or efficacy of the device.

(b) The selection of an alternative product when the choice was not affected by poor performance or questionable safety of the device.

(c) Normal wear and tear of a device; routine service complaints (where no performance problems exist) such as nonresponsiveness of the firm, or unavailability of service manuals, parts, and replacements.

(d) Isolated problems where the chance of recurrence is thought to be either zero or highly unlikely.

If a reportable event occurs, the reporter should fill out the PRP form (Fig. 1) and send it to the USP, 12601 Twinbrook Parkway, Rockville, Maryland 20852 (forms are available from the USP or Fig. 1 may be reproduced and used). If the problem needs immediate reporting or if one does not have the time to fill out the form, USP has a 24 h toll free number (1-800-638-6725) to handle reports. It is advisable to reproduce copies of Fig. 2 and post them or order free stickers from USP. When reporting by telephone, one should have the listed information readily available.

When the USP receives the report, it sends a copy to FDA/CDRH and to the manufacturer, or importer (see Fig. 3). FDA/CDRH contacts the manufacturer and requests an analysis and a response. They also examine their files for similar reports and look for trends among similar products. Meanwhile, the manufacturer examines his own records for trends. The manufacturer investigates the re-

PRODUCT PROBLEM REPORTING PROGRAM

When you call USP, please be ready to provide:

1. Your Name
2. Hospital or Office Address, Zip Code and Phone Number
3. Product Name
4. Lot Number, Expiration Date (if possible)
5. Model and or Serial Numbers
6. Manufacturer's Name and Address
7. Problem Noted (please be brief but complete)

CALL TOLL FREE ANYTIME

800-638-6725*

***In Maryland, call collect (301) 881-0256 between 9:00 AM and 4:30 PM**
REMEMBER TO USE ANY IN-HOUSE REPORTING PROCEDURES

FIG. 2. Product problem reporting program decal with 24 h toll free telephone number.

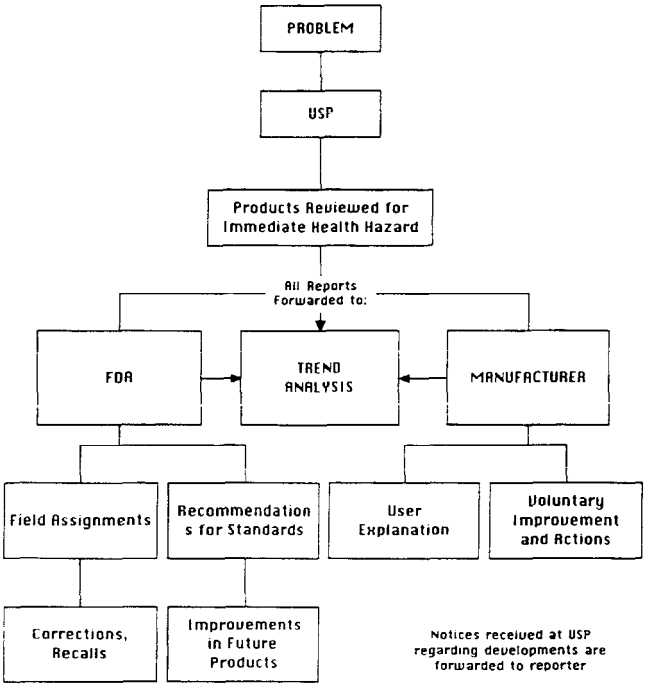


FIG. 3. Flow chart of the medical device and laboratory product problem reporting program.

TABLE I. FDA "recalls" and "recall class."

The FDA has established the following regulatory definitions of "recall class." A FDA "Recall" may involve removal of a product from the market or return to the manufacturer for repair. However, the FDA also uses the word "Recall" to describe field corrections, field repairs, labeling changes, hazard warnings, and other situations.	
"Class I Recall"	"A situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious adverse health consequences or death."
"Class II Recall"	"A situation in which the use of, or exposure to, a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote."
"Class III Recall"	"A situation in which the use of, or exposure to, a violative product is likely to cause adverse health consequences."

port for the level of hazard and the possibility of recurrence in like or similar models. If necessary, the manufacturer will convene a meeting of experts to perform a complete hazard evaluation. A report will be sent to FDA/CDRH including the analysis and recommendation of the manufacturer or importer. FDA/CDRH may agree or may require a different response to the problem. If a hazard exists for other units, FDA/CDRH or the manufacturer may declare a recall. Table I lists the three classes and definitions of recalls. In the case of large, complicated devices, such as medical accelerators, a recall really means that all identified, affected units will be corrected. If a recall is declared, the manufacturer must submit a corrective action plan (CAP) to FDA/CDRH for approval before initiating the corrective action. The FDA regional or district offices assign an investigator to follow the progress of the CAP and to ensure its completion. Problems that do not indicate potential hazards in other units are corrected on an individual basis, without a recall being declared. In either case, the USP informs the original reporter of the action taken.

