

JAN 31 1994

Docket Nos. 030-02981  
030-00462  
030-30452

License Nos. 37-01317-01  
37-01317-02  
37-01317-03

Allegheny General Hospital  
ATTN: Joseph Och  
Radiation Safety Officer  
320 East North Avenue  
Pittsburgh, Pennsylvania 15212

Dear Mr. Och:

SUBJECT: 10 CFR PART 36 REQUIREMENTS FOR TELETHERAPY UNITS BEING  
USED FOR NON-HUMAN APPLICATIONS

This letter refers to our conversation on January 13, 1994 and includes information (see Attachment 1) we have provided to other facilities who have requested to use a teletherapy unit for non-human use in a licensing amendment.

As noted in the Statements of Consideration of Part 36, "Teletherapy machines converted to irradiate materials present hazards similar in nature to other irradiators and thus should meet similar safety standards." Therefore, it is apparent that 10 CFR Part 36 applies to converted teletherapy units. However, a paragraph was added to Paragraph 36.17 stating that the NRC would consider certain exemptions for these devices. NRC is aware that certain provisions of the rule may be impractical for converted teletherapy units, and exemptions will be granted for specific sections of Part 36, provided the requests are technically justified.

Regarding Paragraph 20.203(c)(6), this rule was superseded by 10 CFR Part 36, therefore, you must request exemptions from 10 CFR Part 36. If you provide the following requests, technical justifications and commitments, NRC will consider your exemptions. The following are technical justifications and commitments which we feel are acceptable for exemptions from specific sections of 10 CFR Part 36.

We hope this information will answer your questions concerning the regulations in this area.

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Sincerely,  
Original Signed By:  
Thomas K. Thompson

Thomas K. Thompson  
Senior Health Physicist  
Division of Radiation Safety  
and Safeguards

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Allegheny General Hospital

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Enclosure:  
Attachment I

cc:  
Public Document Room (PDR)  
Nuclear Safety Information Center (NSIC)  
Commonwealth of Pennsylvania

bcc:  
Region I Docket Room  
P. Nessen, RI  
P. Henderson, RI

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DRSS:RI  
Thompson/mlb

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Attachment 1

- 1) Paragraph 36.23(a) "The personnel entrance door or barrier must have a lock that is operated by the same key used to move the sources."

For converted teletherapy units, the use of a single key or even several keys on a key-ring may be impractical. The key-switch on many control panels is a 3-position switch which controls electrical power to the teletherapy unit. The key can only be inserted/removed in the "off" position, and in this position the main power and control circuits are without electrical power. Power is required to move collimators, activate field lights, and to align the system. Requiring a single key may not allow you to operate these powered systems. Therefore, you may be exempt from this requirement, provided that you commit to having the operator present for the entire period of time that the key is in the control panel.

- 2) Paragraph 36.23(b) "... each entrance to a radiation room at a panoramic irradiator must have an independent backup access control to detect personnel entry while sources are exposed."

You may be granted an exemption from this requirement provided that you have an electrical interlock system meeting all of the conditions specified in Paragraph 35.615(b). In addition, you should commit to having an operator present during the entire irradiation who can visually observe the entrance, and to having a radiation monitor that can be read prior to entering the radiation area.

- 3) Paragraph 36.23(c) "... The monitor must be integrated with personnel access door locks to prevent room access when radiation levels are high".

You may be granted an exemption from this requirement provided that you have an electrical interlock system and commit to its use, as described above. In addition, you should commit to having an operator present and having a radiation monitor in the room, as discussed above.

- 4) Paragraph 36.23(f) "Each radiation room ... must contain a control that prevents the sources from moving from the shielded position unless ... the door has been closed within a present time..."

You may be granted an exemption from this requirement provided that you commit that the operator will visually verify that the room is not occupied prior to closing the door, and that the converted teletherapy unit (irradiator) activates a visual and audible alarm in the teletherapy room for at least 15 seconds prior to moving the source from the shielded position. This visual/audible alarm must be interlocked with the teletherapy unit such that the source will not move to the exposed position until the visual/audible alarm has been activated and is finished alarming. Converted

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teletherapy units that are no longer used for patient treatment must meet the requirements of Paragraph 36.23(f) or you must propose an alternative, such as the one described here, to justify an exemption from Paragraph 36.23(f).

- 5) Paragraph 36.27(a) "... The sources must automatically become shielded if a fire is detected."

Paragraph 36.27(b) "... be equipped with a fire extinguishing systems cable of extinguishing a fire without entry of personnel..."

Most converted teletherapy units are designed to retract the source when the electrical power fails, as may occur during a fire. You may be granted an exemption from these requirements provided that you commit: to having smoke detectors, fire extinguishers and a fire alarm at the site to detect and fight small fires, and to alert authorities of the fire; to have a means of measuring the radiation levels in the radiation room during electrical failure; and to instruct the operators to retract the source prior to exiting for fire involving major portions of the facility.

- 6) Paragraph 36.27(b) "... The system must have a shut-off valve to control flooding into unrestricted areas."

If an exemption to 10 CFR 36.27(b) is granted, this requirement no longer applies and an exemption will be granted.

- 7) Paragraph 36.31(a) "The key must be attached to a portable survey meter by a chain or cable ... The door to the radiation room must require the same key."

Converted teletherapy units require that the source activation key be inserted in the console to provide power to the unit to activate field lights and align the head, therefore you may be granted an exemption from this requirement provided that you commit to having administrative controls in place to insure that personnel entering the radiation room use a portable survey meter to verify that the source has retracted.