

STATE OF NEW YORK DEPARTMENT OF HEALTH

11 University Place

Albany, New York 12203-3399

Barbara A. DeBuono, M.D., M.P.H.
Commissioner

Dennis P. Whalen
Executive Deputy Commissioner

NOTICE TO LICENSEES (HDR)

Re: Treatment planning errors

Date: April 2, 1997

This is to bring to your attention a problem that occurred during treatment planning on a Nucletron Plato treatment planning system which contributed to a misadministration. You should review this information for applicability to your program and take action as appropriate to avoid a similar problems. No response to this notice is necessary.

Description of Event

A treatment plan was completed using the Nucletron Plato treatment planning computer and software (version 13.10). The plan included a step size of 5 mm, prescribed dose of 350 cGy and was checked and approved by both the physicist and physician and stored on the program card. The next day the source was replaced with a new higher activity source. On the day of treatment, the plan was updated to include the new source strength. During this step the computer automatically changed the step size from 5.0mm to 2.5mm (the default step size), however the indicated dose remained unchanged at 350 cGy. This was not immediately noticed by the physicist since he was not working in that section of the data page. During the final plan review prior to treatment neither the physicist or physician noticed that the step size was now indicating 2.5 mm. The plan was approved and the treatment was delivered. During subsequent chart review it was noticed that the plan indicated the wrong step size. The actual dose was 665 cGy to half the intended treatment area. Since this was the first of three fractions, the treatment plan has been modified to correct for this error.

Contributing factors to this misadministration included the failure of the licensee to carefully review the plan prior to treatment, failure of the treatment planning computer to provide a warning or error message when it changed the step size and failure to calculate the correct dose when the step size was changed. A similar problem was previously described a Nucletron Technical Bulletin issued in December 1996 (copy enclosed). The manufacturer was notified of this error.

If you have any questions or need additional information concerning this notice, please contact this office.

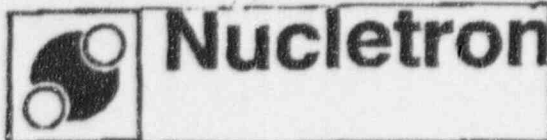
L-4-2 NY
Sincerely,

SP01
Stephen M. Gavitt, Chief
Radioactive Materials Section
Bureau of Environmental Radiation Protection
SMG03@health.state.ny.us

518
9704090136 970402
PDR STPRG ESGNY
PDR

119000





Nucletron Corporation
7080 Columbia Gateway Drive
Columbia, MD 21046-2133
Tel: (410)312-4100
FAX: (410)312-4196

FAX MESSAGE

Date: 14-Feb-97
To: All users of Plato-BPS v.13.1, 13.2
Subj: Safety Alert

Dear Plato User,

Please read the accompanying Technical Bulletin (Plato 261) carefully. This User Notification describes a situation in which it is possible to export incorrect stepsize information to the program card and treatment console.

As an addendum, it is important to note that the described situation refers to reconstruction by catheter describing points. If the reconstruction is done with catheter tracking, the result is the same, but no error messages are displayed in either the plan printout or the journal file.

Proposed solutions:

- Make sure that the stepsize defined in an existing patient and treatment unit are always the same
- Always check the stepsize on the printout from the mHDR after reading in the program card and before proceeding with the treatment.

**Nucletron**

Technical Bulletin

05 December 1996

PLATO 261

Subject:

User Notification

Incorrect check to disable export data
to program card and treatment console


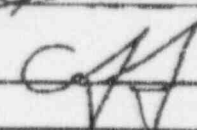
Validity

PLATO BPS v13.1 and v13.2

Approved by:

Product Manager:

Technical Support Manager

**Nucletron****User Notification**

Page 2 of 2

Date of issue: 05 December 1996

091.778/OR196

Validity: PLATO BPS v13.1 and v13.2

Intended use.

All PLATO customers who have installed and use PLATO BPS v13.1 and v13.2 clinically.

Description.

PLATO BPS allows you export data to the program card and treatment console after accessing an existing plan and reading in a treatment unit which has been defined with a different stepsize.

Explanation.

After reading in an existing patient with a treatment unit that has a different stepsize, the journal file printout displays the following error message:

"INACCURATE DOSE CALCULATION MAY RESULT"

"PROGRAM CARD IS DISABLED"

However it is possible to export inaccurate data to the program card and treatment console.

Consequences.

Depending on the sequence, the treatment machine will either double or halve your active treatment length.

Doubling the active treatment length occurs when an existing patient has been created with a stepsize of 2.5 mm and then a customizing file has been loaded with a stepsize of 5.0 mm.

Halving the active treatment length occurs when an existing patient has been created with a stepsize of 5.0 mm and then a customizing file has been loaded with a stepsize of 2.5 mm.

Proposed solutions.

Make sure that the stepsize in an existing patient and treatment unit are always the same.

STATE OF NEW YORK
DEPARTMENT OF HEALTH
ALBANY, N.Y. 12237

0624



U.S. NUCLEAR REGULATORY COMMISSION
OFFICE OF STATE PROGRAMS
DOCUMENT CONTROL DESK
PI-37
WASHINGTON, D.C. 20555

ATTENTION: RICHARD L. BANGART, DIRECTOR