In 1978, the Good Manufacturing Practices (GMP) section of the FDA medical device regulations became effective. These regulations require manufacturers to keep a complaint file and reply to persons who have reported problems directly to them. The Medical Device Reporting (MDR) regulation, which became effective December 13, 1984, applies to all manufacturers and importers of medical devices and makes reporting mandatory if a device (a) may have caused or contributed to a death or serious injury or (b) has malfunctioned and is likely to cause or contribute to a death or serious injury, if such a malfunction recurs. Table II lists the reporting requirements that apply to the manufacturer or importer. The user's voluntary responsibility is to report such events to the manufacturer as soon as possible. Reporting to the PRP accomplishes the same results, but there may be a delay in the manufacturer's receipt of the information.

The USP reporting route is sufficient for the most common problems. However, in the extreme case of a life-threatening problem for radiotherapy units with a large installed base, the user should report this directly and immediately to the manufacturer. At that point, the manufacturer should contact all other users of this machine directly and speedily.

There is also an urgent need to provide more detailed technical explanations of significant overexposures and to incorporate them into the education and training of physicists, radiation oncologists, technologists, machine maintenance technicians/engineers, and manufacturers.

G. Communicating with accelerator manufacturers

Communication between users and vendors is necessary for the continued operational safety of the linear accelerator and its associated equipment. Once a unit has been installed, the user should become familiar with the manufacturer's local, regional, and national representatives. This is necessary, not only for routine repairs and problems, but also in case of very serious problems. The action to be taken by the user after an incident depends on its severity. These are categorized as follows.

(a) Injury or death resulting from use of the equipment. An investigation must be carried out with the highest urgency to warn the therapy community, discover the causes, and solve the problem. The vendors need to inform users whom to contact. An employee of the vendor who is aware of such an event must report it to the company's regulations officer and/or other designated responsible person. Each therapy clinic should as a matter of policy have a named person whom the manufacturer can contact in an emergency.

(b) Potential for injury or death from use of the equipment. In general, all safety related deficiencies that need to be corrected require timely contact and the problem is han-

TABLE II. Medical device reporting requirements.

Reportable event	Type of report	Time limit	Comment
Death or serious injury	Telephone	As soon as possible, but no later than five calendar days	Must be followed by written report
	Written	Within 15 working days	Telephone report must be submitted first
Malfunction likely to cause a death or a serious injury	Written	As soon as possible, but no later than 15 working days	Telephone report not required

dled similarly to the case of injury or death. Labeling a problem as having the "potential for injury or death" is sometimes a matter of personal judgment' Therefore, it is important to be objective in these cases since the consequences can be disruptive and expensive for both users and vendors.

(c) Impact on equipment availability. Problems that cause a significant and ongoing downtime of the equipment need to be resolved quickly, since they can result in physical and psychological discomfort to the patient and create scheduling and economic problems for the clinic.

(d) Impact on equipment usability. Some problems do not prevent treatment, but do disrupt smooth clinical operations. For example, interlocks that require extra intervention to initiate a treatment or frequent terminations during treatment cause aggravating distraction and disruption to the normal clinical procedure. When these problems occur frequently, there is a tendency to override them as a routine procedure. Such a procedure could cause the operator to mistake a serious problem for a routine one, and perhaps cause a potentially hazardous incident. Careful discipline is required of the operator to guard against this.

(e) Inconvenience or user unfriendly equipment features. Most equipment has some features that are awkward to use or require extra time and effort to implement during treatment. Cooperation between user and vendor is required to resolve these problems.

(f) Equipment development. Close cooperation between the user and vendors has resulted in significant improvements to equipment safety features.

There are several points of contact with most vendors. Depending on the reason for contact, possibly different persons may be notified. Vendors have district, regional, and national sales offices and the manager is the appropriate contact. If the item is manufactured in the U.S., the factory is also a point of contact, but such contact should be reserved for urgent safety related problems.

Clinics have frequent and ongoing contact with sales representatives and service personnel, who often serve as conduits for reporting and resolving of problems. This link becomes less certain if third party service is provided or if equipment has been remanufactured and sold by a third party. Third party service should be avoided as a point of contact; instead go directly to the original vendor for safety related problems. For rebuilt equipment, the company that performed the rebuild should be contacted. The followup process provides a mechanism to alert the therapy community for safety-related problems.

Although verbal notification and discussion is an essential and sometimes urgent first step, it should always be followed up with written notification, providing as much specific detail as possible and ensuring that the content addresses the facts and is directed to the problem.

Although vendors should listen to user's suggestions for improvements, the user must understand that not all good ideas are practical to implement for reasons of cost.

