

PHILIPPINE NUCLEAR RESEARCH INSTITUTE  
**REGULATORY BULLETIN**  
NUCLEAR REGULATIONS, LICENSING  
AND SAFEGUARDS DIVISION

BULLETIN No. 02-2

September 30, 2002

**SAFETY CONCERNS REGARDING OLD OR AGEING TELETHERAPY UNITS**

**A. ADDRESSEES**

For Action - All Teletherapy licensees who possess teletherapy units that are 10 years old or more

For Information - All other Teletherapy licensees

**B. PURPOSE**

This bulletin is issued to notify all action addressees about safety concerns related to the use of old or ageing teletherapy units, including second-hand teletherapy units that were directly acquired from foreign medical institutions. It is requested that all other addressees take the appropriate recommended actions and, if required, for all action addressees to provide PNRI with a report describing their findings and notify PNRI when they have completed all actions associated with this bulletin.

**C. DESCRIPTION OF CIRCUMSTANCE**

Considering that teletherapy equipment, primarily the cobalt teletherapy devices, are electro-mechanical that are bound to experience metal fatigue or failures of mechanical parts, the potential safety hazard to patients and radiation workers from injuries due to failures of these components are unavoidable. Problems discovered in these old units include, among others, cracks in the cast iron arms, gantry rotation and timer malfunctions, stuck sources, optical distance indicator errors, failed bolts, pins and screws, and inadvertent movement of patient's couch without switch activation.

Following the discovery of these problems, regulatory authorities, particularly the US-Nuclear Regulatory Commission, became concerned about this possible safety issue and ordered rigid inspection conducted by the manufacturers. As a result of such inspections the manufacturers voluntarily issued advisory bulletins to its users concerning the "end-of-life" or ageing of these machines as the major causes of such problems or failures. The manufacturers stated that, in their opinion, these units have exceeded their useful safe life and should be removed from service. In addition, spare parts were becoming increasingly difficult to provide, and in some cases, were completely unavailable. The manufacturers further stated that routine service, service contracts, replacement sources, and accessories would no longer be available.

## **D. DISCUSSIONS**

The safety issues arising from problems occurring in old and ageing teletherapy units in other countries should be addressed in the Philippine situation in view of the fact that several teletherapy units still operating in the country are 10 years-old or older. Reliable sources show that several incidents of mechanical failures in these units have occurred but were not reported to PNRI. Several worst-case scenarios could be developed as a result of such failures that could lead to serious physical injuries or fatal overexposure to patients or radiation workers.

A broader safety issue that concerns PNRI is related to the withdrawal of the manufacturer/supplier's support to these units. This lack of support may lead to significant incidents of deferred or improper maintenance at a time when service and maintenance requirements are normally increasing as the components age with use and time. Improper servicing, repair, or substitution of spare parts could readily produce device failures that could result in overexposures to patients and workers.

## **E. REQUIRED LICENSEE ACTION**

Those addressees possessing older models of teletherapy units or imported second-hand units must provide information on how they are going to handle the "end-of-useful life" issue and the possible withdrawal of the manufacturer/supplier's support relative to the maintenance and servicing issue.

At a minimum, the licensee concerned should include the following information in the report:

- (1) Make and model number and serial number of the teletherapy unit
- (2) Name of manufacturer/supplier and date of manufacture
- (3) Describe the present use of your teletherapy unit, (e.g., routine clinical use, research, instrument calibration, backup for an accelerator, etc.).
- (4) If used for patient treatment, what is the average weekly patient workload and what alternative(s) are available to treat these patients if the unit has to be shutdown for an extended period of time for repair, service or replacement? (Note that older equipment goes out of service more frequently due to wear and tear.)
- (5) What has been the service and maintenance record of your teletherapy unit(s) for the past five years? List each failure, its cause, length of downtime, and replacement components, if any, that are necessary to return the unit to service.
- (6) Is your teletherapy unit currently covered by a service contract and, if so, by whom? What is the expiration date of the contract? Do you expect to renew the contract and, if so, for what additional period of time? What is covered by the contract?
- (7) Describe your institution's commitment to ensure the continued clinical use of your teletherapy unit? To support such commitment, you should address the following concerns, at a minimum:
  - a) In-house inspections -
    - i) Frequency
    - ii) What will be inspected?
    - iii) Who will perform the inspections?
    - iv) Operational check?
  - b) Service arrangement –
    - i) Pre-arranged or on an "as-required" basis?

- ii) If pre-arranged, specify by agreement or service contract
    - iii) Who will perform the service?
  - c) Parts replacement –
    - i) How will necessary replacement parts be obtained?
    - ii) How will you determine the suitability of replacement parts (equal or better)?
  - d) Identify the organization that will perform the services at source-exchange time or return of the source to the original supplier.
  - e) For any needed repairs or essential inspections for which necessary resources are unavailable or delayed, describe your commitment to halting all use of the unit until the necessary repairs and/or inspections have been accomplished.
- (8) What emergency procedures are available to respond to emergencies or equipment failure mentioned above other than operational emergencies?

## **F. CONTACT PERSON**

Please acknowledge receipt of this Bulletin and submit your report to the contact person. If you have any questions about this matter, please contact:

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