

AEOD TECHNICAL REVIEW

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SUBJECT: REVIEW OF THERAPY MISADMINISTRATIONS THAT INVOLVED  
 MULTIPLE PATIENTS AND THE USE OF COMPUTER TREATMENT  
 PLANNING PROGRAMS

INTRODUCTION:

The Nuclear Regulatory Commission has required the reporting of therapy misadministrations, as well as diagnostic misadministrations by its licensees since November 1980. In addition to therapy misadministrations that occurred at NRC licensees, the Commission has also been informed of some therapy misadministrations by Agreement State licensees.

Over the eight-year period in which the misadministration reporting rule has been in effect, NRC has received 64 reports of therapy misadministrations from its licensees. In 62 of these reported events, a single individual was over- or undertreated. There were, however, two events in which several individuals were over- or undertreated. In one of these events, wedge factors were measured incorrectly; in the second, the over- or undertreatments arose in conjunction with the use of a computer program. When the total numbers of patients involved in the events that were reported to the NRC from the beginning of the reporting requirements through 1988 is examined, the following distribution is obtained:

<u>Number of Events</u>	<u>Number of Individuals</u>	<u>Percent of Patients Affected</u>
62	62	45
1 (wedge factor)	53	39
1 (computer)	21	15

The two events in which multiple patients were over- or undertreated account for more than 50% of the patients. Although NRC has not received any other reports of events in which erroneous measured data (i.e., wedge factors) were used, NRC has become aware of other events in which errors in the use of computer programs has resulted in multiple patients receiving too much or too little radiation. In four additional events, the error involved computer treatment planning systems and was generally a systematic error.\* In addition, in each of the cases involving a computer, the errors that resulted in the misadministrations went undetected for relatively long periods of time.

In the five events involving errors associated with the use of computer programs, an average of about 21 patients received the wrong amount of radiation. These seem to represent a proportionally greater risk than other therapy events.

\* That is, a similar type of error was present in all or many of the misadministrations that were reported by a given licensee.

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The use of computer programs to perform all or some portion of the calculations necessary to establish a therapy treatment plan may involve both the entry of machine constants into the computer program, an infrequent procedure, and the use of the program in developing treatment plans, a frequent procedure.

If the use of computer treatment planning systems in therapy treatments is analyzed, there are two situations that may increase the probability of occurrence of a systematic error:

Use of a new machine - This category, present only for the use of computers for planning teletherapy treatments, includes the initial operation of an existing teletherapy machine following a source exchange.

Use of a new computer treatment planning program - This category includes the use of an updated or modified version of an existing program. Since machine constants must be reentered into the program, this category is associated with the first category given above.

Systematic errors can also arise if a user misunderstands the computer program, uses the programs, and consistently misuses the computer output as input to manual calculations.

In addition to these situations, the use by a hospital or licensee of consultants to perform dosimetry calculations may also increase the probability of a systematic error, since communications between the hospital staff and the consultants' staff may be poor.

This review was undertaken because of the accumulation of data on multiple misadministrations that involved the use of computers. A total of five such events (four teletherapy; one brachytherapy) have occurred over an eight-year period; 108 patients were over- or undertreated in these events. The purpose of the review is to determine whether a more detailed review of the use of computer programs in therapy planning should be undertaken.

## ANALYSIS OF EVENTS

### Description of Events:

#### Event 1:

Teletherapy	
Cumberland, MD	250 beds
October 1987 - November 1988	13 months

In a recent event, a hospital reported a series of 33 overexposures to patients had occurred over a 13-month period. An error in the computer program resulted in 33 patients receiving doses in excess of 75% of the prescribed dose. Several cases of erythema were observed in the patients.

The teletherapy source had been exchanged in March 1987, but the necessary changes to the computer program file had not been made for brain treatment therapy. Between August 1987 and October 1988, 33 patients received palliative doses in excess of 75% of the prescribed dose.

In March 1987, the consulting physicist had been directed by the physician to change the source strengths in the computer programs to be used at the hospital. The physician stated that one type of brain treatment protocol (one using 'trimmer bars') would not be used and it was then agreed that the computer program file for that protocol should not be changed.

The physician later decided to again treat patients using 'trimmer bars.' The computer program file was used without being updated. A complicating factor was the fact that the consulting firm was a different firm than the one used by the hospital in March 1987.