H. Accumulation of data

Manufacturers generally provide a list and charts of the machine parameters that should be checked and recorded daily or weekly. This data set provides the background for investigating any fault. In-house personnel may want to monitor additional parameters. Detailed QA records of daily, weekly, and monthly checks, and annual calibrations should, of course, be maintained.[23-24]

V. RADIATION THERAPY TECHNOLOGIST TRAINING

Before a technologist starts working with a treatment machine, he or she should be given extensive training on (i) the normal operation of the machine, (ii) the meanings of the various interlocks and fault lights, as well as the appropriate response to their occurrence, (iii) any unusual aspects of the machine that could be important during routine treatments, and (iv) quality assurance tests. This instruction is a standard procedure required of cobalt-60 licensees by the NRC and should also apply when the technologist is reassigned to a machine after a lengthy absence or a period of time spent on a machine with different operating characteristics. Manufacturers routinely provide initial instruction on machine operation, but it is not advisable not to rely on these instructions on a regular long term basis. The instructional procedure should be repeated at regular intervals. Continuing education is also a valuable part of the technologists training. Lectures and seminars on subjects pertinent to machine operation, quality assurance, and safety can supplement the initial training. The ACR manual on quality assurance in radiation therapy provides a comprehensive review of this subject for technologists.[25]

A. Initial training

All technologists starting work on a machine for the first time require some formalized training to include the main components listed below.

1. General overview of accelerator

The training should start with a good general overview of the machine. This includes a complete familiarization with the design, characteristics, special features, performance parameters, and controls of the accelerator. A technologist should be able to identify all major components of the machine. The product data pamphlets, and operator instruction manuals are often a good source of general information on a machine. A primer on the theory and operation of linear accelerators provides a useful basic introduction to this topic in a simplified style.[26] It can be helpful to emphasize the difference between the machine on which the operator is being trained and the machine on which he or she has been working. Some accelerators have special options that require specialized training, and these should be clearly identified. It is crucial to identify the potential for malfunction on a particular accelerator. Relating to a personal knowledge of malfunction or experience with malfunction can sometimes make valuable impressions on the trainee.

2. Operation of control console

Familiarity with the components at the treatment control desk is essential. The radiation treatments on a computer-controlled linear accelerator are initiated via input through a keyboard or a key pad. The machine setup parameters are displayed on monitor screens. All parameters displayed on the screen should be explicitly understood by the operator. The operator should be trained to watch for messages that indicate the state of operation and provide warning of an error. The significance of each displayed message should be stressed, especially with reference to the ways in which it may affect the patient treatment. The technologist should not be permitted to override major fault conditions during patient treatments. The meanings of the various interlocks and the appropriate response to their occurrence should be clearly identified to the operators. A simple written description of interlocks and fault indication codes is helpful for the technologists. They can use it as a quick reference to identify fault conditions on the machine.

3. Treatment room area

A technologist should be able to identify and operate all electromechanical controls on the machine inside the treatment room. A thorough knowledge of hand-pendant, collimator-head, and treatment table controls is essential for safe operation. Technologists should be especially aware of collision prevention and "emergency off' devices on the machine and walls. Some manufacturers provide a computer-assisted setup facility on their accelerators. The use of this facility requires a complete understanding of conditions in which there may be a collision of the treatment table and the gantry arm. The safe use of all treatment accessories should also be demonstrated to the technologists.

4. Emergency procedures

All operators should be familiar with the location and use of emergency stop buttons because it may become necessary to activate these buttons in case of interlock failure or patient emergency. A written emergency procedure should be posted at the treatment control desk. This is mandated by some state regulatory agencies.

5. Safety procedures

All safety procedures should be explained to the technologists to ensure the safety of both patient and user. The importance of mechanical, electrical, and radiation safety should be stressed to satisfy local regulations and ensure acceptable standards of good practice. Safety is compromised when attempts are made to override any safety interlocks. The training should emphasize that only qualified service personnel familiar with the safety procedures are allowed to have access to high-voltage components or remove equipment covers for service.

6. Remote viewing of patients

The technologists should be aware of the importance of remote visual and aural contact with the patient during the treatment. It is especially important during dynamic treatments in which the table or gantry move. Remote viewing of the patient is mandated by some state regulatory agencies.

B. Continuing education of operators

Refresher education is a valuable part of the operator training. It is especially necessary when the technologist is reassigned to a machine after a lengthy absence or a long period working on another medical accelerator with different operating characteristics. It is best provided by a physicist, who should also describe institutional experience with the use of the machine. Continuing education in the form of lectures and seminars at regular intervals on subjects pertinent to machine operation, quality assurance, and safety can supplement previous training. Active participation by current operators of the machine in the lectures and seminars should be emphasized, as they can relate to the safety issues and problems very effectively.

VI. COMPUTER-CONTROLLED MACHINES

Ensuring safe operation for a computer-controlled accelerator is more difficult than it is for a machine with traditional electromechanical controls.[27] The complexity of interactions between hardware and software in a real-time environment makes it currently impossible to demonstrate that the design of a real-time control system is correct and that all possible failures have been eliminated. It is not possible to test all combinations of inputs, in all possible sequences, and from all possible sources. Much of the design testing must be performed in a simulation mode. Simulation of all conditions that might lead to a system failure is difficult, and there is no way to guarantee that a simulation is accurate, since operating conditions often differ from test conditions. Unlike a conventional hardware control system, a software control system is usually designed specifically for a particular application. Therefore, it has no historical usage information and has not been improved through prior use in other applications. When automated treatment techniques are used, greater attention must be paid to the initial setup and data entry, because errors in these areas will be faithfully reproduced for each treatment by the control computers. The revised IEC publication 601-2-1 provides an insightful perspective of safety requirements for medical accelerators, including computer and microprocessor systems.[28]

A. Software errors

Even for software alone, it is generally impossible to prove or demonstrate correct functioning under all circumstances. It is not possible to anticipate the myriad of conditions that can arise through the interaction of the components, and unexpected system actions occur, even in highly structured systems. Some software products have major "bugs", and will not work properly for some users.

Software is generally distributed for use when the rate of discovering new errors slows to a level that the developers consider acceptable and safe. This does not mean that the software has been verified to be 100% error free. One manufacturer of hardware and software for critical care systems uses a rigorous software quality assurance program with four indicators to determine when software should be released for use by customers: (i) a steady decline in the number of defects found per unit test time, (ii) reaching the predetermined threshold in defects per 1000 lines of code, (iii) specified period of test time without detection of a critical defect, and (iv) satisfactory completion of a Clinical Tria1.[29]

A FDA study indicates that recalls of medical devices because of computer-related problems doubled from 1980 to 1985.[30] In most cases, software errors were the primary problem. Also cited were inadequate software quality assurance practices, poor software design, poor conditioning of ac power or inadequate rejection of interference, and faults due to radiated electromagnetic interference. Other system failures may be caused by security violations, by human mistakes during operation and maintenance, by interfacing problems such as timing errors, or by hardware states unanticipated in the software design and implementation. Serious malfunctions of all the above types, some involving loss of life, have occurred in computer-controlled systems.[30-33]

An important requirement for computer-controlled hardware systems is that the system fall into a "safe" state when a hardware failure occurs. In the case of linear accelerators, a safe state is one in which the radiation beam is off, all motions are halted, and it is possible to remove the patient from the machine. Not all system failures cause safety problems, Safety is difficult to demonstrate because it requires testing of failure modes without damaging the system. It must be an integral part of the design and specification for the control systems, not added as an afterthought. Software quality assurance must be part of the manufacturing, testing, and installation procedures.

Software-related failures in computer-controlled systems fall into two main categories: errors built into the software itself and errors introduced into the software by the environment or by hardware failure. Errors may be inherent in the software because of incorrect specifications, which lead to incorrect design, incorrect design in spite of correct specifications, or programming errors. Correct software may subsequently become corrupted by computer hardware failure and by environmental effects such as radiation damage to random access memory.

B. Testing

As with all computer hardware and software, testing of computer-controlled real-time systems serves several distinct purposes. During development, testing is performed to verify that the system is performing according to its design specifications. "Alpha testing" is done in-house by the manufacturer. Later, during field testing or "beta testing," the adequacy of the system design and specifications is verified. This involves real clinical use of the software, with detailed reporting back to the vendor. During both phases, changes in the specifications, design, and implementation are made as needed. Once the product is mass produced and distributed, field testing is needed to verify that each copy of the product performs as intended. In this report we address this final testing. The documentation, procedures, and testing described are intended to assist the users in fulfilling their responsibility to demonstrate that the computer controlled linear accelerator in the field is performing safely and in compliance with the manufacturer's specifications. The recommendations in this report are not intended to uncover design flaws, although deficiencies may surface during independent testing.

1. Acceptance testing

Even with correct design and implementation, errors in hardware and software can occur during the manufacturing and installation processes. The purpose of acceptance testing is to verify the proper and safe operation of the particular machine purchased by the user. Acceptance testing for a computer-controlled linear accelerator should include all the tests performed on conventional therapy machines, plus additional tests to verify proper operation of software, communications, and hardware/software/user interfaces. The emphasis in this report is on those additional tests. Functions to be tested are described, but specific tests are not identified, because the testing details will vary among machine designs. Whenever possible, tests should be performed in the operational mode that is used to treat patients.

The user interface should be vigorously tested to ensure that a meaningless accidental input does not put the machine into a hazardous state. All screen display control device and cursor movements should be tested. All lockout functions, key switches, and passwords should be verified for proper functioning and integrity. Any special functions and control keys accessible by the operator should be carefully tested.

Treatment and service modes of operation should be clearly identified and maximally isolated to prevent accidental treatment of patients in a service mode. Proper reinstatement of interlocks should be verified after any "bypass" in the service mode. Error messages to the operator should be explicit, detailed, documented, meaningful, and correct.