Event 2:

Teletherapy	
Mount Kisco, NY	250 beds
Hudson, NY	170 beds
Troy, NY	300 beds
- 1987	4+ years

An employee\* of a consulting firm prepared treatment plans using computer programs at three hospitals. While the individual was on vacation, a second employee of the consulting firm was called in by one of the hospitals to revise a treatment plan. The second member of the consulting firm discovered a serious error in the treatment plan developed by the first employee. The second employee then reviewed more plans generated by the first employee and found additional errors. The hospital was notified and retained independent physicists to review all treatment plans used since their program began in 1982.

Twenty-one misadministrations were found. All of the erroneous treatment plans had been prepared by the same individual. None of the errors were attributable to errors in the computer programs; many errors were found in the manual calculations that were made using output from the computer programs. In this event, the errors appeared to be random, although a systematic error was also found.

Two other hospitals at which the individual worked were informed of the errors in dosimetry calculations at the first hospital. At the second hospital, two more misadministrations ascribable to errors in dosimetry calculations were identified. At the third hospital, the computer system computed the machine treatment time and hence no misadministrations were found.

\* The individual who performs the dose treatment calculations is ordinarily referred to as a dosimetrist. This title has not been used in this evaluation to emphasize the fact that there is no regulatory control over the training or experience of the individual who performs the dose calculations. The American Society of Medical Dosimetrists has established a board certification examination for dosimetrists.

It should be noted that there were additional errors found in treatment plans at the first two hospitals but the errors did not result in delivered doses differing from prescribed doses by more than 10%.

Event 3:

Teletherapy	
Marquette, MI	250 beds
September 1985 - October 1986	13 months

During a quality assurance review of hospital records by an external organization in April 1988, an error was discovered in the procedure used in manual calculation of the beam on-time using information generated by the treatment planning computer.

Detailed review of records showed that 21 patients had been undertreated by about 15% prescribed dose during the period from September 1985 to October 1986.

Event 4:

Teletherapy	
Rochester, NY	500 beds
May 1988 - August 1988	4 months

During a 4-month period from May 1988 to August 1988, 14 people received doses that differed from the prescribed dose by more than 10%. The hospital was using a computer program in treatment planning. The procedure used was to enter fractional wedge factors into a utility file in the computer; these factors were then used by the computer to normalize isodose curves to the values they would have in an open (wedgeless) plan. A manual calculation applied the wedge factors to obtain the correct treatment time.

In April 1988, the data in the computer wedge factor file was altered so that the wedge correction factors were applied automatically by the computer. When a second correction factor was manually applied, substantial errors in treatment times resulted. The greatest overdose was 81%.

Event 5:

Brachytherapy	
Albuquerque, NM	300 beds
December 1977- October 1979	13 months

A computer treatment planning program used to calculate the delivered dose from implanted I-125 seeds provided its output as rads per hour. A conversion factor was used to convert the dose rate to rads delivered through end of isotope life. Supplemental treatment (accelerator) was used to achieve the planned radiation dose.

From December 1977 to October 1979, 18 prostate cancer cases were treated at the hospital; severe adverse reactions were noted and questioned by urologists.

Investigation showed that use of an incorrect dose conversion factor lead to the conclusion that too little dose had been delivered by the seeds and unnecessary accelerator radiation provided to some patients. The error seems to have arisen from the double use of a conversion factor, once when the source strengths were input to the computer and again when the dose to end of life was calculated from the computer output.

#### Causes of the Events:

The event that occurred at Cumberland, MD, (Event 1) appears to have arisen from an administrative decision that was complicated by a change of consulting physicists. The duration of the event was lengthened because the occurrence of erythema in one patient did not result in a prompt review of the computer treatment plans.

The other four events, numbers two through five, all involved errors in manual calculations used to convert computer output to the desired item, for example, machine on-time or total dose delivered. (Other errors occurred in Event 2.)

The errors can most easily be ascribed to a lack of knowledge of the individual performing the dose calculations. This easy answer, however, avoids other sources of the individual's error.

Was the individual required to have adequate training in the use of the computer program and to demonstrate his or her ability to use the program correctly?

Was the program documentation adequate to serve as a self-programmed instruction text? Was the computer program user friendly, with good on-screen guidance to the user, and well-labelled output?

Were controlled and validated procedures developed to provide the person using the computer program with defined methods to go from the computer output to the desired answer?

Without answers to these questions, the cause of the four events must be ascribed to a combination of lack of training and a lack of procedures. In addition, the program may have been poorly designed from the point of view of on-screen labelling, etc.

#### CONCLUSIONS

There have been five events reported to NRC that involved the use of computer programs. More than 100 people received therapy doses that differed from the prescribed dose by more than 10 percent. The significance of the events and the problems identified in the use of computer planning programs warrant additional assessment of the use of computer programs in therapy planning.