Testing of the safety interlocks on a computer-controlled accelerator is similar to that for a conventional machine. The safety interlocks include emergency off switches, anticollision devices, and excess dose rate and excess dose per pulse sensors. Some safety interlocks may be actuated through the computer control system rather than direct hard wiring. Sensitivity for activation and resulting speed of beam-off and motion termination should be tested for all the safety interlocks.

A few other tests are unique to computer-controlled machines. If the accelerator is equipped for computer-assisted setup, the safety of operation in that mode should be verified. The return of the machine to a safe condition in the event of a computer or computer-related hardware fail-

ure should be verified. If power conditioning and isolation for the computer(s) are not used, the computer and machine operation should be carefully monitored for any adverse effects of occasional power transients.

During acceptance testing, the user should document the values of machine operation parameters, range limits for parameters, and safety interlock settings. These values can then be used for comparison with the results of future tests following machine repairs and software modifications by the manufacturer.

2. Software related quality assurance and maintenance

Routine scheduled maintenance and testing is done on conventional machines to prevent, uncover, and correct hardware malfunctions that can compromise safe operation. Hardware changes occur over time because of normal wear of components and environmental stresses, such as radiation damage. In computer-controlled machines, hardware changes may also affect software operation by corrupting essential data or the programs themselves. Even if the software may have passed acceptance testing without demonstrable errors, latent bugs may appear as the hardware ages.

Following routine and preventive maintenance, all safety interlocks should be checked. Because software and hardware are intimately linked in a computer-controlled machine, even a minor change in hardware (such as replacement of parts) can produce aberrations in the operation of the machine if there is a flaw in the software design or implementation. Integrity of software and data should be verified using the appropriate tools supplied by the manufacturer.

Similarly, all safety interlocks should be tested following nontrivial repairs. If repairs require beam tuning procedures that change the operating parameter database, then all treatment beam characteristics should be verified. If repairs are extensive or involve critical components, full acceptance testing may again be necessary to ensure proper operation.

In the case of software updates, the integrity of the software and database should be determined after installation. All tests suggested by the manufacturer to verify correct operation of the new software should be performed. All safety interlocks should be tested. Treatment beam parameters that may be affected by the software changes should be verified. Full acceptance testing may be necessary, depending on the nature and extent of the software changes.

VII. SOFTWARE AND COMPUTER-CONTROL SYSTEMS DOCUMENTATION

Manufacturers should provide users with certain appropriate documentation to facilitate the testing and demonstration of safety of computer-controlled accelerators in the field. Proprietary information must be clearly labeled by the manufacturer and confidentiality must be respected by the user.

Documentation of system design, development, and quality assurance practices should be made available. ANSI/IEEE standards provide minimum requirements for the contents of software quality assurance and software verification and validation plans.[34,35] Preliminary hazard analysis identifies critical safety areas and functions, identifies and evaluates hazards, and identifies the safety design criteria to be used. Operating and support hazard analysis identifies hazards and risk reduction procedures during all phases of system use and maintenance, especially hazards created by the man-machine interface.

Manufacturers should provide purchasers with test procedures that guide the user through on-site testing of therapy machines. For computer-controlled accelerators these procedures must include additional tests for the computer control system. Purchasers should consider the manufacturer's recommended test procedures as a minimum set to be supplemented as necessary with further testing.

For the user to understand and properly execute the computer control system test procedures, the manufacturer's documentation should include a description of the design philosophy for each subsystem and the relationships between subsystems, functional specifications for the hardware, and software of each subsystem, and detailed descriptions of input-output functions (menus, input formats, special function keys, displays of machine operating conditions, etc.).

Procedures, techniques, and utilities for verifying and maintaining software and data integrity should be provided. For machine maintenance and tuning, users may need access to databases containing machine operating parameters. They also may need access to the computer operating system to install software upgrades. Some type of system security (e.g., passwords) should be provided to prevent unauthorized and accidental access. Utilities to verify that software and data files are unchanged (e.g., by calculating and comparing check sums) should also be provided by the manufacturer.

As part of the development process, manufacturers conduct extensive in-house and field testing of software and hardware. Field testing can be logistically difficult and expensive. However, a new product cannot be considered safe until it has been verified in the clinical environment by a medical staff with actual patients. Identification of the field test sites and access to the test data will help minimize the validation and verification efforts by other users. Users should verify that the tests they feel are important were conducted and selectively repeat or add new tests.

One of the advantages of computer-controlled accelerators is that new capabilities can be added by changing software. However, this capability is also a disadvantage for users, because they must treat the design changes in software (i.e., updates) in the same way that they would treat design changes in hardware, namely, with extensive testing to verify proper and safe machine operation. To assist the user in properly verifying new versions of software, the documentation for software updates should include the following: (a) reasons for all changes, including bug fixes; (b) details of modifications made; (c) details of

TABLE III. Model safety program for medical accelerator facility.

1 *Use of the medical accelerator*
- 1.1 The unit should be operated only by authorized personnel who are trained in the safe operation of the unit; this typically includes radiation therapy technologists, radiation physicists, dosimetrists, and machine maintenance personnel.
- 1.2 Instructions on how the unit is to be operated should be maintained at the console.

2 *Safety device checks*
- 2.1 The console and room radiation warning lights and door interlock should be checked daily by the radiation therapy technologist. Their status should be recorded in the unit's daily log.
- 2.2 All ancillary equipment, including but not limited to that for patient aural and visual communication, should be in good working order and regularly tested at appropriate intervals as part of a continuing Quality Assurance (QA) program. Treatment should not proceed if specific ancillary equipment essential to treatment is inoperative.

3 *Personnel dosimetry*
- 3.1 Appropriate personnel monitors (e.g., film badges) should be provided by the institution's Radiation Safety Office.
- 3.2 The personnel monitors should be supplied with a specified frequency, e.g., monthly.
- 3.3 The personnel dose reports should be reviewed by Radiation Safety Office staff and reported values exceeding the investigative levels of the institution's ALARA program should be referred to the ALARA Investigator for timely review. Monthly personnel reports should be posted conveniently for ready access by involved personnel.

4 *Procedures for securing the medical accelerator*
- 4.1 The treatment room should be secured during nonworking hours and when left unattended.

5 *Instrument calibration and checks*
- 5.1 Radiation survey meters should be calibrated annually. A description of the sources calibration frequency and equipment procedures should be documented.
- 5.2 The dosimetry system used for full calibration should be calibrated every two years by an AAPM Accredited Dosimetry Calibration Laboratory (ADCL).
- 5.3 The dosimetry system(s) used for periodic QA checks should be calibrated on a yearly basis by a qualified radiation oncology physicist by intercomparison with a dosimetry system calibrated by an ADCL

6 *Acceptance testing and full calibration of medical accelerator*
- 6.1 Testing and full calibration should be made by a qualified radiation oncology physicist following the procedures given in the AAPM Code of Practice for Medical Linear Accelerators and the AAPM TG21 Protocol.

7 *Software quality assurance and testing*
- 7.1 Acceptance testing procedures for new software and/or new computer-control features should be designed specifically to test the software and control aspects of the system. All safety interlocks and new functionality should be tested rigorously after review of all vendor documentation and testing information which is available.
- 7.2 Routine updates of software for a computer-controlled machine should be treated as if it includes the possibility of major changes in system operation. All vendor information supplied with the update should be studied carefully, and then a detailed software/control system test plan created. All safety interlocks and dosimetry features should be carefully tested, regardless of the scope of the changes implied by the update documentation.

8 *Periodic QA measurements of medical accelerator*
- 8.1 QA measurements should be performed following procedures and frequencies recommended by AAPM Report No. 13.
- 8.2 The results of the spot check measurements should be reviewed (and initialed) by the radiation oncology physicist.

9 *Servicing and inspection of the medical accelerator*
- 9.1 Only persons or firms specifically authorized by the physicist in charge at the institution should perform any maintenance or repair of the unit.
- 9.2 Appropriate dosimetry measurements should be performed after any maintenance or service is performed. The responsibility for release of the accelerator to clinical service after maintenance is the radiation oncology physicist.
- 9.3 A full inspection of the medical accelerator should be done by the manufacturer at intervals not to exceed three years.

10 *Radiation survey*
- 10.1 A radiation survey should be performed by a qualified physicist before initial use and whenever any changes are made in the shielding, location, or use of the unit that could effect radiation levels in surrounding areas.

11 *Emergency procedures*
- 11.1 Emergency procedures should be posted at the medical accelerator control console.
- 11.2 All new treatment personnel should be trained in emergency procedures as soon as they report to duty. Practice drills in emergency procedures should be conducted by the qualified radiation oncology physicist or his designee with all appropriate personnel at least once a year.

12 *Procedure for notifying the proper person in the event of an accident or an unusual occurrence*
- 12.1 In the case of an accelerator malfunction, individuals listed on facility's "Emergency Procedures" should be notified.
- 12.2 In the case of a suspected treatment misadministration, follow guidelines listed in Section 4 of this (TG-35) report.

13 *Record keeping*
- 13.1 Copies of the following documents should be maintained by the institution.
  - a. Records of results of safety device checks.
  - b. Records of personnel dose monitoring.
  - c. Records of survey instrument calibrations.
  - d. Records of calibration of the dosimetry system used for full calibration measurements.
  - f. Results of acceptance test and full calibration measurements.
  - g. Results of periodic QA measurements.
  - h. Record of evaluation of the training and experience of the "qualified radiation oncology physicist."
  - i. Records of training of new personnel and annual refresher training of personnel.
  - j. Records of full inspection and all maintenance work performed.
  - k. Records of radiation surveys.
  - l. Copies of applicable regulatory statutes.

TABLE IV. Operational recommendations (Modified from Karzmark, 1987).

1. Remove the patient from the treatment room as a first step when uncertainty in normal treatment unit operation occurs; err on the side of safety rather than staying on schedule.
2. Establish and maintain good communication among the technologists who operate the treatment units in a given facility and between them and the radiation oncologists, physicists, engineers and service personnel. Maintain a continuing informal dialogue on the running characteristics of treatment units. Technologists, who are most directly involved with machine operation, provide the most important first line of defense against accidents.
3. Identify a primary technical consultant, preferably involved in the dialogue noted above, to whom technologists have recourse in the event of unexpected behavior of the treatment unit. This would normally be a maintenance engineer or qualified radiation oncology physicist. Identify a hierarchy of consultants in the event of the primary consultant is unavailable. Post a dated list of these consultants at the operating console of each treatment unit. Involve the consultant promptly and restrict the technologist's ability to easily resume treatment when significant malfunctions occur.
4. Prepare a written procedure with specific steps to be followed by the technologist in case of specific malfunctions. Review this with the technologist. The technical consultant would be called only when these steps fail to solve the problem.
5. Ensure that all ancillary equipment, including but not limited to that for patient aural and visual communication, is in good working order and regularly tested at appropriate intervals as part of a continuing Quality Assurance (QA) program. Treatment must not proceed if specific ancillary equipment essential to treatment is inoperative.
6. Incorporate in the QA program periodic reviews of all relevant safety procedures with treatment technologists. Reiterate the location and function of emergency off buttons. Maintain an archival log describing routine operating conditions and QA tests for each treatment unit together with a description of technical problems immediately after they occur and their solutions. Be alert to changes in performance, both gradual and sudden. The technical, medical and administrative managers of the organization responsible for radiation treatment should endorse the QA program in writing.
7. Have a full-time, qualified radiological physicist available at all facilities which employ dual or multimodality megavoltage treatment equipment, a practice already observed in most countries at all megavoltage facilities. A part-time consultative physicist does not appear to provide an adequate safeguard against the hazard here addressed.
8. Incorporate redundancy with no common failure modes where safety is involved. For example: confirm computer actions with manual methods.

planned/expected operational changes following installation of the update; (d) site-dependent and user-accessible data or software, which may be affected; (e) procedures for testing operations affected by the update, (f) revised design specifications, support documentation, and/or operations manuals; and (g) results of beta tests.

In spite of extensive in-house and beta testing by the manufacturer, new problems are occasionally discovered by users in the field. Manufacturers should provide procedures for reporting such problems. These procedures should use standardized forms and should clearly describe the information to be submitted with the report. System utilities for automatic error logging, crash dump analysis, etc. would be useful for reporting system problems. Manufacturers should respond to the reports with a written acknowledgment, followed by a timely response evaluating the severity of the problem, a recommended temporary solution, or a recommendation to suspend treatments, and a proposed permanent solution with a time schedule for implementation.

VIII. SUMMARY

Ensuring safe operation for a medical accelerator is a difficult task. Users must assume more responsibility in using contemporary equipment. Additionally, users must work closely with manufacturers in promoting the safe and effective use of such complex equipment.

Complex treatment techniques and treatment modality changeover procedures merit detailed, unambiguous written procedural instruction at the control console. A thorough "hands on" training period after receiving instructions, and before assuming treatment responsibilities, is essential for all technologists. Unambiguous written instructions must also be provided to guide technologists in safe response when equipment malfunctions or exhibits unexpected behavior or after any component has been changed or readjusted. Technologists should be given a written list of the appropriate individuals to consult when unexpected machine behavior occurs. They should be assisted in identifying aberrant behavior of equipment. Many centers already provide this instruction, but others may not. Practiced response and discussion with technologists should be a part of an ongoing quality assurance program. An important aspect of a safety program is the need for continuous vigilance.

Table III gives a summary of a comprehensive safety program for medical accelerators. Table IV gives a list of summary recommendations as an example of how one might mitigate the consequences of an equipment failure and improve procedures and operator response in the context of the environment described. Most of these recommendations can be implemented almost immediately at any individual treatment center.

[1]E. J. Joyce, "Malfunction 54', unraveling deadly medical mystery of computerized accelerator gone awry," Am. Med. News **1,** 3 (1986).
[2]E. J. Joyce, "Firm warns of another therac 20 problem," Am. Med. News **20,** 7 (1986).
[3]E. J. Joyce, "Software 'bug' discovered in second linear accelerator." Am. Med. News **20,** 7 (1986).
[4]E. J. Joyce, "Accelerator linked to 5th radiation overdose," Am. Med. News **1,** 6 (1987).
[5]E. J. Joyce, "Software flaw known before radiation killed 2," Am. Med. News **3,** 16 *(1987).*
[6]B. G. Levi, "Soviets assess cause of Chernobyl accident," Phys. Today **39,** 17-20 (1986).
[7]R. J. Catlin, "Causes and lessons learned," *Proceedings of the Symposium on Handling of Radiation Accidents* (Publisher, Vienna, 1969), pp. 37-450.
[8]C. J. Karzmark, "Procedural and operator error aspects of radiation accidents in radiotherapy," Int. J. Radiat. Oncol. Biol. Phys. **13,** 1599-1602 (1987).
[9]C. J. Karzmark, "Advances in linear accelerator design for radiotherapy," Med. Phys. **11,** 105-128 (1984).

[10]J. A. Purdy, D. A. Gocr, "Dual energy x-ray beam accelerators in radiation therapy: An overview, Nucl. Instrum. Methods B **10/11,** 1090-1095 (1985).
[11]C. J. Karzmark, "Some aspects of radiation safety for electron accelerators used for both x-ray and electron therapy:" Br. J. Radiol. **40,** 697-703 (1967).
[12]P. O'Brien, H. B. Michaels, J. E. Aldrich, and J. W. Andrew, "Characteristics of electron beams from a new 25-MeV linear accelerator," Med. Phys. **12,** 799-805 (1985).
[13]P. O'Brien, R. B. Barnett, H. B. Michaels, and R. A. Siwek, "Measurements of high intensity beams from medical linear accelerators," Med. Phys. **14** (1987).
[14]Therac-25 Safety Analysis Safety Level Discussion Document. AECL Medical Internal Publication ME-G00-88-04:1987.
[15]B. Emami, J. Lyman, A. Brown, L. Coia, M. Goitein, J. E. Munzenrider, B. Shank, L. J. Solin, and M. Wesson, "Tolerance of normal tissue to therapeutic irradiation," Int. J. Radiat. Oncol. Biol. Phys. **21,** 109-122 (1991).
[16]P. Rubin and G. W. Cassarett, "A direction for clinical radiation pathology," *Frontiers of Radiation Therapy and Oncology VI,* edited by J. M. Vaeth (University Park Press, Baltimore, MD, 1972). pp. 1-16.
[17]P. Rubin, R. A. Cooper, T. L. Phillips, *Radiation Biology and Radiation Pathology Syllabus* (American College of Radiation, Chicago, IL, 1978).
[18]A. R. Eames, "Quantitative reliability techniques-A guide to better medical equipment design," Eng. Med. **5,** 31 (1981).
[19]E. E. Pochin, "Quantification of risk in medical procedures," Proc. R. Soc. London Ser. A **376,** 87 (1981).
[20]Sayer, "The use of quantitative reliability techniques in the design of medical equipment," UKAEA Systems Reliability Report No. SRS/GR/34, 1975.
[21]Joint Airworthiness Regulation. JAR 25.1309:3.
[22]M. Rozenfeld and D. Jette, "Quality assurance of radiation dosage: Usefulness of redundancy," Radiol. **150,** 241-244 (1984).
[23]American Association of Physicists in Medicine 'Code of practice for x-ray therapy medical accelerators," Med. Phys. **2,** 110 (1975).
[24]Physical aspects of quality assurance in radiation therapy, AAPM Report No. 13, 1984.
[25]*ACR Quality Assurance in Radiation Therapy: A Manual for Technologists,* edited by M. J. Wizenberg, American College of Radiology, Chicago, IL, 1982.
[26]J. Karzmark, and R. J. Morton, "A primer on theory and operation of linear accelerators in radiation therapy," (Medical Physics, Madison, WI 1989).
[27]M. Weinhous, J. Purdy, and C. Granda, "Testing of a linear accelerator's computer control system," Med. Phys. **17,** 95-102 (1990).
[28]IEC Revision of Publication 601-2-1, "Medical electrical equipment part 1: Particular requirements for the safety of medical electron accelerators in the range 1 MeV to 50 MeV," Based on IEC Document No. 62C (secretariat) 1981, p. 62.
[29]E. H. Schmuhl, "Software QA for critical care systems," in *Proceedings of the 7th Annual Conference of the Engineering in Medicine and Biology Society* (IEEE, New York, 1985), pp. 171-174.
[30]I. Bassen, J. Silbcrberg, F. Houston, W. Knight, C. Christman, and M. Greberman, "Computerized medical devices: usage trends, problems, and safety technology," in *Proceedings of the 7th Annual Conference of the Engineering in Medicine and Biology Society* (IEEE, New York, 1985), pp. 180-185.
[31]B. J. Bonnett, "Software system safety," in *Proceedings of the 7th Annual Conference of the Engineering in Medicine and Biology Society* (IEEE, New York, 1985), pp. 186-192.
[32]N. Leveson "Software safety: Why, what, and how," Comput. Surv. **18,** 125-163 (1986).
[33]P. G. Newmann, 'Some computer-related disasters and other egregious horrors," in *Proceedings of the 7th Annual Conference of the Engineering in Medicine and Biology Society* (IEEE, New York, 1985), pp. 1238-1239.
[34]*ANSI/IEEE Standard 730-1984: Sofiware Quality Assurance Plans* (IEEE, New York, 1984).
[35]*ANSI/IEEE Standard 1012-1986: Software Verification and Validation Plans* (IEEE, New York, 1986).